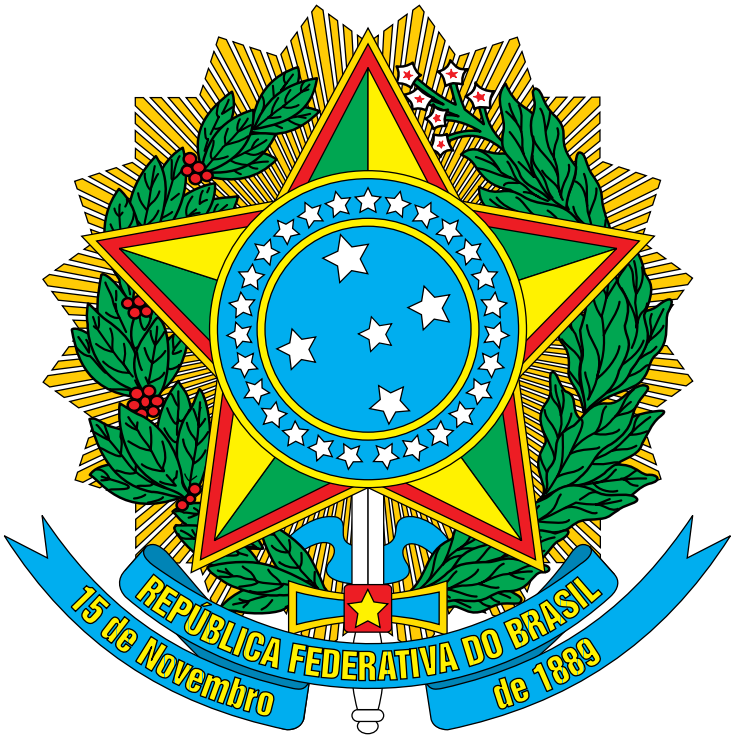

Brazilian pharmacopeia
National Form

2nd edition - Review 02

Esta tradução é um produto de termo de cooperação entre a Agência Nacional de Vigilância Sanitária (ANVISA) e a Organização Pan-Americana de Saúde (OPAS), e não substitui a versão em português.

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Review 02

1. Pharmaceutical forms 2. Pharmacopeias 3. Farmacotecnica 4. Medicine: Manipulation 5. Medicine: Quality Control I.T.

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SUMMARY

1 PREFACE

In the 1950s there was a maximum Brazilian industrial advancement that put the country in the route of the industrial modernization making it attractive to international investments.

The first great transformation in the pharmaceutical sector was in that time, when through fusions great world-wide pharmaceutical laboratories joined small national laboratories. The ways were thus open for the current situation of the Brazilian pharmaceutical industrial park, for the important higher education of the pharmacist, for the creation of globalized legislation and of the comfortable situation in which Brazil stands before other developed countries.

In September 1955 and, subsequently in February 1959, the then Presidents Joao Cafe Filho and Juscelino Kubitscheck signed Decrees n° 37.843 and n. 45.502 approving the second publication of Pharmacopeia of the United States of Brazil and determining the preparation of a National Form.

The existence of a form was justified by the need to adjust to the new world order being, mainly, by International Pharmacopeia, of the World Health Organization welcomed by Brazil in the 2nd Pan- American Congress of Pharmacy and Biochemistry carried out in Peru in 1951.

In parallel, the not less important Pharmacopeia of the United States of America, was already dictating the legal profile of a pharmaceutical code in which the quality parameters of drugs and pharmaceutical inputs used in the manufacture of medicines and health products should be indicated.

Following the trend, Brazil adopted \the same directive preparing a national pharmacopeia with monographs focusing the quality and quantitative evaluation of the pharmaceutical inputs and indicating the transposition of the magisterial and officinal formulas for a form in which a great number of drugs and different officinal galenic preparations which composed the base of the first edition of Brazilian pharmacopeia. Only in 2005, under the Presidency in the Permanent Commission of Review of the Brazilian Pharmacopeia, of Dr. Celso Figueiredo Bittencourt, the country manages to publish its first National Form.

From the seventieths and on countless pharmaceutical establishments focused on manipulation appear in the country, a reality indisputable today, and those have been giving invaluable service to society, whether through preparation of presently orphan medicines or through specific dosage determined by the prescriber. We should also mention that the magisterial sector developed, and continues to develop, an important role in the regulation of the Brazilian pharmaceutical market.

Covered by the legislation that determines to a pharmacist the prerogative of preparing and controlling the industrialized and manipulated medicines – whether allopathic or homeopathic, (Decree n. 85.878 of April 7th 1981) these professionals have proper formation in order to integrate health teams, bringing together knowledge and skill, acquired through years of work, following ethical principles that make them a respected professional.

The magisterial process, performed in a handicraft form, is safe since it is based on rigorous procedures by expert professionals prepared to the performance of their functions, legitimately supported by the legislation in force.

Based on these premises, the Thematic Technical Committee "Magisterial and Officinal Products" of the Brazilian Pharmacopeia Commission, integrated by professionals of known technical, scientific and intellectual capability worked tenaciously in the preparation of the form now handed to the society with special direction for pharmacies with manipulation and to university centers of formation of this important professional segment.

The formulas included in this document are of established use pressing need to public health and, thus, widely prescribed. In all the cases, the presented Formulations passed a rigorous literature review intended to avoid any kind of incompatibility between their components. All the presented bases were manipulated and tested in laboratories and they aim to provide quality products provided the determinations in the monograph are followed.

The members of the committee cared to include in the form new informative texts to facilitate the user understanding and to avoid, thus, any possibility of mistake induction during the process of transformation of pharmaceutical inputs in medicine.

By their part, the directors of Agencia Nacional de Vigilancia Sanitaria did not measure efforts to promote the necessary meetings to the development of the works. The members of the committee, in their workplaces, also did not measure efforts to develop and test the products through own resources that, again, demonstrates the commitment with the sector and the responsibility with the society that looks in the manipulated medicine a valid alternative for the treatment it is being subjected.

The process of preparation of a manipulated medicine requires a rigid control since most of times its quantity prevents a pharmacopeic analysis of the quality evaluation of the final product. This quality is obtained through a totally controlled Formulation process, which leads to the final product. For such, it is necessary to have in hands pharmaceutical inputs originated from qualified suppliers and with well prepared analytical certificates which translates the real specificity of the input, according to pharmacopeic requirements.

The committee has plans for considerable advancements in future publications of the form in view of the constant growth of the sector and the need to actively participating of a citizenship constructive action, with inclusion of the Brazilian Pharmacopeia through its components.

The publication now presented has basic insertion in the magisterial sector, however the presented Formulations may be freely used in the production of medicines of simplified notification in accordance with the specific legislation to which they are subject.

Considering the importance of the work, the Brazilian Pharmacopeia Commission changed the name of the work from *National Form* to *Brazilian Pharmacopeia National Form* in its second edition *(.FNFB 2)* understanding that this title would be more representative of its content in addition to reinvigorate a category of pharmaceutical formation strongly present in the daily life of the Brazilian.

Gerson Antonio Pianetti
President of the Brazilian Pharmacopeia Commission

2 BRAZILIAN PHARMACOPEIA

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Universidade de São Paulo – USP

COORDINATION OF THE BRAZILIAN PHARMACOPEIA
Agência Nacional de Vigilância Sanitária – Anvisa

MÔNICA DA LUZ CARVALHO SOARES – Coordinator

Especialistas em Regulação e Vigilância Sanitária
ANDREA REZENDE DE OLIVEIRA
JAIMARA AZEVEDO OLIVEIRA
LUIZ AUGUSTO DA CRUZ
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MAGISTERIAL AND OFFICINAL PRODUCTS

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ELISABETE PEREIRA DOS SANTOS
Universidade Federal do Rio de Janeiro – UFRJ

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Universidade de São Paulo – USP

JOSÉ ANTONIO DE OLIVEIRA BATISTUZZO
Faculdade Oswaldo Cruz – SP

LETÍCIA NORMA CARPENTIERI RODRIGUES
Universidade Federal de São Paulo – UNIFESP

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FACIAL – Farmácia de Manipulação

PATRICIA HAUSCHILDT DE OLIVEIRA MENDES
Agência Nacional de Vigilância Sanitária – Anvisa

PAULA RENATA APARECIDA NIGRO RIVERA CARAZZATTO
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ROBERTO PONTAROLO
Universidade Federal do Paraná – UFPR

SILVÂNIA VAZ DE MELO MATTOS
Agência Nacional de Vigilância Sanitária – Anvisa

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NORMALIZATION OF NOMENCLATURE, TEXTS

ANTÔNIO BASÍLIO PEREIRA – Coordinator
Universidade Federal de Minas Gerais – UFMG

FERNANDO HENRIQUE ANDRADE NOGUEIRA
Universidade Federal de Minas Gerais – UFMG

ISABELA DA COSTA CÉSAR
Instituto de Ciências Farmacêuticas de Estudos e Pesquisas – ICF

JOSÉ ANTÔNIO DE AQUINO RIBEIRO
Empresa Brasileira de Pesquisa Agropecuária – Embrapa

LAÍS SANTANA DANTAS
Agência Nacional de Vigilância Sanitária – Anvisa

PAULA CRISTINA REZENDE ENÉAS
Universidade Federal de Minas Gerais – UFMG

COLLABORATORS

ACÁCIO ALVES DE SOUZA LIMA FILHO
Farmácia Ophthalmos – São Paulo, SP

ADRIANA SILVEIRA PEREIRA DE MELO
Farmácia Escola – Universidade Federal do Rio de Janeiro – UFRJ

ADRIANO ANTUNES DE SOUZA ARAÚJO
Universidade Federal de Sergipe – UFS

ALESSANDRA TOLEDO COUTO BARBERATO
Farmácia Becker – São José dos Campos, SP

ANA ELISA NEVES JUNCIONI
Farmácia Byofórmula – São José dos Campos, SP

ANDREA REZENDE DE OLIVEIRA
Agência Nacional de Vigilância Sanitária – Anvisa

ANGÉLICA MARIA BRASIL VITA
Farmácia Ophthalmos – São Paulo, SP

ANTÔNIO BASÍLIO PEREIRA
Universidade Federal de Minas Gerais – UFMG

ANTÔNIO CARLOS DA COSTA BEZERRA
Agência Nacional de Vigilância Sanitária – Anvisa

CARLOS EDUARDO DE OLIVEIRA PEREIRA
Universidade Federal de Minas Gerais – UFMG

CELINA SHIZUKA OITA
Farmácia Ophthalmos – São Paulo, SP

CLÉVIA FERREIRA DUARTE GARROTE
Universidade Federal de Goiás – UFG

EDUARDO CHAVES LEAL
Instituto Nacional de Controle de Qualidade em Saúde – INCQS/FIOCRUZ

ELFRIDES EVA SCHERMAN SCHAPOVAL
Universidade Federal do Rio Grande do Sul – UFRGS

ELISABETE PEREIRA DOS SANTOS
Farmácia Escola – Universidade Federal do Rio de Janeiro – UFRJ

ELIZA YAEKO YAMAMOTO
Farmácia do Hospital das Clínicas – FMUSP

ÉRICO MARLON DE MORAES FLORES
Universidade Federal de Santa Maria – UFSM

FABIANE LENISE JASNIEVSKI
Farmácia Artepharma Mafra, SC

FELIPE DA SILVA GONÇALVES
Farmácia Escola – Universidade Federal do Rio de Janeiro – UFRJ

FERNANDO HENRIQUE ANDRADE NOGUEIRA
Universidade Federal de Minas Gerais – UFMG

GERSON ANTÔNIO PIANETTI
Universidade Federal de Minas Gerais – UFMG

GLÁUCIA MIRANDA PINHEIRO
Farmácia Escola – Universidade Federal do Rio de Janeiro – UFRJ

GUILHERME DINIZ TAVARES
Faculdade de Ciências Farmacêuticas – Universidade de São Paulo

ISABELA DA COSTA CÉSAR
Instituto de Ciências Farmacêuticas de Estudos e Pesquisas – ICF

JAIMARA AZEVEDO OLIVEIRA
Agência Nacional de Vigilância Sanitária – Anvisa

JOSÉ ANTÔNIO DE AQUINO RIBEIRO
Empresa Brasileira de Pesquisa Agropecuária – Embrapa

JOSÉ ANTONIO DE OLIVEIRA BATISTUZZO
Faculdade Oswaldo Cruz – SP

JOSÉ CARLOS TAVARES CARVALHO
Universidade Federal do Amapá – UNIFAP

JOSÉ LUIS MIRANDA MALDONADO
Conselho Federal de Farmácia – CFF

KÁTIA REGINA TORRES
Ministério da Saúde – MS

LAÍS SANTANA DANTAS
Agência Nacional de Vigilância Sanitária – Anvisa

LAURO DOMINGOS MORETTO
Sindicato da Indústria de Produtos Farmacêuticos no Estado de São Paulo – Sindusfarma

LEANDRO MACHADO ROCHA
Universidade Federal Fluminense – UFF

LENIR RIBEIRO YAGO GOMES
Farmácia Ao Pharmacêutico – Campinas, SP

LETÍCIA NORMA CARPENTIERI RODRIGUES
Universidade Federal de São Paulo – UNIFESP

LUIZ ALBERTO LIRA SOARES
Universidade Federal de Pernambuco – UFPE

LUIZ AUGUSTO DA CRUZ
Agência Nacional de Vigilância Sanitária

LUIZA DE CASTRO MENEZES CÂNDIDO
Universidade Federal de Minas Gerais – UFMG

MÁRCIA MACIEL ANTUNES
Farmácia Facial – São Luis, MA

MARIA LÚCIA SILVEIRA MALTA DE ALENCAR
Agência Nacional de Vigilância Sanitária – Anvisa

MIRACY MUNIZ DE ALBUQUERQUE
Universidade Federal de Pernambuco – UFPE

NAIALY FERNANDES ARAÚJO REIS
Universidade Federal de Minas Gerais – UFMG

ONÉSIMO ÁZARA PEREIRA
Associação Brasileira da Indústria Farmoquímica e de Insumos Farmacêuticos – ABIQUIFI

PATRICIA HAUSCHILDT DE OLIVEIRA MENDES
Agência Nacional de Vigilância Sanitária – Anvisa

PAULA CRISTINA REZENDE ENÉAS
Universidade Federal de Minas Gerais – UFMG

PAULA RENATA APARECIDA NIGRO RIVERA CARAZZATTO
Pharmácia Específica – Bauru, SP

PAULA ROCHA CHELLINI
Universidade Federal de Minas Gerais – UFMG

REJANE HEYSE RIBAS
Farmácia Artepharma – Mafra, SC

ROBERTO PONTAROLO
Faculdade de Farmácia – Universidade Federal do Paraná – UFPR

RODRIGO LUPATTINI
Farmácia RX Pharmaceutica – Juiz de Fora, MG

SILVANA TERESA LACERDA JALES
Associação dos Laboratórios Farmacêuticos Oficiais do Brasil – ALFOB

SILVÂNIA VAZ DE MELO MATTOS
Agência Nacional de Vigilância Sanitária – Anvisa

TIAGO ASSIS MIRANDA
Universidade Federal de Minas Gerais – UFMG

VANESSA PINHEIRO
Farmácia RX Pharmaceutica – Juiz de Fora, MG

VLADI OLGA CONSIGLIERI
Faculdade de Ciências Farmacêuticas – Universidade de São Paulo

YUKIKO ETO
Farmácia Byofórmula – São José dos Campos, SP
•

3 GENERALITIES

- *All the inputs employed in the preparation of the products contained in this code must meet the quality and safety specifications described in the current edition of the Brazilian Pharmacopeia or, if it is not available, in the international codes nationally recognized.*

TITLE

- The complete title of this work is "Brazilian Pharmacopeia National Form, 2nd edition". It may be called "FNFB 2".

REPRESENTATIONS AND ACRONYMS

- A/O Water in oil emulsion
- BHT Butyl hydroxytoluene
- BPL Good laboratory practices
- BPM Good manipulation practices
- CAS Chemical abstract service number
- CQ Quality control
- DCB Brazilian common denomination
- DCI International common denomination
- DMSO Dimethylsulfoxide
- EDTA Edetate Dissodium
- GL Gay Lussac
- GQ Quality garantee
- LCD *Liquor carbonis detergens,* saponated tar
- O/A Oil in water emulsion
- PEG Polyethylene glycol
- POP Standard operational procedure
- PVP-I Povidone iodine
- qs Sufficient quantity
- qsp Sufficient quantity for
- UV Ultraviolet

DEFINITIONS

Water for intravenous

- Water for intravenous is the input used in the preparation of medicines for parenteral administration, as vehicle or in the dissolution or dilution of substances or preparations.

Water for pharmaceutical use

- Water for pharmaceutical use is the several kinds of water used in the synthesis of drugs, in the Formulation and production of medicines, in tests laboratories, diagnoses and other applications related to health, including as main component in the cleaning of utensils, equipment and systems.

Purified water

- It is the drinkable water which underwent some type of treatment to draw possible contaminants and to meet purity requirements established in the Brazilian Pharmacopeia monograph.

Sterile purified water
- It is purified water that was subjected to a classic sterilization process.

Ultra-purified water
- It is the purified water that passed by additional treatment to draw possible contaminants and to meet the purity requirements established in the Brazilian Pharmacopeia monograph.

Aromatic waters
- Those are water solutions saturated of essential oils or other aromatic substances which name them. They have characteristic odor of the drugs with which they are prepared.

Analysis
- Technique, method or procedure applied to assess the attributes or characteristics of the medicines, cosmetics or inputs as raw materials or packing material. The analyses must not be confused with the quality control, but treated as tools for taking decision on the approval or not of a given product or input.

Sit bath and steam bath
- It is boiling water bath, unless the monograph specifies another temperature. The expressions hot water and very hot water indicate approximate temperatures between 60°C and 70°C and between 85°C and 95°C, respectively.
- Sit bath means exposure to fluent steam or other type of heat, corresponding in temperature to that of fluent steam.

Good laboratory practices
- It is part of the Quality Guarantee (GQ) that assures that the works developed in the laboratory (analyses, appliances calibration, register of results, among others) are solidly planned, produced, monitored and registered, filed and reported, and meet the quality principles, including organization and personnel.

Good manipulation practices
- It is a part of the Quality Guarantee that assures that the products are solidly manipulated and controlled in accordance with the required quality standards.

Capsule
- It is a solid pharmaceutical form, in which the active principle and the excipients are contained in a soluble, hard or soft covering, of formats and varied sizes, usually containing a single dose of the active principle. The covering normally is composed of jelly, but it can also be of starch or of other substances.

Eye drops
- It is a liquid pharmaceutical product intended to the application on the ocular mucous membrane. *Packaging conditions*

The conditions of packaging described in the monographs use the following definitions:
  - *Well closed container* – It is that which protects its content against losses and contamination by strange solids, in the usual manipulation, storage, distribution and transport conditions.
  - *Hermetic container* – Is that which is air tight or gastight in the usual conditions of manipulation, storage, distribution and transport.

- *Opaque container* – Is that which obstructs the visualization of the content, including all colors. It constitutes a barrier against light.
- *Perfectly closed container* – Is that which protects its content against losses or contamination by solids, liquids and strange fumes, efflorescence, deliquescence or evaporation, in the usual manipulation, distribution, storage and transport conditions.
- *Container for the single dose* – It is the hermetic container with a given quantity of the medicine intended to be administered all at once and that after opened will not be able to be closed with sterility guarantee.
- *Container for multiple doses* – It is the hermetic container which makes possible drawing successive portions of its content, without changing concentration, purity and sterility of the remaining portion.

Quality control (CQ)

- Set of operations (planning, coordination and performance) aiming to check the compliance of attributes or characteristics of the product finished or in process, raw materials and other materials, with pre-established specifications.

Colorants

- There are substances added to medicines, dietetic products, cosmetics, perfumes, hygiene products and similar, house cleaning products and similar, with the effect of giving them color and, in certain types of cosmetics, transfer it to the skin surface and attachments. For their use, observe the legislation and resolutions published by Anvisa.

Cosmetics

- Those are products for external use, intended to hygiene, protection or embellishment of different parts of the body.

Cream

- It is the pharmaceutical semisolid form consisting of an emulsion composed by a lipophilic phase and a hydrophilic phase. Contains one or more active principles dissolved or scattered in an appropriate base and it is used, normally, for external application in the skin or in the mucous membranes.

Brazilian common denomination (DCB)

- It is the denomination of the drug or pharmacologically active principle, approved in the federal body responsible for sanitary vigilance. Currently, it acquired a wider conception and it also includes the denomination of inactive inputs, hyperimmune serums and vaccines, radioactive drugs, medicinal plants, homeopathic and biological substances.

International common denomination (DCI)

- It is the denomination of the drug or pharmacologically active principle, recommended in the World Health Organization.

Mass density and relative density

- Mass density (p) of a substance is the rate of its mass per its volume at 20° C.
- The relative density usually adopted (dfS) is defined as the relation between the mass of a substance to the air at 20° C and the mass of an equal volume of water in the same temperature.

Drug

- It is all substance of animal, mineral or vegetable origin from where the active principle is extracted, which has pharmacological action.

Elixir

- It is the pharmaceutical, liquid, limpid, hydroalcoholic preparation, of slightly sweet, pleasant taste, presenting alcoholic content from 20% to 50%. Elixirs are prepared by simple dissolution and they must be put in amber bottles and kept at a fresh place and sheltered from light.

Primary packing

- It is that which is in direct contact with its content during all time. It is considered a primary packing material: ampoule, tube, envelope, case, vial, glass or plastic bottle, ampoule bottle, cartridge, can, pot, bag of paper and others. There must not be any interaction between the primary packing material and its content that can change the concentration, quality or purity of the packed material.

Secondary packing

- It is that which makes possible the full protection of the packaging material in the usual transport, storage and distribution conditions. It is considered a secondary packing: cardboard boxes, card cartridges, wood or plastic material or card case, among others.

Emulsion

- It is the pharmaceutical liquid form of one or more active principles consisting of a two phase system with at least two immiscible liquids and in which one of the liquids is scattered in the form of small drops (internal or scattered phase) in another liquid (external or continuous phase). Normally it is stabilized through one or more emulsifying agents.

Spirit

- It is the liquid alcoholic or hydroalcoholic pharmaceutical form, containing aromatic or medicamental principles and classified in simple and composed. Spirits are obtained by dissolution of aromatic substances in ethanol, generally in the proportion of 5% (p/v).

Sterility

- Sterility is the absence of viable microorganisms.

Excipients or adjuvant substances

- Those are all substances added to the product aiming to improving its stability or acceptance as a pharmaceutical form. They have the function of stabilizing and preserving the chemical-physical aspects and characteristics of the formula. Depending on the Formulation, the excipients may work as diluents, desintegrants, agglutinant, lubricants, preservatives, solvents, edulcorants, aromatizer, viscosity provider agents, vehicle, antioxidant agents etc. In general, excipients are therapeutically inert, harmless in the added quantities and they must not damage the therapeutic efficiency of the medicine.

Fusion range

- It is the range of temperature comprised between the starting (in which the substance begins to fluidify) and the end of the fusion (evidenced by the disappearance of the solid phase) of a substance.

Drug
- *See Active Pharmaceutical Input*.

Farmacopeic
- Medicine or method which preparation mode is indicated in the Pharmacopeias.
- The expression farmacopeic replaces the expressions: official and officinal, used in previous publications of Brazilian Pharmacopeia, being equivalent to these expressions for all intents and purposes.

Pharmaceutical form
- It is the final state of presentation of the pharmaceutical active principles, after one or more pharmaceutical operations performed with the addition or not of proper excipients, in order to facilitate its use and obtain the therapeutic effect wished, with characteristics appropriated to a given administration mean.

Quality Guarantee (GQ)
- It is the organized effort, monitored and documented to assure the quality of the product and interbatches and intrabatch units with the same characteristics and in accordance with the previously established specifications.

Gel
- It is the semisolid pharmaceutical form of one or more active principles containing a jellifying agent to provide viscosity to a system in which colloidal dimension particles – typically between 1 nm and 1 pm – are uniformly distributed. A gel may contain suspended particles.

Hydrophilic Gel
- It is the gel resulting from the preparation obtained by the incorporation of jellifying agents – tragacanth, starch, cellulose byproducts, carboxyvinyl polymers and double magnesium and aluminum silicates to water, glycerol or propylene glycol.

Hydrophobic Gel
- It is the gel consisting, usually, of liquid parafin with polyethylene or fatty oils with colloidal silica or aluminum or zinc soaps.

Active pharmaceutical input
- It is an active chemical substance, drug or raw material which has pharmacological properties with medicamental purpose used for diagnosis, relief or treatment, used to modify or to explore physiologic systems or pathological states in benefit of the person in whom it is administered. When it is intended to use in medicines it must meet the requirements provided for in the individual monographs.
- The active and inactive pharmaceutical inputs used in this form, the synonymities and CAS number information are listed in ATTACHMENT C.

Lotion
- It is the liquid water or hydroalcoholic preparation, with variable viscosity, for application in the skin, including scalp. It may be a solution, emulsion or suspension containing one or several active or adjuvant principles.

Batch or start

- Established quantity of raw material, packing material or product obtained in a single process, which essential characteristic is homogeneity.

Raw material

- It is all active or inactive substance, with defined specification, used in the preparation of the products. It must be of pharmaceutical degree and meet the specifications provided for in the Pharmacopeia.

Packing material and packing

- It is the covering, container or any form of packaging, removable or not, intended to cover, pack, put in vase, protect or maintain, specifically or not, the medicines, drugs, pharmaceutical inputs and related products, the cosmetics, cleaning products and other products. The packaging conditions are described in the individual monographs. For the range of preservation temperature used in this form refer to: General Information/Preservation.

Medicine

- It is the pharmaceutical product, technically obtained or prepared, containing one or more drugs and other substances, with preventive, curative, palliative or diagnosis purposes.

Magisterial medicine

- It is any medicine which prescription details the composition, the pharmaceutical form and the dosage. It is prepared in the pharmacy, by a qualified pharmaceutical professional or under its direct supervision in which there is a prescriber-pharmacist-user relation established and intended to an individual patient.

Number CAS

- The number of register is the code given out by Chemical Abstracts Service – CAS, of American Chemical Society, designated to identify each chemical substance. It is composed by a set of three groups of numbers, being the last two composed by two and a numeral, respectively.

Ovum

- It is the solid pharmaceutical form, of single dose, containing one or several active principles scattered or dissolved in a proper base that has several formats, usually ovoid. They fuse in the body temperature.

Paste

- It is the salve containing a large amount of solids in dispersal (at least 25%). It must meet the specifications established for salve.

Pastille

- It is the solid pharmaceutical containing one or more active principles, usually, in a slightly sweet base and with taste. It is used for dissolution or slow disintegration in the mouth. It can be prepared by modeling or by compression.

Powder

- It is the solid pharmaceutical form containing one or more active principles and with reduced particle size, with or without excipients.

Effervescent powder

- It is the powder containing, in addition to the active ingredients, acid substances and carbonates or bicarbonates, which release carbon dioxide when the powder is dissolved in water. It must be dissolved or disperse in water before the administration.

Powder for solution

- It is the powder intended to be reconstituted to compose a solution.

Powder for suspension

- It is the powder intended to be reconstituted to compose a suspension.

Salve

- The pharmaceutical form is usually semisolid, for application in the skin or in mucous membranes, which consists of the solution or dispersal of one or more active principles of low proportions in a proper non water base.

Term for use of magisterial products

- The term for using magisterial products is the expiry date for using the manipulated product, defined by the pharmacist, according to specific criteria for each Formulation and preservation conditions, up to which, the manipulated product should keep its efficiency and safety.

Expiration

- It is the time during which the inputs or products may be used, characterized as the period of useful life and based on specific stability studies. The validity term shall be indicated in the primary and secondary packings. When indicating month and year, it is understood that the expiry date is the last day of the month. The storage and transport conditions specified by the manufacturer must be maintained.

Standard operational procedure (POP)

- It is the document with the description of how a repeated given task or activity should be performed. The goal is to assure that the procedures are always performed likewise, following the same quality standards and criteria, independently of the operator.

Magisterial process

- Set of operations and procedures carried out in quality and traceability conditions of the whole process turning inputs into magisterial products, for direct dispensation to a user or to its person in charge, with directions for its safe and rational use.

Hygiene product

- It is the product for external use, antiseptic or not, intended to cleaning or physical disinfection.

Dietetic product

- It is the product technically prepared to meet the dietetic needs of persons in special physiologic conditions.

Magisterial products

- Magisterial Products[1] are those obtained in Pharmacies applying the Good Practices of Manipulation (BPM), from: prescriptions of qualified professionals or indication by the pharmacist[2] and purchase order[3], dispensed to a user or person legally in charge and establishing a relation prescriber- pharmacist-user.

Tag

- It is the identification directly applied on containers, coverings, cartridges or any other packing protector, external or internal.

Solution

- It is the liquid, limpid and homogeneous pharmaceutical form, which contains one or more active principles dissolved in a proper solvent or in a mixture of miscible solvents.

Molar solution

- It is the solution containing a gram molecule of the solute in 1000 mL of the solution. The multiples and submultiples of the molar solution are also designated by whole numbers or decimal fractions like: 2*M,* 1 *M,* 0.5*M,* 0.1 Mete.

Indicator Solution

- It is the indicator solution in specific solvent and established concentration. It is designated by "SI". *Solution reagent*
- It is the reagent solution in specific solvent and established concentration. It is designated by "SR". *Volumetrical solution*
- It is the reagent solution, of known concentration, intended to use in quantitative determinations. In the Brazilian Pharmacopeia the concentration of the volumetrical solutions is expressed in molarity. It is designated by "SV".

Suppository

- It is the solid pharmaceutical form of several sizes and formats, adapted for introduction in the rectal, vaginal or urethral orifice of the human body, containing one or more active principles dissolved in a proper base. They, usually, merge, melt or dissolve at the body's temperature.

Suspension

- It is the liquid pharmaceutical form containing scattered solid particles in a liquid vehicle, in which the particles are not soluble.

Plug

- It is the salt base preparation capable to support variations in the ion activity.

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1 Medicines, cosmetics, hygiene, dietetic and nutritional products, for diagnosis or use in medical, odontological procedures and others manipulated by the Pharmacy, until their dispensation.

2 Indication performed by the pharmacist, for over-the-counter magisterial products.

3 Purchase order (signed by the technical person in charge of the establishment) – performed for magisterial products used in clinics, surgical centers, hospitals, wards, laboratories, and others, in compliance with the law in force.

Freezing point or temperature

- Freezing point or temperature of a liquid or cast solid is the highest temperature in which it solidifies. For a pure substance merging without decomposition, the freezing point of the liquid is the same as its flashing point.

Boiling point or Temperature

- Boiling point or temperature of a liquid is the corrected temperature in which the liquid boils under steam pressure of 101.3 kPa (760 mm of Hg).

Flashing point or temperature

- Flashing point or temperature of a substance is the temperature in which it is completely molten.

Dye

- It is the resulting alcoholic or hydroalcoholic preparation of the extraction of vegetable or animal drugs or of the dilution of the respective extracts. It is classified as simple and composed, in accordance with if it is prepared with one or more raw materials.

Syrup

- It is the water pharmaceutical form characterized by high viscosity, which presents no less than 45% (p/p) of sucrose or other sugars in its composition. Syrups generally contain flavor agents. When it is not intended to immediate consumption it must be added with authorized antimicrobial conservatives.

GENERAL INFORMATION

Water

- The water mentioned in the formulas is purified water or higher specification water. The water must meet the requirements described in the current edition of Brazilian Pharmacopeia. When the use of water exempted from carbon dioxide is prescribed, use recently distilled and boiled water, for at least five minutes and protected from atmospheric air during the cooling.

Preservation

- The substances must be preserved under conditions that avoid their contamination or deterioration. The preservation conditions of the products appear in the respective monographs.
  - in freezer – temperature from -20 to 0°C;
  - in refrigerator – temperature from 2 to 8°C;
  - in cold place – temperature must not exceed 8°C;
  - in fresh place – temperature from 8 to 15°C;
  - at room temperature – temperature from 15 to 30°C;
  - in hot place – temperature from 30 to 40°C;
  - excessive heat – temperatures above 40°C.
- When it is necessary to preserve a drug in fresh place it is possible to preserve it in refrigerator, unless otherwise indicated in the individual monograph.
- When in the monograph the preservation conditions are not specified, they include protection against moisture, freezing and excessive heat.

Doses and approximate measures

- In case of lack of devices for appropriate measures (dispenser, measure spoons etc.) for the dispensation of medicines, approximate portions may be used. In general, domestic use measures are used to provide the patient with the correct use of the dose.
- Such measures have the following indication capability:
  - Coffee spoon . . . . . 3 mL
  - Teaspoon . . . . . 5 mL
  - Dessertspoon . . . . . 10 mL
  - Tablespoon. . . . . 15 mL

Doses smaller than 3 mL are usually indicated in drops.

Expression of concentrations

- The concentrations defined in percentage are expressed as follows:
  - *Per cent p/p (weigh in weight) or % p/p* – Expresses the number of g of a component in 100 g of mixture.
  - *Per centp/v (weigh in volume) or %p/v* – Expresses the number of g of a component in 100 mL of solution.
  - *Per cent v/v (volume in volume) or % v/v* – Expresses the number of mL of a component in 100 mL of solution.
  - *Per cent v/p (volume in weight) or % v/p* – Expresses the number of mL of a component in 100 g of mixture.

The expression per cent, used without other attribution, means: mixture of solids and semisolids, per cent p/p; for solutions or suspensions of solids in liquids, per cent p/v; for liquids solutions, per cent v/v; for solutions of gases in liquids, per cent p/v; to express content of essential oils in vegetable drugs, per cent v/p.

Preparation of solutions

- All solutions used in tests, trials and reactions are prepared with purified water, unless otherwise indicated in the individual monograph.

Solubility

- The solubility indicated must not be taken in the strict sense of physics constant, however, it complements and corroborates with the other trials, and may have a definite value if the substance does not present the minimum solubility required, mainly, in water.
- The indications on solubility refer to the determinations performed at 25°C. The expression solvent refers to water, unless otherwise indicated in the individual monograph.
- The expression parts refers to the dissolution of 1 g of a solid in the number of milliliters of the solvent established in the number of parts.
- The approximated solubilities mentioned in the monographs are qualitatively attributed as related in Table 1 (FB 5):

Table 1 – Solubility descriptive terms and its meanings.

Solvent	Descriptive term
Very soluble	Less than 1 part
Easily soluble	From 1 to 10 parts
Soluble	From 10 to 30 parts
Lightly soluble	From 30 to 100 parts
Less soluble	From 100 to 1 000 parts
Much less soluble	From 1 000 to 10 000 parts
Practically insoluble or insoluble	More than 10 000 parts

4 GENERAL METHODS

4.1 DETERMINATION OF WEIGHT IN CAPSULES OBTAINED BY THE MAGISTERIAL PROCESS

Among the different pharmaceutical forms manipulated in pharmacies, the hard gelatinous capsules for oral use are the most used. However, the pharmacopeic test for determination of weight of manipulated capsules is, most times, impracticable due to its destructive nature. In this form, a method for determination of average weight in hard capsules is described, employing non destructive test. Three parameters shall be determined for analysis of the product: Average weight of manipulated capsules (‘Pkiedw), Relative standard deviation (DPR) and Variation of theoretical content (%).

Average weight of manipulated capsules (P_{Mecho})

The average weight is the arithmetical average of the weight of ten units of manipulated capsules, in grams. When the quantity of capsules manipulated for complying with the prescription is less than ten units, the determinations must be carried out when all the units are weighed, individually. The variation limits tolerated for the Average weight of the manipulated capsules (P_{Mecho}) are presented in Table 1

Procedure – weigh, individually, ten units of undamaged manipulated capsules and determine the average weight, in grams, according to the following equation and compare the value obtained with those in Table 1:

$$P_{Médio} = \frac{P_{cáps.1} + P_{cáps2} + P_{cáps.3} + ... + P_{cáps.10}}{10}$$

Table 1 – Criteria for evaluation of the weight determination for solid pharmaceutical forms in single dose (Brazilian Pharmacopeia, 5 ed).

Pharmaceutical form	Average weight	Limits of Variation
Hard capsules	less than 300 mg	± 10.0%
	300 mg or more	±7.5 %

Relative standard deviation (DPR)

- The *Standard relative deviation (DPR)* calculated must not be higher than 4%. The relative standard deviation is given in percentage and is calculated according to the following equations:

$$DPR = \frac{DP}{P_{Médio}} \times 100$$

in what:

DP is the standard deviation of P_{Medio}

The standard deviation of *the Average Weight (Pmmo)* is calculated using the following equation:

$$DP = \sqrt{\frac{\sum_{i=1}^{n} (P_{cáps.i} - P_{Médio})^2}{n-1}}$$

where:

- $P_{caps.i}$ = weight of each unit of manipulated capsules
- n = number of manipulated hard capsules employed in the determination of the average weight

Variation of the theoretical content of the capsules

- The maximum and minimum theoretical values of the capsules content allow to obtain an estimate of the acceptable variation of weight of the capsules, supposing that the mass of powders encapsulated is homogeneous. So, if the Good Practices of Manipulation are followed, as for the mixture of powders, it is possible to conclude that the quantity of drug is uniformly distributed between the capsules and, thus, the acceptable content variation must be contained in the 90 to 110% range. To determine the *Variation of theoretical content* in the capsules, it is necessary to determine the average weight of the empty capsules *($P_{Medio\ -caps.vazias}$)* and the theoretical weight of the capsules *($P_{tedrico}$)*.
- The *Average weight of the empty capsules ($P_{Medio-ccips.vazias}$)* is obtained individually weighing 20 empty capsules and calculating the arithmetical average, according to the equation:

$$P_{Médio-cáps.vazias} = \frac{P_{cáps.vazia1} + P_{cáps.vazia2} + P_{cáps..vazia3} + ... + P_{cáps.vazia20}}{20}$$

- The *Theoretical Weight of the capsules ($P_{teorico}$)* is obtained with the sum of $P_{Medio-cdps.vaaas}$ and the theoretical weight of the adjuvant substances and drugs which compose the formula:

$$P_{teórico} = P_{Médio-caps.vazias} + P_{excipientes} + P_{fármacos}$$

- The *theoretical variation of content* of the capsules is estimated establishing the *Minimum theoretical powder quantity* ($Q_{teor.min}$). and the *Maximum theoretical powder quantity* ($Q_{teor.max}$)., in accordance with weigh extremes obained in the weighing of the capsules. Thus, the weighs of the lighter capsule and of the heaviest capsule must be observed, according to the equations:

$$Q_{teor.mín.} = \frac{P_{cápsulamaisleve}}{P_{teórico}} \times 100 \quad \text{e} \quad Q_{teor.máx.} = \frac{P_{cáps.maispesada}}{P_{teórico}} \times 100$$

where:

- $P_{capsuiamaisieve}$ is the lowest individual weight observed in the weighing of the capsules manipulated for determination of *average Weight*.
- $P_{capsuiamaispesada}$ is the maximum individual weight observed in the weighing of the capsules manipulated for determination of *average Weight*.
- The calculated minimum and maximum theoretical quantities of content of the capsules shall range from 90 to 110%.

5 GOOD PRACTICES OF MANIPULATION[1]

The goal with this chapter is to present directions for good manipulation practices (BPM) so that the quality requirements of the manipulated products may be met and result in the guarantee of their efficiency and safety.

The quality of the magisterial products depends a lot on the scientific knowledge, on the professional qualification and technical competence of the pharmacist and on the continuous interaction between pharmacist, prescriber and patient. However, equally important and necessary factors are the organization and the constant control by the pharmacist of preparation techniques, raw materials, equipment and instruments used, storage conditions of the inputs and products and of the documentation on all the procedures, materials and resources employed in the preparation of the magisterial products in all their phases, including those subsequent to the dispensation. The organization of an integrated, documented and traceable management system assuring continuous control of getting the medicines and the activities practiced in the pharmacy is critical for the therapeutic success of the patient, making possible to protect professional responsibilities of doctor and pharmacist, as well as to meet the sanitary standards in force.

The integrated control system through which it is possible to manage the quality is called Quality Guarantee.

QUALITY GUARANTEE (GQ)

- The Quality Guarantee has the goal to:
  a) assure the preparation of specifications, standard operational procedures (POP), BPM manual, manipulation orders, analytical methodology and specifications for raw materials, products and packing material, environmental conditions control and cleaning programs for workplaces, storage and dispensation of the products and inputs, training of personnel, auditing and inspections, calibration, equipment and instruments maintenance and checking, among other documented procedures;
  b) assure the fulfillment of the specifications, procedures, controls, trainings, auditing and other tasks previously listed, and provide their registers;
  c) look after the management of the registers and of the documentation involved and its filing;
  d) provide proper physical sizing and organization of spaces to perform the several tasks and for the safe storage of chemical substances, solvents, counterproof material, reagents, documents, among others, as well as of allocation of equipment and personal;
  e) predict and provide all subsidies necessary to assure safety and efficiency of the products obtained in the pharmacy and for meeting the technical, fiscal and sanitary standards in force.

In the BPM that constitute an integrant part of the GQ, the minimum requirements are established for pharmaceutical evaluation of the prescription, manipulation, conservation, dispensation of magisterial and officinal products, fragmentation of industrialized products, as well as criteria for acquisition of raw material and packing materials. The BPM are applied through POP prepared by the responsible pharmacist and which must be an integrant part of the

1 The BPM includes the fulfillment of the requirements arranged in the technical regulation of Practices of Manipulation in Pharmacies (Anvisa 's Collegiate Directorship Resolution, RDC N°67/2007) and amendments.

Good Practices of Manipulation Manual. The pharmacist is the professional qualified to create, update or invalidate those procedures.

Every POP must be written with clear and direct language, describe all stages of the procedure to be executed, include necessary materials and equipment and the access to it must be easy for the operators. It can only be performed by operators previously trained and qualified to perform that activity. There must be control of copies, dates of preparation and modification, and contain the names of the persons in charge for the preparation, review and approval.

QUALITY CONTROL

- The pharmacy must have and area intended to Quality Control activities, which facilities are sized according to the demand and meet the proper criteria as for the organization of the physical space and equipment. The main analyses performed are related to the different phases of getting the magisterial product, from the acquisition of the inputs. Thus, in this area, raw materials, products in processing and finished products are analyzed. The packaging materials and packing also must be evaluated as for their specifications.

Raw materials and other inputs

In the acquisition of raw materials and other inputs, it is desirable that the suppliers are qualified through the criteria established by the legislation in force, which include: proof compliance by the distributor with the health inspection bodies, the performance of an auditing *in loco* to check the compliance with the good practices of manufacture or of fragmentation, the correspondence of the analytical results obtained in the pharmacy with those provided by the distributor (or manufacturer) and the history of raw materials and other inputs supply approved according to the specifications.

The specifications of each material or input, prepared by the pharmacy, must be based on the official monographs, mainly of the Brazilian Pharmacopeia and, if it is not available, of the other pharmacopeias recognized by the health inspection bodies. In case there are no official specifications those must be prepared in accordance with the manufacturer. For proper choice of raw materials, as for the type of salt, hydration degree, particle size, polymorphism, isomerism, incompatibilities with other substances, stability, the pharmacist should consult the relevant scientific literature and evaluate that more proper for using, considering the pharmaceutical form; formula composition; type of vehicle or excipient; stability and pH, among other parameters.

Inspection of Receiving

The Inspection of Receiving is carried out in the time of delivery of any material acquired by the pharmacy and it must be performed by properly trained and qualified employee, who will perform the register accordingly. Thus, drugs, raw materials, packaging and cleaning materials, among others, must be subjected to the receiving inspection. It is critical to check the entirety of the packing and of the tag and certify that the raw material transport conditions were appropriate. The materials must be followed by analysis certificates provided by the distributor or manufacturer, in which the specifications and the analytical methods applied are described with their respective results. The storage conditions included in the tag must be checked against the scientific data obtained by the pharmacist and they are part of the specifications. Based on the criteria established in the legislation in force, the tags should include compulsory items.

Quality control of raw materials, finished products and products in process

Whilst the raw materials are under evaluation, they must receive specific tags, such as "in quarantine" to indicate that they are not released for consumption, needing to wait for the results for taking the decision on the approval of the material. It is thus recommended that the raw materials in analysis or evaluation be stored in a different location apart from that in use in the pharmacy, however, under controlled and proper conditions.

The minimum tests required for raw materials, finished products and products in processing are described and have their periodicity defined in the sanitary legislation, including the physical- chemical and/or microbiological tests for vegetable or synthetic origin raw materials, supply and purified water, galenic bases and diluted powders, among others. Controls are also highlighted for finished products in solid form and of low therapeutic rate, which should met specific requirements.

All the stages to get the product must be checked and registered, such as weighing, volume measurements, pH measurements during preparation, among others.

Pharmacotechnics quality control or process control

All preparation operations for medicines, cosmetics, nutritional supplements, among others, must be described in POP, followed by production order. Each Formulation must include documentation in which the weighing is registered and checked. The weighing and volume measurements, the pH measurements, dilution operations and mixture of powders, agitation and heating are considered critical stages. The heating should have well established criteria for temperature and heating time.

In the mixture of powders, to facilitate getting homogeneous mixtures, the following pharmacotechnical practices are recommended:

- always mix powders of similar tenuousness and, if required, there should be an operation of grinding and sieving to homogenize the particle size;
- start the mixture with the powder present in the formula in less quantity and continue adding the others according to growing quantity order;
- use mixture indicator (allowed colorant) when there is need to mix small amounts of active substance to a large mass of excipient;
- yet in the previous case, adopt the geometrical dilution principle; after the mixture of powders, pass through tamis.

INSPECTIONS AND AUDITING

The GQ must anticipate and promote inspections and periodic internal auditing. In addition to being compulsory, these inspections aims to help in the compliance with laws and regulations; correct BPM faults; detect potential mistakes in the manipulation or in the quality control; review the procedures with preventive purposes, avoid marketing of products that may be a risk to public health; help to implement new procedures or techniques; help in the investigation of claims for toxic side-effects, alterations, adulterations or contaminations and to improve the quality of the medicines and assure their efficiency and safety.

The auditing and inspections are based on the official inspection itineraries, including, as a minimum, the requirements of vigilance bodies, and may include specific items, in accordance with the need the pharmacist consider proper.

The auditing and inspections reports must be written in plain and direct language, pointing the non compliant items. As a practical result, each non compliance registered in the report must be immediately assessed and the term and persons responsible for its correction should be indicated.

6 CONSIDERATIONS ON THF STABTT JTY OF PHARMACEUTICAL PRODUCTS

Stability is defined as the time in which a product maintains, within specified limits and in its whole period of use, the same properties and characteristics it had when it was obtained. Stability depends on factors related to the product itself, called intrinsic factors, such as composition of the pharmaceutical form, chemical-physically properties of active principles and excipients, pH, present impurities, type and properties of the packing materials and of the process used in their acquisition. Depending on the pharmaceutical form, particle size and polarity, especially in emulsions and suspensions, ionic power of the solvent system in the solutions and intermolecular connections (hydrogen bridge, dipole-dipole interaction, van der Waals forces) also impact stability.

Stability is also impacted by factors related to environment, extrinsic factors, such as temperature, moisture, gases (oxygen, carbon dioxide) and light, among others. The impact of the extrinsic factors in the stability can be minimized using specific excipients, appropriate packings and proper storage conditions.

The reactions in solid state are relatively slow, so, the stability of drugs in the solid state rarely is a concern in the dispensation. However, solids drugs with low fusion temperature must not be combined with others with which they make an eutectic mixture.

THE TEMPERATURE EFFECT

In general, the speed of a chemical reaction increases exponentially to each 10°C increase in temperature. This relation has been observed for almost all drug hydrolysis reactions and some oxidation reactions. The real factor of speed increasing depends on the each reaction activation energy. The activation energy is a function of the specific reactivity linked to the Formulation (ex.: solvent, pH, additive). On the other side, the pharmacist must be conscious of which low temperatures may cause damages. Refrigeration, for example, may cause extreme viscosity in some liquid drugs and cause supersaturation. Freezing may break or cause a great increase in the size of the emulsions droplets and, in some cases, lead to the formation of less soluble polymorphics of some drugs.

TYPES OF STABILITY

Depending on the aspects being considered, the pharmaceutical products stability may be classified in chemical, physical, microbiological, therapeutical and toxicological. Any changes in physical, chemical, microbiological, therapeutical or toxicological characteristics of the medicines which extrapolate the acceptable and pre-established limits, puts in risk the safety and the efficiency of the products.

Chemical stability

- For a chemical product to have stability, each drug included must have chemical entirety and declared power within specified limits. The loss of chemical stability may be determined by intrinsic and extrinsic factors and lead to changes in the concentration of the active principle, bringing the reduction of the dose intended to a patient. Additionally, decomposition products may present high toxicity, bringing risks to a patient. The limit generally accepted for chemical decomposition of pharmaceutical products is of a maximum 10%, provided the decomposition products are safely identified and their effects previously acknowledged. In

general, the pharmaceutical products must contain from 90 to 110% of the active principle declared in the tag.

Physical stability

- There is physical stability in the pharmaceutical products if their specified physical properties are maintained, including appearance, palatability, uniformity, dissolution and suspensibility. Physical characteristics of the pharmaceutical forms may change with time, such as hardness and dissolution rate in pills, uniformity, appearance, viscosity, taste, odor or, yet, separation of phases and formation of deposition. The confidence of the patient is impacted if color, taste, odor or other characteristics of the product change with time. Thus, even if the drug has a good chemical or microbiological stability, the physical changes may decrease the time of use of the medicine. The impact of pH on the physical stability of two phase system, specially emulsions, is also important.

Microbiological stability

- A product can be considered stable from a microbiological point of view if it keep the sterility or resistance to microbial growth in accordance with the specified requirements. Antimicrobial agents present must keep their preservative efficiency as per the specifications. The microbiological stability of the pharmaceutical product is a measure of its resistance to microbial growth, bacteria and funguses, originating from the inputs and from the environment during the acquisition, stocking and use. Microbial growth takes place in non-sterile products with high water content, such as solutions and water base dispersions. Thus, for non-sterile products, it is necessary the inclusion of preservative or preservative system in the Formulation. Solid pharmaceutical forms with relatively small quantities of water may not require preservative.

Therapeutic stability

- It is the maintenance of the therapeutic properties of the medicine. The therapeutic effect depends on the content of the drug and of its bioavailability. Thus, any change in the pharmaceutical form that decreases the quantity of the drug, affects the therapeutic stability, since it decreases its concentration in the action site. The chemical or enzymatic degradation, the non-release of a drug from the pharmaceutical form, its insolubilization or precipitation are examples of therapeutic stability loss causes.

Toxicological Stability

- To have toxicological stability, the medicine must not undergo significant increase in the toxicity. This toxicity increase may be due to the degradation byproducts resulting from the several reactions that take place between components of the Formulation or related to the microbiological stability loss.

MAIN DECOMPOSITION REACTIONS OF THE MEDICINES

Depending on the properties of the drug and on the extrinsic and intrinsic factors, the reactions listed as follows may occur and cause loss of the content of the drug in the product. In general, these reactions do not provide obvious visual or olfactory proofs of their occurrence.

Hydrolysis

- Esters, amides, lactones, lactams and imines are the functional groupings most susceptible to hydrolysis. The lactam and azomethine (or imine) bonds in benzodiazepinics are also sensitive to hydrolysis. The presence of water or moisture is a basic condition for occurrence

of this reaction that may be catalyzed by the pH, by the presence of divalent cations in low pH solutions and by temperature. It is necessary to study in which pH range the drug has less hydrolysis percentage and match it with the product pH, decreasing the speed in which this reaction takes place.

Oxidation

The molecular structures most susceptible to oxidation are hydroxyl groups directly connected to an aromatic ring (phenol and byproducts such as catecholamines and morphine), conjugated dienes (retinol/vitamin A and unsaturated fatty acids), heterocyclic aromatic rings, nitrous byproducts and nitrite and aldehydes (presents in flavorants). The oxidation byproducts in general have no activity and, although some of them are colored, they may not visible, depending on the dilution. The oxidation is favored by the pH, when this is higher than the optimum, in the presence of ions of polyvalent heavy metal such as copper and iron, and exposure to oxygen and UV radiation. These two last oxidation causes justify the use of antioxidant substances, ions sequestrants, external opaque packing, amber glass or plastic packing. Nitrogen atmosphere is recommended during the filling out of the ampoule bottle in case of products very sensitive to oxygen.

Photochemical decomposition

- Exposure to UV radiation may cause oxidation (photo-oxidation) and/or breaking of covalent bond (photolysis). Nifedipine, nitroprusside, riboflavine and phenothiazines are very unstable to photooxidation. In sensitive compounds, the photochemical energy produces free radicals, intermediary reactives, which can perpetuate chain reactions. Temperature and the presence of divalent metal are catalysts of photolysis.

Racemization

- It is the conversion of a drug to an optical isomer (enantiomer), which results in the mixture of both, very often followed by loss of therapeutic activity. The reaction takes place with molecules which present asymmetrical carbons and may have as catalysts the presence of light, pH changes, solvent type, among others.

Others

- Decomposition reactions more specific and uncommon than those above may occur and also bring loss of efficiency of the active principles, such as epimerization (e.g., tetracyclines), decarboxylation (e.g., carbenicillin disodium, carbenicillin free acid, ticarcillin disodium and ticarcillin free acid) and dehydration (tetracycline).

STABILITY OF MAGISTERIAL PRODUCTS

The stability studies aims to generate evidences on how the quality of a drug or of a medicine in function of the time changes, before a series of environmental factors, such as temperature, moisture and light. The information obtained also guide on the validity of the medicine and the storage conditions. Such studies start with the development of the Formulation, when all intrinsic factors, such as formula, compatibility between components, pH and properness of primary packing, and others, are evaluated. Once the pharmaceutical product is defined and obtained, a long period of sampling storage follows, already in its final packing, under controlled temperature and moisture conditions, which simulate those to which the product will be exposed in the distribution and marketing chain. In Brazil, defined as Climatic Zone IV, those conditions are temperature of (30 ± 2)°C and relative humidity of (70 ± 5) %.

For the industries, there are currently defined three types of stability studies: accelerated, long duration and follow-up. The validity is attributed considering the product in its primary sealed packing. Upon opening the medicine packing for using, for example, multidose medicine, in the form of solution or suspension, that acquires the characteristic of an extemporaneous medicine. That is due to the fact that the exposure, manipulation, use and storage conditions by the user may involve risk factors that were not previously evaluated in the stability studies.

The manipulated medicine is produced customized, i.e., to meet to a particular need of a patient and for immediate use. Therefore, it is given not an validity term but an expiry date for its use (term of use), which range from a few days to a few months. The criteria for establishing the term of use are, thus, different from those applied in the studies of validity term of industrialized products. The definition of this expiry date has been a great challenge, since the stability of extemporaneous products varies from a Formulation to other. This variation depends on the drug, on the Formulation components, on the pharmaceutical form type (if solid, liquid or semisolid), on the manipulation process, on the packing and environmental conditions, among others. For those reasons it is not possible to generalize an expiry date for all products. On the other side, the knowledge of the chemical reactions by which the drugs degrade provides the manipulator a mean to establish such conditions that the degradation rate could be minimized or avoided. Thus, to attribute the term of use of a manipulated product, it is necessary to consider the chemical nature of the drug, its degradation mechanism, the primary packing, expected storage conditions and expected duration of the therapy.

To assure safety, efficiency and quality of the manipulated product correct calculations, precise measures, proper conditions and procedures for the development of the Formulation, quality inputs and good sense of the pharmacist, who must be a qualified professional for this purpose, are necessary. Additionally, a proper formula with a proved stability profile must be looked in the specific literature. In the cases in which no formula is found in the literature, the pharmacist shall develop it based on scientific principles. That is a slow process which may demand a very careful analysis:

a) of the degradation potential of the active ingredient by oxidation, hydrolysis, photolysis or thermolysis;
b) of the interactions between excipients and active principle, especially if pills or capsules are used as source of the drug, when it is not available in the market;
c) of the type of packing more appropriate to protect the product from environmental factors which could impact the stability;
d) of the most proper Formulation, matching stability and adequacy of the pharmaceutical form to facilitate the administration;
e) of the storage and preservation conditions and considerations attributing a term of use for the Formulation.

Oral use liquid formulas may be more complex than solid ones. The main reason is the addition of components that will be aggregated for the adequacy of the pharmaceutical form (vehicle, preservative, buffering agent, aromatizing agent, viscosity corrective and suspension agent, among others). All those aspects must be evaluated in the development of the Formulation. Additionally, it is necessary to be careful when the stability of the drug in the solid state is taken as a base, since it may be less stable in solution or in suspension.

A challenge for pharmacists is to provide proper pharmaceutical forms for patients with different needs, mainly pediatric and old patients. Incapable of swallowing solid forms, they use liquid formulas that allow reliability in the dose and reproductiveness of the measure. It is

a common practice to prepare liquid forms from solid forms (pill/capsule), when the drug is not commercially available. The excipients present in the commercial product may be a problem for the manipulator, since there can be potential interactions between the components of the commercial product and those who will be collected in the manipulation. The expiry date of the commercial product cannot be exceeded for the product obtained. Thus, the manipulator must resort to literature or to the manufacturer of the medicine to obtain information on the stability. Articles and scientific publications may be also used as information source on stability, compatibility and degradation of the components. All stability data must be interpreted with caution regarding the new Formulation.

7 CONSIDERATIONS FOR PREPARATION OF GALENIC BASES

The bases of the National Form are liquid or semisolid nature vehicles intended to the incorporation of active substances. The semisolid bases include formulas of creams, gels, pastes, salves and hair conditioners, and liquid formulas, such as lotions, syrups and shampoos. The base formulations presented in this chapter as suggestions must be previously evaluated in the presence of the active components added or if there is any other change. In the choice of the basis for incorporation of the drug or other actives it must be considered:

a) the purpose of the Formulation, the desired therapeutic effect and the place of administration;
b) the chemical-physical properties of the drug intended to incorporation, such as solubility, pH, chemical compatibility with other components of the formula and stability.

GENERAL CONSIDERATIONS ON VEHICLES AND PHARMACEUTICAL EXCIPIENTS

The pharmaceutical vehicles may present themselves in liquid or semisolid form and in this last case they are also called excipients. The vehicle may be solution, suspension or emulsion. Depending on the administration mean and on the chemical-physical characteristics of the dissolved or scattered substances, adjuvant substances with specific functions, such as cosolvents, antioxidants, chelating agents, pH correctors, colorants, edulcorants and extracts, thickeners, and others, are added.

The solutions are liquid preparations containing one or more active principles dissolved in a solvent or mixture of solvents. They are classified, depending on the administration road, in oral or topical. Among oral solutions, syrups are solutions containing high concentrations of sugar and elixirs, in addition to edulcorated, they present hydroalcoholic vehicle to favor the dissolution of certain less soluble drugs. Topical solutions are intend for application on the skin and mucous membranes.

The term lotion is used to designate topical preparations for use on the skin, however it includes dispersions, i.e., suspensions and emulsions. Dispersions may be liquid or semisolid and, in the first case, it has higher viscosity than solutions, to decrease the internal phase settling. For this reason, they should have their formula adjusted for quick and homogeneous redispersion, after short agitation.

Vehicles or semisolid excipients are intended to external use, on the skin or mucous membranes, and they are classified as salves, creams, gels and pastes. In **Table 1** the types of bases for salves and their main characteristics are presented. Additionally, the gels are constituted by dispersal of colloidal particles, and they may contain carbomers, bentonite magma or aluminum hydroxide. Pastes have characteristics similar to salves, however they seem less oily, present large amount of incorporated solids, have high siccative power, little or no penetration in the skin and they are of difficult removal.

Table 1 – Characteristics of the different types of salve for topical use.

Base type	Characteristics	Mains Constituents
Oleaginous: composed by fatty substances	Insoluble in water, can not be washed, anhydrous, no water absorption, emollient, occlusive and fatty	White Petrolatum, liquid petrolatum, white wax
Of absorption abhydrous: hydrocarbon and emulsifying bases which compose water in oil emulsions when water is added.	Insoluble in water, non washable, anhydrous, can absorb water, emollient, occlusive and fatty.	Lanolin, mixture of alcohol cholesterol, stearyl alcohol, bee white wax and vaseline, vaseline mixture, wax and sorbitan sesquioleate.
Of absorption water in oil emulsive: emulsive bases containing water	Insoluble in water, non washable, can absorb (little) water, emollient, occlusive and fatty.	Cold cream.
Washable emulsive: constituted by oil in water emulsions, also called creams.	Soluble in water, washable, contains water, can absorb water, non occlusive and non fatty.	Autoemulsionant waxes
Soluble in water: bases generally composed by polyethylene glycols.	Soluble in water, washable, can contain or absorb water, non occlusive and non fatty.	Polyethylene Glycols

MAIN CONSTITUENT OF SEMISOLID BASES

Autoemulsionant waxes

- The concentrations of the autoemulsionant waxes are chosen in function of the emulsionant capability and of the desired viscosity for the final product. Climatic changes may result in differences of viscosity in the final product. In regions with higher temperatures, the product may present lower viscosity and may be necessary to increase the proportion of the wax for correction of the base consistency for topical use. In regions with lower temperatures, the opposite may be evidenced.

Emollients

- Those are substances used in topical use products, such as oils or lipids, aiming to softening or smoothen the skin or, yet, to make her more flexible. The occlusion promoted by the emollients decrease the transepidermal water loss and, consequently, increases the corneal stratum hydration.
- Creams and creamy lotions have, in general, at least one emollient in their composition. The chemical structure of the emollients influence their interaction with the skin and the sensory property of the final product. The mineral oil, vegetable oils, triglycerides, fatty acid esters, lanolin and polydimethylsiloxanes have higher occlusive power.
- Oils create a fattier sensation, while fatty acids esters present a lighter sensation in the skin and are less occlusive than waxes and oils. The concentration and type of emollient may be modified to change some characteristics of the Formulation such as spreadability, cost, compatibility, solubilizing capability, drug release, cutaneous penetration, occlusion, among others.

Preservatives

- The preservatives present in the Formulations are selected according to their action spectrum, innocuity and physical chemical compatibility. They may be replaced provided the efficiency, stability and compatibility are maintained.

pH

- The Formulation pH is important not only in the stability of the active principles. Below pH 3.4, fatty acid esters, present in the fatty phase of the emulsions, tend to hydrolyze and, as result, the product may present unpleasant odor.

Water

- The water used as a vehicle for manipulation of the bases is the purified water.

MANIPULATION OF PRODUCTS USING THE SUGGESTED BASE FORMULAS

If the bases for topical use are manipulated in containers previously tared, it is possible to determine the quantity of water necessary to complete the evaporated portion, weighing the container and adding sufficient water to the final product, under slow agitation.

Raw materials originating from different manufacturers may provide differences in aspect, pH, viscosity and consistency of the product. For this reason, it is recommendable to evaluate the raw material at the receiving, for the necessary adjustments of these characteristics.

Many active substances, even when chemically compatible with the excipient, may lead to decreasing in viscosity, destabilizing the Formulation. In these cases, to avoid consistency loss, it is possible to use a concentrated base.

This method consists in stipulating the maximum quantity of active principles to be added to the base without incurring in its destabilization and, next, recalculate the raw materials concentrations to be used for the manipulation of the base.

Example: to add a maximum of 30% of active principles to the Formulation 70% of the base is used; to add a maximum 20% of active principles to the Formulation 80% of the base is used; to add a maximum of 10% of active principles to the Formulation, 90% of the base is used, and so on.

The concentrated base can be obtained by two methods, increasing the concentration of the auto- emulsioning wax or another agent of consistency present in the Formulation or decreasing the quantity of water used for the base manipulation.

Method 1 – increase of the concentration of the formula components.

By this method, having the percentage of active principles to be added *(Pa),* the quantities of raw materials in the concentrated formula of the selected base are calculated through correction factor *(F),* obtained with the equation:

$$F = \frac{100 - Pa}{100}$$

in what
Pa = percentage of active principles to be added;
F = correction factor.

Example

- If the addition of active principles is of up to 30% and the chosen base, the **NON IONIC LOTION II,** the factor *F* calculated is of: $F = (100\text{-}30)/100$, thus, $F = 0.7$. When the quantities of the raw materials are divided in the lotion by *F (0.7)* we have the concentrated formula

Component	Quantity	Quantity in the concentrated base
Phase A (watery)		
di sodium edetate	0.10 g	0.1/0.7 = 0.14 g
Paraben preservative solution	3.3 g	3.3/0.7=4.71 g
Purified water qsp	100 g	l00g
Phase B (oily)		
Octyl Stearate	5 g	5/0.7 = 7.14
Non-ionic auto-emulsifying wax	10 g	10/0.7 = 14.28
Butyl-hydroxytoluene	0.05 g	0.05/0.7 = 0.07 g
Phase C (complementary)		
cyclomethicone	2 g	2/0.7 = 2.85 g
imidazolidinyl urea preservative solution at 50%	0.06 g	0.6/0.07 = 0.85 g

How to use

- Use 70% of anionic base lotion to add the active principle(s) and complete the volume with water, if necessary. If the concentration of the active principle(s) reaches 30%, water addition is not necessary. Thus, in the incorporation of the active principles we have:

Components	Quantity
active principles	up to 30%
concentrated anionic base lotion	70%
water (if necessary) asn	100%

Method 2 – decrease of the quantity of water used in the manipulation of the base.

Getting the concentrated base by this method is obtained with the drawing of the water at the same proportion in which the active principles are added. For example, to incorporate up to 30% of active principles to the **NON-IONIC LOTION II,** instead of completing the total mass of the formula for 100 g with water, it is necessary to complete to 70 g, as in the following example:

Components	Quantity	Quantity in the concentrated base
Phase A (watery)		
di sodium edetate	0.10g	0.10g
Paraben preservative solution	3.3 g	3.3 g
Purified water qsp	100g	70g
Phase B (oily)		
Octyl Stearate	5g	5g
Non-ionic auto-emulsifying wax	10g	10g
Butyl-hydroxytoluene	0.05 g	0.05 g
Phase C (complementary)		
cyclomethicone	2 g	2 g
imidazolidinyl urea preservative solution at 50%	0.6 g	0.6 g

Use way

- In this case, in the moment of the manipulation of the product, the active principles are added up to 30% to 70% of concentrated base and water is added to complete the remainder of the mass to 100%, if necessary.

8 MONOGRAPHS

8.1 MAGISTERIAL AND OFFICINAL PRODUCTS

8.2 BASES FOR THE PREPARATION OF FORMULATIONS

8.3 AUXILIARY SOLUTIONS

8.1 MAGISTERIAL AND OFFICINAL PRODUCTS

ACETYLCYSTEINE 5% OR 10%, OPHTHALMIC SOLUTION

PHARMACEUTICAL FORM
- Eye drops.

FORMULA

Component	Quantity
acetylcysteene	0.5 g or 1 g
vehicle qsp	10 mL

Note: *the vehicle is a phosphate buffer pH 7.4 prepared with sterile purified water.*

DIRECTIONS FOR THE PREPARATION
- Dissolve the acetylcysteine in half of the total quantity of the vehicle and agitate up to complete dissolution. Check the Formulation pH (that shall be between 6.0 and 7.5) and complete the volume. Leave in rest for approximately two hours in refrigerator, to homogenize and filter using sterilizing filtration system with 0.22 pm porosity membrane, directly for the previously sterilized dropper bottle.

Note: *the eye drops must be a sterile solution. Proceed to sterilizing filtration in laminar flow chapel, properly adorned. The bottle must be a dropper, to facilitate the administration, and sterile, to prevent contamination of the solution. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In sterile, milky, sealed, perfectly closed dropper bottle. Preserve in refrigerator, sheltered from light.

WARNINGS
- Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Do not wash the dropper. Keep away from children.

INDICATIONS
- Dry eye syndrome, associated to tear secretion deficiency or abnormal production of mucus; as topic mucolytic for conjunctivitis in kids; and to inhibit the formation of collagenase, which occurs in chemical bums, obstructing its action on the cornea stroma.

DIRECTIONS FOR USE
- External use.
  - Apply one to two drops, three to four times a day or at the doctor's discretion.

ACETIC ACID 2% TO 5%, SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
glacial acetic acid	2 g to 5 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Transfer the glacial acetic acid to proper container containing 30 mL of water and slowly complete the volume with the same diluent, homogenize and filter.

PACKING AND STORAGE
- In well closed glass container, at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- For diagnosis purposes in colposcopy and peniscopy.

DIRECTIONS FOR USE
- External use.
  - At the doctor's discretion.

BORICATED WATER 2%

SYNONYMITY
- Boric acid solution 2% (p/v).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
boric acid	2g
sterile purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Heat part of the water to approximately 50°C, dissolve the boric acid and let it cool.
- Complete the volume with sterile purified water. Homogenize and filter.

PACKING AND STORAGE
- In proper well closed amber glass or opaque plastic container and at room temperature.

WARNINGS
- Reject the solutions seven days after opening the bottle. Stop using in case of change in color or odor. Keep away from children. It is recommended to include in the tag the flowing sentence: do not ingest. External use only.

THERAPEUTIC INDICATIONS As antiseptic in ophthalmitis.

DIRECTIONS FOR USE
- External use.

BORICATED WATER 3%

SYNONYMITY
- Boric acid solution 3% (p/v).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
boric acid	3g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Heat part of the water to approximately 50°C, dissolve the boric acid and let it cool.
- Complete the volume with sterile purified water. Homogenize and filter.

PACKING AND STORAGE
- In proper well closed amber glass or opaque plastic container and at room temperature.

WARNINGS
- Reject the solutions seven days after opening the bottle. Stop using in case of change in color or odor. Do not apply in large areas of the body, when injuries or burns are present. Product for use in adults only. Keep away from children. It must not be used in the breasts during breastfeeding without consulting a doctor. It is recommended to include in the tag the flowing sentence: “Do not ingest. External use only”.

THERAPEUTIC INDICATIONS
- Antiseptic, tranquilizer and lightly adstringent in exudative dermatites.

DIRECTIONS FOR USE
- External use.
  - Apply two to three times a day in gauze or cotton compresses.

STRONG ALIBOUR'S WATER

SYNONYMITY
- Copper-zinc solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
copper sulfate	1 g
zinc sulfate	3.5 g
camphorated alcohol	1 mL
saffron dye	1 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the cupric sulfate and the zinc sulfate. Transfer to proper container and dissolve in 80 mL of water. Under agitation, add the saffron dye and the *camphorated alcohol*. Complete the volume with purified water, homogenize and filter.

Note: *it is possible to obtain the weak Alibour's water through dilution of strong Alibour's water to a tenth.*

PACKING AND STORAGE
- In proper well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- As astringent and local antiseptic in impetigo, pyodermitis and injuries treatment.

DIRECTIONS FOR USE
- External use.
  - May be used pure or diluted in water at 10% (v/v), in bath or compresses or at the doctor's discretion.

LIME WATER

SYNONYMITY
- Calcium hydroxide suspension.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
calcium hydroxide	1 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the calcium hydroxide. Transfer to proper container, dissolve with sufficient quantity of water, complete the volume and agitate. Leave it in rest until getting limpid supernatant, which must be decanted and rejected. Complete the volume again, homogenize and leave it in rest. In time of employment, use proper volume of the limpid supernatant.

PACKING AND STORAGE
- In proper perfectly closed amber glass or opaque plastic container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Astringent and to facilitate the cicatrization of burns and ulcers.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, three to four times a day.

PEROXIDE 10 VOLUMES

SYNONYMITY
- Hydrogen peroxide solution at 3% (p/p).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
concentrated hydrogen peroxide solution qs	3 g of H2O2
acetanilide in qs of ethylic alcohol	0.5 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container, dissolve the peroxide of hydrogen in sufficient quantity of water and add acetanilide. Complete the volume with purified water and homogenize.

Note: *Hydrogen peroxide quickly decays when in contact with oxidant and reducer substances, with organic matters and oxidizable substances, with alkaline substances, iodide, permanganates and other substances. Its decomposition is accelerated by presence of metal, light and agitation.*

PACKING AND STORAGE
- In proper well closed opaque plastic or amber glass container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

THERAPEUTIC INDICATIONS
- Topical Antiseptic.

DIRECTIONS FOR USE
- External use.
  - Topical application with cotton.

CAMPHORATED ALCOHOL

SYNONYMITY
- Alcoholic camphor solution, camphor spirit.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
camphor	10 g
ethylic alcohol 96 °GL qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the camphor in ethylic alcohol, complete the volume with the same solvent. Homogenize and filter.

PACKING AND STORAGE
- In amber glass bottle with lid and stopper, protected from light and in fresh place.

WARNINGS
- It must not be used in children younger than two years. Keep away from children. Keep the bottle well closed.

INDICATIONS
- Symptomatic treatment of myalgias and arthralgias. It can also be used for relieving itches.

DIRECTIONS FOR USE
- External use.
  - Gently apply in the location and massage, three to four times a day. It is used diluted in oils, liniments and topical solutions.

ETHYLIC ALCOHOL 70% (P/P)

SYNONYMITY
- Disinfectant alcohol, antiseptic alcohol, ethylic alcohol 77% (v/v).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
ethylic alcohol 96 °GL	75.73 g
purified water qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, mix the ethylic alcohol and the water. Agitate. Leave it in rest until complete the elimination of the blisters and check the ethanolic title of the solution as described in *Determination of alcoholic degree* **(ATTACHMENT A).**

PACKING AND STORAGE
- In proper perfectly closed high density amber glass or opaque plastic container, sheltered from light, at room temperature.

WARNINGS
- Keep away from heat sources. Keep away from children.

INDICATIONS
- Antiseptic and solvent.

DIRECTIONS FOR USE
- External use.
  - As antiseptic, Apply on the skin. As disinfectant, apply on the surfaces or objects to be disinfected.

EXAMPLE
- In order to prepare 1000 mL of disinfectant alcohol 70% (p/p) or 77 °GL, starting from ethylic alcohol at 96 °GL and apparent temperature of 21°C proceed as follows:
  - refer to *Table B. 1* **(ATTACHMENT B),** doing the intersection between the apparent readings obtained: 96 ° (96c) and 21°C. The table indicates that the actual alcoholic degree value is 94.7 °GL at 15°C.
  - refer to *Table A.l* **(ATTACHMENT A)** to determine the ponderal title of the alcohol AT 94.7 °GL. It will be necessary to round it up to 95 °GL and do the correlation between the 1st and the 3rd column of the table. In the table it is indicated that the ponderal title of the alcohol at 95 °GL is 92.43 g.
  - calculate the quantity of ethylic alcohol to be weighed, according to the expression:

$$Y = \frac{P \times b}{a}$$

where
Y = quantity of ethylic alcohol to be weighed;
P = quantity, in weight, of disinfectant alcohol to prepare; b = ponderal title desired: 70% (p/p);

a = ponderal title of the ethylic alcohol (corrected in *Table A.l* at 15°C).

Thus,

$$Y = \frac{1000g \times 70g}{92,43g} = 757,30 \text{ g of ethylic alcohol}$$

weigh 757.30 g of ethylic alcohol, complete for 1000 g with water and mix.

ETHYLIC ALCOHOL 77% (V/V)

SYNONYMITY
- Disinfectant alcohol, antiseptic alcohol, ethylic alcohol 70% (p/p).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
ethylic alcohol 96 °GL	81.3 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container, mix the ethylic alcohol and the water. Agitate. Leave it in rest until complete the elimination of the blisters and check the ethanolic title of the solution as described in *Determination of alcoholic degree* **(ATTACHMENT A).**

PACKING AND STORAGE
- In proper perfectly closed high density amber glass or opaque plastic container, sheltered from light, at room temperature.

WARNINGS
- Keep away from heat sources. Keep away from children.

INDICATIONS Antiseptic and solvent.

DIRECTIONS FOR USE
- External use.
- As antiseptic, Apply on the skin. As disinfectant, apply on the surfaces or objects to be disinfected.

EXAMPLE
- In order to prepare 1000 mL of disinfectant alcohol 77 °GL or 77% (v/v) at 15°C, starting from ethylic alcohol with apparent alcoholic degree 96 °GL and apparent temperature of 21°C proceed as follows:
  - refer to *Table B. 1* (ATTACHMENT B), doing the intersection between the apparent readings obtained: 96° (96c) and 21°C. The table indicates that the actual alcoholic degree value is 94.7 °GL at 15°C.
  - calculate the quantity of ethylic alcohol to be weighed, according to the expression:

$$X = \frac{v \times b}{a}$$

where
X = quantity of ethylic alcohol to be measured;
v = volume of disinfectant alcohol to prepare;
b = alcoholic degree desired: 70% (p/p);
a = actual alcoholic degree of ethylic alcohol (corrected in *Table A.l* at 15°C).

Thus,

$$X = \frac{1000 \text{ mL} \times 77 \text{ g}}{94{,}7 \text{ g}} = 813{,}09 \text{ mL of ethylic alcohol}$$

measure 813.09 mL or 815 mL of ethylic alcohol, complete the volume for 1000 mL with water and mix.

GLYCERINATE ETHYLIC ALCOHOL 80%

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
ethylic alcohol 96 °GL	83.33 mL
glycerol	1.45 mL
peroxide hydrogen 3% tp/v)	4.17 mL
purified water qsp	100 mL

Note: *the final concentration of the ethylic alcohol is 80% (v/v), of the glycerol is 1.45% (v/v) and of the hydrogen peroxide is 0.125% (v/v).*

DIRECTIONS FOR THE PREPARATION
- Mix the ethylic alcohol, the hydrogen peroxide and the glycerol. Complete the volume with purified water. Homogenize.

PACKING AND STORAGE
- In proper well closed plastic container, protected from light, in temperature lower than 25°C.

WARNINGS
- Keep away from children.

INDICATIONS
- Antiseptic.

DIRECTIONS FOR USE
- External use.
  - Apply for skin antisepsis.

ALCOHOL GEL

PHARMACEUTICAL FORM Alcoholic Gel.

FORMULA

Component	Quantity
ethylic alcohol 96 °GL	75.73 g
carbomer 980	0.5 g
triethanolamine solution at 50% (p/v)	qs
purified water qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Mix the ethylic alcohol and the water. Disperse the carbomer 980 under agitation. Complete the volume with purified water and adjust the pH between 5.0 and 7.0 with *triethanolamine solution at 50% (p/v)*, to obtain the proper consistency.

PACKING AND STORAGE
- In proper well closed plastic container, protected from light and at temperature lower than 25°C.

WARNINGS
- Keep away from children.

INDICATIONS
- Antiseptic.

DIRECTIONS FOR USE
- External use.
  - Apply in the skin antisepsis and in the disinfection of surfaces and materials.

ISOPROPYL GLYCERINATED ALCOHOL 75%

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
ispropyl alcohol	75.15 mL
glycerol	1.45 mL
hydrogen peroxide 3% tp/v)	4.17 mL
purified water qsp	100 mL

Note: *the final concentration of the isopropyl alcohol is 75% (v/v), of the glycerol is 1.45% (v/v) and of the hydrogen peroxide is 0.125% (v/v).*

DIRECTIONS FOR THE PREPARATION
- Mix the isopropyl alcohol, the hydrogen peroxide and the glycerol. Complete the volume with purified water. Homogenize.

PACKING AND STORAGE
- In proper well closed plastic container, protected from light, at temperature lower than 25°C.

WARNINGS
- Keep away from children.

INDICATIONS
- Antiseptic.

DIRECTIONS FOR USE
- External use.
  - Apply for skin antisepsis.

BENZOATE OF BENZILA, LOTION 10% OR 25%

PHARMACEUTICAL FORM Lotion.

FORMULA

Component	Quantity
benzyl benzoate	10 g or 25 g
anionic lotion qsp	100 mL

DIRECTIONS FOR THE PREPARATION

Add the benzyl benzoate to the *anionic lotion* and homogenize until getting an uniform product. PACKING AND STORAGE

- In well closed plastic or glass container, sheltered from light and at room temperature.

WARNINGS

- The lotion at 25% (p/v) is not recommended for use in children. Keep away from children. Dilution of the product may decrease his efficiency.

INDICATIONS

- Scabies.
  - Adults: lotion at 25% (p/v).
  - Children and newborn babies: lotion at 10% (p/v).

DIRECTIONS FOR USE

- External use.
  - Apply in the body after bath, from the neck to the feet, during three days. Repeat after a week or at the doctor's discretion. In newborn babies and children up to six months, the application period of the lotion at 10% (p/v) is from six to twelve hours.

BENZYL BENZOATE, LOTION 25% FOR ENVIRONMENTAL USE

SYNONYMITY
- Anti-acarus lotion.

PHARMACEUTICAL FORM
- Lotion.

FORMULA

Component	Quantity
benzyl benzoate	25 g
cetostearyl alcohol	3g
triethanolamine lauryl sulfate qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Heat the cetostearyl alcohol in water bath at 70°C. Pour slowly under constant agitation, the triethanolamine lauryl sulfate. Draw from the heating. Keep agitation until reaching room temperature. Add, under agitation, the benzyl benzoate. Homogenize.

PACKING AND STORAGE
- In perfectly closed bottle. Store in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children. Agitate before using. It must never be ingested.

USE
- Cleaning of environments infested by acarus.

DIRECTIONS FOR USE
- In the time of the use dilute in the proportion of a tablespoon for a liter of water. Apply once in a week, in the morning and on a sunny day, with the help from a clean cloth, sponge or spray, in the furniture, mattress, cushions, curtains, floors etc. Then, vacuum the environment. Leave the environment exposed to aeration and heat, and to at the end of the afternoon proceed to a new aspiration, carefully. Repeat this procedure weekly for three months, and after this period reduce it to a monthly application. It is necessary to use the day of the application to change the bed clothes.

CALAMINE, LOTION

SYNONYMITY
- Calamine suspension.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
calamine	8g
zinc oxide	8g
glycerol	2 mL
bentonite magma*	25 mL
paraben preservative solution	1 mL
purified water qsp	100 mL

* Obtained by the dispersion of 5 g of bentonite in 80 mL of heated water at 70 °C. Leave it in rest for 24 hours and complete the volume with purified water until obtaining 100 g.

DIRECTIONS FOR THE PREPARATION
- Disperse the bentonite magma in equal water volume and add the *preservative paraben solution*. Apart, disperse the calamine in the glycerol, add the zinc oxide and the bentonite magma water dispersion, homogenizing well. Complete the volume with water.

PACKING AND STORAGE
- In an opaque well closed plastic container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children. Do not apply on the eyes or open wounds.

INDICATIONS
- Anti-inflammatory and anti-itching.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, three to four times a day.

KETOCONAZOLE 2%, CREAM

PHARMACEUTICAL FORM

- Cream.

FORMULA

Component	Quantity
Phase A (waterish)	
iso-octyl stearate	15 g
cetostearyl alcohol/sodium lauryl sulfate	10g
propylene glycol	20 g
liquid petrolatum	5 g
mixture of lauryl glycoside, polyglyceryl dipolyhydroxy stearate and glycerol	2g
Phase B (waterish)	
purified water qsp	100 g
Phase C (complementary)	
butyl-hidroxytoluene	0,2 g
ketoconazole	2g
Phase D (complementary)	
imidazolidinyl urea preservative solution at 50%	0,6

DIRECTIONS FOR THE PREPARATION

- In a proper container, fuse **Phase** A **(oily)** components at 70°C. In another container, heat the water **(Phase B, waterish)** until reach 75°C. Pour the oily phase on the waterish phase under moderate agitation. Keep agitation until a temperature of approximately 40°C. Add **Phase D.** In porcelain mortar pulverize **Phase C** components. Incorporate in the mortar a quantity of the cream ready until the formation of a homogeneous paste. Add the remainder of the cream and mix well. Check the pH, which shall be between 5.0 and 6.0. If necessary adjust the pH with *citric acid solution from 25% to 50%*.

Note: *ketoconazole is photosensitive. Manipulate in environment with as little light as possible.*

PACKING AND STORAGE

- In an opaque, perfectly closed container. Keep under refrigeration, sheltered from light and heat.

WARNING

– Keep away from children.

INDICATIONS

- Superficial mycosis, including dermatophytosis (*Tinea comporis, Tinea cruris, Tinea manum* and *Tinea pedis*), cutaneous candidiasis and versicolor ptyriasis.

DIRECTIONS FOR USE

- External use.
  – Apply in the infected areas once a day or at the doctor's discretion.

KETOPROFEN 2.5%, GEL

PHARMACEUTICAL FORM
- Gel.

FORMULA

Component	Quantity
ketoprofen	2,5 g
ethylic alcohol 96 °GL	qs
hydroalcoholic gel at 50% qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind the ketoprofen in a mortar until getting fine powder. Solubilize the ketoprofen in sufficient quantity of alcohol. Add the hydroalcoholic gel geometrically until reach the desired amount.

Note: *drug sensitive to light. It is recommended to avoid light incidence during production process and storage.*

PACKING AND STORAGE
- In opaque, perfectly closed container. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Non-hormonal anti-inflammatory and analgesic.

DIRECTIONS FOR USE
- External use.
  - Apply on the affected area two to four times a day, massaging lightly or at the doctor's discretion.

CETYL PYRIDINE CHLORIDE 0.05% TO 0.1%, SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
cetyl pyridine chloride	50 mg to 100 mg
non cariogenic edulcorant	qs
flavoring agent	qs
colorant	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the cetyl pyridine chloride in sufficient quantity of purified water. Add the edulcorant and the colorant. Homogenize. Add the flavoring agent. Complete the volume with purified water. Filter.

Note: *the cetyl pyridine chloride is incompatible with anionic surfactants.*

PACKING AND STORAGE
- In proper well closed container and at room temperature.

WARNINGS
- Do not use in children younger than six years. Keep away from children.

INDICATIONS
- Cationic antiseptic, astringent. Used for decreasing the accumulation of plaques and prevention of gingivitis.

DIRECTIONS FOR USE
- Mouth wash one tablespoon (15 mL), one to two times a day or according to the direction of the dentist. For children from six to 12 years use diluting the product with equal parts of water.

SODIUM CHLORIDE 5%, OPHTHALMIC SOLUTION

PHARMACEUTICAL FORM
- Eye drops.

FORMULA

Component	Quantity
sodium chloride	0,5 g
benzalkonium chloride	1 mg
sterile purified water qsp	10 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the sodium chloride and the benzalkonium chloride in sterile purified water. Filter the solution using sterilizing filtration system with 0.22 pm porosity membrane, directly for the bottle dropper previously sterilized.

Note: *the eye drops must be a sterile solution. Proceed to sterilizing filtration in laminar flow chapel, properly adorned. The bottle must be a dropper, to facilitate the administration, and sterile, to prevent contamination of the solution. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In sterile, milky, sealed, perfectly closed dropper bottle. Preserve in refrigerator, sheltered from light.

WARNINGS
- Reject the solution 30 days after opening the bottle. Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Keep away from children.

Note: *in order to remain stable, sodium chloride solutions must not be frozen or subjected to extreme heat temperatures.*

INDICATIONS
- Auxiliary therapy for decreasing cornea edema or as hyperosmotic agent.

DIRECTIONS FOR USE
- External use.
  - Apply one or two drops each three or four hours.

FERRIC CHLORIDE, GEL

SYNONYMITY
- Hemostatic Gel.

PHARMACEUTICAL FORM
- Gel.

FORMULA

Component	Quantity
ferric chloride	25 g
purified water	30 g
high viscosity hydroxyethyl cellulose qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Solubilize the ferric chloride in the water. Leave the solution in rest for approximately two hours, for total dissolution of the ferric chloride. Filter and slowly add the *high viscosity hydroxyethyl cellulose gel*, homogenizing.

PACKING AND STORAGE
- In perfectly closed bottle. Keep in fresh place, sheltered from light, heat and moisture.

WARNINGS
- Keep away from children.

THERAPEUTIC INDICATIONS
- Antihemorrhagic.

Note: *ferric chloride may cause irritation of the mucous membranes.*

DIRECTIONS FOR USE
- External use.
  - Apply in the location after the procedure.

COAL-TAR 1%, SALVE

SYNONYMITY
- Coal-tar salve 1% (p/p), mineral tar salve 1% (p/p).

PHARMACEUTICAL FORM
- Salve.

FORMULA

Component	Quantity
mineral tar	1 g
polysorbate 80	5 g
white petrolatum qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, add the mineral tar and the polysorbate 80. Homogenize. Incorporate the mixture to the white petrolatum until getting an uniform aspect.

PACKING AND STORAGE
- In proper, opaque, well closed container, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Psoriasis.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, at night, with removal in the morning or at the doctor's discretion.

COAL-TAR, SOLUTION

SYNONYMITY
- *Liquor carbonis detergens (LCD),* saponated tar, mineral tar solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
mineral tar	20 g
polysorbate 80	5 g
soap bark tree dye qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container, heat the mixture of mineral tar and polysorbate 80 in water bath at 100°C. Add the soap bark tree dye, slowly, under agitation. Draw from the heating, keep under agitation for 1 hour and after, leave it in rest for separation of the phases. Purify and complete the supernatant volume with the soap bark tree dye.

Note: *the soap bark tree dye may be replaced by ethylic alcohol.*

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS Keratoplastic and anti-itching.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas one to two times a day.

LACTIC-SALICYLATE COLLODION

SYNONYMITY
- Compound elastic collodion.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
salicylic acid	2g
lactic acid	2 mL
elastic collodion qsp	10 mL

Note: *the elastic collodion is a pyroxylin alcoholic-ethereal solution (nitrocellulose, cotton gunpowder) 5%, castor oil 5%, ethylic alcohol 20% and ether qsp 100%. Put on the skin the alcohol and the ether evaporates, remaining a fine adherent ricinic pyroxylin film. It has protective topical action and it serves as vehicle for incorporation of several substances.*

DIRECTIONS FOR THE PREPARATION
- Grind the salicylic acid and transfer to proper container. Add 5 mL of elastic collodion and, under agitation, add the lactic acid. Complete the volume with the elastic collodion and homogenize. Manipulation in chapel with immediate packaging and exhaustion system is recommended.

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children. Do not use near the eyes. Avoid contact with mucous membranes and non damaged skin. Protect from light.

INDICATIONS
- Common warts and callosities.

DIRECTIONS FOR USE
- External use.
  - Protect the areas around the injury with white petrolatum. Apply once a day, during a week, four layers of collodion, waiting for each layer to dry before reapplying it.

DIPHENHYDRAMINE HYDROCLORIDE 2,5 MG/ML, ANNOYS

PHARMACEUTICAL FORM
- Syrup.

FORMULA

Component	Quantity
diphenhydramine hydrocloride	0,3 g
ammonium chloride	3 g
sodium citrate	1,35 g
mint flavorant	qs
paraben preservative solution	2g
raspberry syrup	12 mL
simple syrup qsp	120 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the diphenhydramine hydrocloride, the ammonium chloride and the sodium citrate in sufficient quantity of purified water. Add the *paraben preservative solution*. Homogenize and add the raspberry syrup. Complete the volume with *simple syrup*. Homogenize.

PACKING AND STORAGE
- In amber glass container, perfectly closed. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Antihistamine and antiemetic.

DIRECTIONS FOR USE
- Internal use.
  - Adults – 5 mL to 10 mL each two or three hours.
  - Children – 2,5 mL to 5 mL each three hours or at the doctor's discretion.

CHLORHEXIDINE DIGLUCONATE 0.05%, TOPICAL SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
chlorhexidine digluconate solution 20% (p/v)	0,25 mL
isopropvl alcohol	5.7 mL
benzalkonium chloride 50% (p/v)	1 mL
polysorbate 20	2 mL
lactic acid 85% (v/v) qs	pH 5,5 – 6,5
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Disperse the chlorhexidine digluconate 20% (p/v) with 50 mL of purified water. Add the isopropyl alcohol and then the benzalkonium chloride 50% (p/v), under agitation. Disperse the polysorbate 20 apart in 20 mL of purified water, homogenize and pour in the previous solution. Adjust the pH with the lactic acid 85% (v/v). Complete the volume with purified water.

Note: *the chlorhexidine digluconate action reduces in alkaline pH, in the presence of organic materials, anionic detergents and tannins; it increases, however, in elevated temperature, neuter pH, presence of non ionic detergents and quaternary ammonium salts.*

PACKING AND STORAGE
- In perfectly closed amber container. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Topical Antiseptic. Use in injuries, bums and other cutaneous injuries.

DIRECTIONS FOR USE
- External use.
  - In local application, as antiseptic.

CHLORHEXIDINE DIGLUCONATE 0,1%, ORAL SOLUTION

PHARMACEUTICAL FORM Solution

FORMULA

Component	Quantity
chlorhexidine digluconate solution 20% (p/v)	0,5 mL
compound fragrance	qs
polysorbate 20	1 mL
aspartame	0,1 g
colorant	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Dilute the chlorhexidine digluconate solution at 20% (p/v) in 50 mL of purified water. Add the aspartame and the *compound fragrance*. Homogenize. Add the polysorbate 20 and homogenize until obtaining complete dispersal. Add the colorant and complete the volume with purified water. If necessary adjust the pH will to 7.0.

Note: *the chlorhexidine digluconate action reduces in alkaline pH, in the presence of organic materials, anionic detergents and tannins; it increases, however, in elevated temperature, neuter pH, presence of non ionic detergents and quaternary ammonium salts.*

PACKING AND STORAGE

- In perfectly closed container. Keep at fresh and dry place, sheltered from light and heat.

WARNINGS

- Keep away from children.

INDICATIONS

- Buccal Antiseptic.

DIRECTIONS FOR USE

- External use.
  - Use a measure of 10 mL to 20 mL in mouth washes during at least 30 seconds, three times a day or at the doctor's discretion.

CHLORHEXIDINE DIGLUCONATE 0,5%, TOPICAL SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
chlorhexidine digluconate solution 20% (p/v)	2.5 mL
isopropvl alcohol	5.7 mL
benzalkonium chloride 50% (p/v)	1 mL
polysorbate 20	2 mL
lactic acid 85% (v/v) qs	pH 5.5 -6.5
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dilute the chlorhexidine digluconate solution at 20% (p/v) in 50 mL of purified water. Add the isopropyl alcohol and then the benzalkonium chloride 50% (p/v), under agitation. Disperse the polysorbate 20 apart in 20 mL of purified water, homogenize and pour in the previous solution. Adjust the pH with lactic acid 85% (v/v). Complete the volume with purified water.

Note: *the chlorhexidine digluconate action reduces in alkaline pH, in the presence of organic materials, anionic detergents and tannins; it increases, however, in elevated temperature, neuter pH, presence of non ionic detergents and quaternary ammonium salts.*

PACKING AND STORAGE
- In container perfectly closed amber. Keep at fresh and dry place, sheltered from light and heat.

WARNINGS
- Keep away from children. Due to its irritating power the product is not recommended to use in mucous membranes and other sensitive tissues.

INDICATIONS
- Topical Antiseptic. Use in preoperative skin antisepsis.

DIRECTIONS FOR USE
- External use.
  - For cleaning the skin before surgical procedure.

DIMETHYL SULFOXIDE 50%, GEL

SYNONYMITY
- DMSO 50%, Gel.

PHARMACEUTICAL FORM
- Gel.

FORMULA

Component	Quantity
dimethyl sulfoxide	50 g
gel of carbomer qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Add the gel in a mortar. Pour the dimethyl sulfoxide slowly, homogenizing.

Note: *dimethyl sulfoxide is an organic solvent with irritating property to the skin. The use of gloves and masks is recommended. Dimethyl sulfoxide is incompatible with plastic materials.*

PACKING AND STORAGE
- In perfectly closed glass container. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Anti-inflammatory, antiseptic, vasodilator and local painkiller.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas one to two times a day.

DISODIUM EDTA 0.35%, OPHTHALMIC SOLUTION

SYNONYMITY
- Ophthalmic solution of disodium edetate 0.35%.

PHARMACEUTICAL FORM Ophthalmic solution.
- Eye drops.

FORMULA

Component	Quantity
edetate dis sodium	35 mg
methylcellulose 1% (p/v)	2.5 mL
isotonizing buffer solution pH 7,4 qsp	10 mL
Isotonizing buffer solution pH 7.4	
monosodium phosphate, anhydrous	0.16%
di sodium phosphate, anhydrous	0.76%
sodium chloride	0.58%
sterile purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Prepare the isotonizing buffer solution pH 7.4 and reserve. Grind the sodium edentate apart. Dissolve the disodium edetate in 5 ml of the isotonizing buffer solution pH 7.4. Add the methyl cellulose at 1% (p/v) and homogenize. Complete the volume with isotonizing buffer solution pH 7.4. Sterilize by autoclaving at 121°C. 1 Atm. for 30 minutes and put in previously sterilized dropper bottle, in laminar flow chapel, properly adorned.

Note: *the preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In perfectly closed sterile dropper type bottle, with seal. Keep at room temperature and sheltered from light.

WARNINGS
- Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Do not wash the dropper. Keep away from children.

INDICATIONS
- To inhibit the formation of collagenase, that takes place in chemical burns and to obstruct the action of this enzyme in cornea stroma. It is also used as calcium ions chelant in cornea opaquenesses in which there is deposit of this ion.

DIRECTIONS FOR USE
- External use.
  - Apply a drop four times a day or at the doctor's discretion.

SODIUM FLUORIDE 0.05%, SOLUTION

PHARMACEUTICAL FORM

- Solution.

FORMULA

Components	Quantity
sodium fluoride	50 mg
paraben preservative solution	2g
extract	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Dissolve the sodium fluoride in sufficient quantity of water. Add the *paraben preservative solution* and homogenize. Incorporate sufficient quantity of extract. Complete the volume with purified water.

Note: *waterish solutions of sodium fluoride have pH near 7.0. They decay slowly, becoming alkaline when stored in glass and are incompatible with magnesium and calcium salts.*

PACKING AND STORAGE

- In perfectly closed plastic container. Keep at room temperature and sheltered from light.

WARNINGS

- Avoid ingestion. Watch to prevent children from swallowing the sodium fluoride solution after topical application in the teeth. Keep away from children.

INDICATIONS

- Dental caries prevention.

DIRECTIONS FOR USE

- External use.
  - In mouth washes, mainly at night, after brushing the teeth. The patients should be instructed to not swallowing the solution and, for optimal benefit, not eating or drinking approximately for 30 minutes after using the solution.

ALUMINUM HYDROXIDE, SUSPENSION

SYNONYMITY
- Antacid aluminum suspension.

PHARMACEUTICAL FORM Suspension.

FORMULA

Components	Quantity
aluminum hydroxide	6g
sodium saccharin	10 mg
sodium benzoate	0.525 g
carmellose sodium (high viscosity)	1 g
glycerol	2.5 mL
flavoring agent	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Disperse the carmellose sodium in the glycerol and then add part of the water. Add the previously sieved aluminum hydroxide and homogenize until the formation of a paste. Dissolve the sodium saccharin apart in sufficient quantity of water, add the sodium benzoate, the flavoring agent and, then, pour this solution on the carmellose dispersion. Add water, under agitation, until completing the volume.

PACKING AND STORAGE
- In well closed opaque plastic container or glass amber, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children. Keep in fresh place.

INDICATIONS
- Antacid.

Note: *has obstipant action*.

DIRECTIONS FOR USE
- Internal use.
  - Take 5 mL to 10 mL four times a day, 15 minutes before the meals and before going to bed or at the doctor's discretion.

ALUMINUM AND MAGNESIUM HYDROXIDE, SUSPENSION

PHARMACEUTICAL FORM Suspension.

FORMULA

Component	Quantity
aluminum hydroxide	6g
magnesium hvdroxide	4 g
glycerol	2.5 mL
sodium saccharin	10 mg
sodium benzoate	0.525 g
carmellose sodium (high viscosity)	1 g
flavoring agent	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Disperse the carmellose sodium in the glycerol and add part of the water. Add the previously sieved aluminum hydroxide and magnesium hydroxide. Mix until obtaining a homogeneous paste. Dissolve the sodium saccharin apart in sufficient quantity of water, add the sodium benzoate, the flavoring agent and, then, pour this solution on the carmellose dispersion. Add water, under agitation, until completing the volume.

PACKING AND STORAGE

- In well closed opaque plastic or amber glass container, sheltered from light and at room temperature.

WARNINGS

- Agitate before using. Keep away from children. Keep in fresh place.

INDICATIONS

- Antacid.

DIRECTIONS FOR USE

- Internal use.
  - Take 5 mL to 10 mL four times a day, 15 minutes before the meals and before going to bed or at the doctor's discretion.

SODIUM HYPOSULPHITE 1% TO 2%, SOLUTION

SYNONYMITY
- Sodium thiosulfate solution 1% to 2%.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
sodium thiosulfate	1 g to 2 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the sodium thiosulfate. Add heated water until complete dissolution. Complete the volume with water, homogenize and filter.

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and moisture and at room temperature.

WARNINGS
- Exclusive use in medical doctor's office.

INDICATIONS
- To remove brownish-yellow coloration left in the epithelium colored by iodine, after Schiller test.

DIRECTIONS FOR USE
- External use.
  - At the doctor's discretion.

SODIUM HYPOSULPHITE 40%, SOLUTION

SYNONYMITY
- Sodium thiosulfate solution 40% (p/v).

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
sodium thiosulfate	40 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the sodium thiosulfate. Add heated water until complete dissolution. Complete the volume with water, homogenize and filter.

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and moisture, and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Versicolor pityriasis.

DIRECTIONS FOR USE
- External use.
  - Apply once a day, after bath, followed by a tartaric acid acidifying solution at 5% (p/v), for 20 days. After this period, Exposure to the sun is recommended, to match the skin shade.

POVIDONE IODINE 1% TO 5%, OPHTHALMIC SOLUTION

SYNONYMITY
- PVP-I eye drops, polyvinylpyrrolidone iodine eye drops.

PHARMACEUTICAL FORM
- Eye drops.

FORMULA

Component	Quantity
povidone iodine	0,1 g to 0,5 g
sterile purified water qsp	10 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the povidone iodine in sterile purified water. Filter the solution directly to previously sterilized dropper bottles, using sterilizing filtration system with 0.22 pm porosity membrane.

Note: *the eye drops must be a sterile solution. Perform the sterilizing filtration in laminar flow chapel, properly adorned. Condition in previously sterilized dropper type bottle, in order to not contaminate the solution. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In perfectly closed milky dropper bottle, with sealing. Keep at room temperature, sheltered from light.

WARNINGS
- Reject the solution 30 days after the bottle is opened. Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Keep away from children.

INDICATIONS
- Ophthalmic Antiseptic, in ophthalmic surgeries preoperative procedures, in the prevention against neonatal gonococcal ophthalmia.

Note: *povidone iodine is an iodophor with action against funguses, bacteria, virus, protozoa, cysts and spores. In the concentration of 1% (p/v) it has action against, among others, Chlamydia trachomatis and Neisseria gonorrhoeae. In the concentration of 5% (p/v) it has action against Herpes Simplex type II.*

It must not be used in cases of sensibility to iodine, open wounds, in occlusive dressings and in cases of hyperthyroidism. The absorption of iodine by using povidone iodine may interfere with thyroide functions examinations.

DIRECTIONS FOR USE
- External use.
  - Preoperative: two to three drops and then wash the eye(s) with sterile solution for irrigation.
  - Prevention of gonococcal ophthalmia: one or two drops in each eye, right after birth.

POVIDONE IODINE 10%, SOLUTION

SYNONYMITY
- PVP-I Solution, polyvinylpyrrolidone iodine solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
novidone iodine	10 g
glycerol	5 mL
propylene glycol	1,5 mL
citric acid solution at 25% qsp	pH 5.5
purified water qsp	100 mL

DIRECTIONS FOR PREPARATION
- Dissolve povidone iodine in part of the water. Filter. Add the glycerol, homogenize and then add propylene glycol. Complete the volume with water. Adjust pH for 5.5 with *citric acid solution at 25%*.

Note: *the povidone iodine at 10% (p/v) (1% free iodine) may be prepared in the pharmaceutical form of carmellose sodium gel for buccal antisepsis, before surgical procedures. The contact of the product with the eyes must be avoided. The product may stain clothes and skin.*

PACKING AND STORAGE
- In perfectly closed amber bottle, sheltered from light and at room temperature.

WARNINGS
- Keep away from children. Stop using in case of change in the solution's color or odor.

Note: *It must not be used in cases of sensibility to iodine, open wounds, in occlusive dressings and in cases of hyperthyroidism. The absorption of iodine by using povidone iodine may interfere with thyroide functions examinations.*

INDICATIONS
- Topical Antiseptic. Its action takes place by the presence of free iodine. It is effective against *Staphylococcus aureus, Escherichia coli, Streptococcus mutans, other Streptococcus, Candida albicans and optional anaerobic microorganisms.*

DIRECTIONS FOR USE
- External use.
  - Apply topically in the affected areas or before surgical procedures.

ARTIFICIAL TEAR

SYNONYMITY
- Hidroxypropyl methylcellulose 0.5% (p/v) or 1% (p/v).

PHARMACEUTICAL FORM
- Eye drops.

FORMULA

Component	Quantity
hydroxypropyl methylcellulose	50 mg or 100 mg
benzalkonium chloride	1 mg
sterile purified water qsp	10 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the hidroxypropyl methylcellulose in heated sterile purified water (50°C to 90°C), with agitation. Add the benzalkonium chloride. Complete the desired volume with cold diluent, under constant agitation, until the solution is cooled. Leave it in rest for 12 hours, under refrigeration, complete the hydration of the hidroxypropyl methylcellulose. Filter the solution directly for the previously sterilized dropper bottle, using sterilization system with 0.45 pm porosity membrane. The solution must be filtered under pressure or filtered in membrane with larger pore and autoclaved.

Note: *the eye drops must be a sterile solution. Perform the sterilizing filtration in laminar flow chapel, properly adorned. Condition in sterile dropper bottle. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In perfectly closed bottle dropper with sealing. Keep at room temperature.

WARNINGS
- Reject the solution after 30 days from the opening of the bottle. Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Keep away from children. It must not be used with contact lenses hidrofilicas.

INDICATIONS
- Ocular lubricant for the relief of the dry eyes or in ocular irritations associated to the defective production of tears, lubrication of proteses ocular and for use with rigid contact lenses. For use with contact lenses hidrofilicas Formulations must be used without preservatives.

DIRECTIONS FOR USE
- External use.
  - Apply one to two drops, three to four times a day or when necessarily.

MILK OF MAGNESIA

SYNONYMITY
- Oxide of hydrated magnesium, hydrated magnesia.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
magnesium hydroxide	8g
citric acid solution at 25%	0.4 mL
paraben preservative solution	1 mL
flavoring agent	qs
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Disperse the hydroxide of magnesium in part of the water. Add the *paraben preservative solution,* the *citric acid solution 25%* and the flavoring agent. Homogenize. Complete the volume with water.

Note: *the milk of magnesia absorbs slowly the carbon dioxide for the exposure to the air.*

PACKING AND STORAGE
- In container of opaque, perfectly closed plastic, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
  – Antacid and laxative.

Note: *in case of use as laxative, not to use in presence of abdominal pain, nausea, vomiting, alterations in the intestinal habits for any more than two weeks, sangramento resuch and upsets of the renal function.*

DIRECTIONS FOR USE
- Internal use.
  – As antacid: 5 mL to 15 mL (a teaspoon to a tablespoon), two to three times a day.
  – As laxative: 30 mL to 60 mL (two to four tablespoons).

HOFFMANN LIQUEUR

SYNONYMITY
- Alcoholized Ether.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
ethylic ether	35 mL
ethylic alcohol 96 °GL qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Add the alcohol to the ethylic ether, homogenize and filter.

Note: *volatile vehicle. It must be prepared in exhaustion chapel.*

PACKING AND STORAGE
- In perfectly closed glass container, and at room temperature.

WARNINGS
- Keep away from children. Local irritation and photosensitivity may occurr.

INDICATIONS
- Use as skin degreaser and for removal of adhesive strips. It is also used as vehicle in Formulations for acne, alopecia, topic antimycotics, in Formulations containing metalloid iodine and potassium iodide.

DIRECTIONS FOR USE
- External use.

LIDOCAINE 2%, SOLUTION

PHARMACEUTICAL FORM

- Solution.

FORMULA

Component	Quantity
lidocaine hydrochloride	2g
sodium saccharin	0,1 g
paraben preservative solution	2,5 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Dissolve the lidocaine hydrochloride in water. Add the sodium saccharin, homogenize, add the *paraben preservative solution* and complete the volume with water. Homogenize and filter.

PACKING AND STORAGE

– In well closed opaque plastic or amber glass container, sheltered from light and at room temperature.

WARNINGS

- It must not be ingested. Keep away from children. The administration in children must only be done with medical recommendation and adults' supervision.

INDICATIONS

- Topical anesthetic. Use in painful processes of the oral cavity.

DIRECTIONS FOR USE

- External use.
  – Apply in the affected surface using swab, up to four times a day, at intervals longer than three hours.

CALCAREOUS OIL LINIMENT

SYNONYMITY
- Calcareous liniment.

PHARMACEUTICAL FORM
- Liniment.

FORMULA

Component	Quantity
lime water	50 mL
linseed oil	50 mL
butyl-hy dr oxytoluene	50 mg

DIRECTIONS FOR THE PREPARATION
- Grind the butyl-hydroxytoluene. Add the linseed oil. Add the *lime water*, under vigorous agitation, until complete homogenization.

Note: *other rich vegetable oils may also be used in essential fatty acids, such as almond oil or sunflower oil.*

PACKING AND STORAGE
- In well closed opaque plastic or amber glass container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
- In itching dermatosis and bums.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, three to four times a day.

BUROW'S SOLUTION

SYNONYMITY
- aluminum acetate solution 5%.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
aluminum acetate	5 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the aluminum acetate. Add water, gradually, until complete the volume. Homogenize and filter.

PACKING AND STORAGE
- In well closed glass container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Astringent and antiseptic. In acute dermatitis, cutaneous exudative processes and in the relief of skin burns.

DIRECTIONS FOR USE
- External use.
  - Dilute the solution between 1/10 and 1/40 and do compresses each three or four hours or at the doctor's discretion.

DAKIN'S SOLUTION

SYNONYMITY
- Sodium hypochlorite solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
active chlorine*	0.5 g
sodium bicarbonate solution 5% (p/v) qs	pH 9.0- 10.0
purified water qsp	100 mL

* Use the corresponding quantity of the diluted sodium hypochlorite solution containing 2.0 to 3.0% (p/v) sodium hypochlorite or 1.9% to 2.9% (p/v) active chlorine, in order to obtain a final concentration of 0.5% active chlorine in the Formulation.

DIRECTIONS FOR THE PREPARATION
- Standardize the diluted sodium hypochlorite solution as provided for in the monograph diluted sodium hypochlorite solution of Brazilian Pharmacopeia 5th edition. Dilute around 25 mL or volume equivalent to 0.5 g of active chlorine of the diluted sodium hypochlorite solution, in water. The pH of the solution must be adjusted with sodium bicarbonate so that it is between 9.0 and 10.0. The final solution does not produce permanent pink coloration when a sample is pulverized with bicarbonate phenolphtalein. The final product must contain a minimum 0.45 g and a maximum 0.50 g of active chlorine.

PACKING AND STORAGE
- In well closed glass amber container, sheltered from light and in refrigerator.

WARNINGS
- Keep away from children.

INDICATIONS
- Local Antiseptic, for dressings of wounds and ulcers. Used in dentistry, in the irrigation of devitalized canals.

DIRECTIONS FOR USE
- External use.
  - In local applications.

LIQUOR CARBONIS DETERGENS (LCD) 5% TO 10%, SHAMPOO

SYNONYMITY
- Saponated Coal-tar shampoo.

PHARMACEUTICAL FORM
- Shampoo.

FORMULA

Component	Quantity
liquor carbonis detergens	5 mL to 10 mL
allantoin	0.5 g
triclosan	0.3 g
clioquinol	2g
citric acid solution at 40% qs	pH 6.5
non ionic shampoo qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Evaporate the solvent of *liquor carbonis detergens* in water bath, in nearly 70% and wait. Separately, grind the triclosan, the allantoin and the clioquinol. Add the *liquor carbonis detergens* and mix until the formation of a homogeneous paste. Complete the volume with the shampoo. Adjust the pH with the *citric acid solution at 40%*.

Note: *the LCD is a preparation made of standardized mineral tar extracts (coal-tar) in soap bark tree dye, according to specific monograph, in this Form. It has reducing and anti-itching action.*

PACKING AND STORAGE
- In well closed opaque plastic container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Local irritation and photosensitivity may occur. Keep away from children.

INDICATIONS
- Psoriasis, dandruff, eczema and scalp seborrheic dermatitis. It has reducing and anti-itching action. It may be used in concentrations of 1% to 5% in treatment of eczemas and dermatitis, and in concentrations of 5% to 20% in the treatment of psoriasis.

DIRECTIONS FOR USE
- External use.
  - Apply the shampoo on the previously wetted hair, gently massaging for some minutes. Rinse it off. If necessary, repeat the application.

LIQUOR CARBONIS DETERGENS (LCD) AND SALICYLIC ACID, SHAMPOO

SYNONYMITY
- Salicylic acid and saponated coal-tar shampoo.

PHARMACEUTICAL FORM
- Shampoo.

FORMULA

Component	Quantity
liquor carbonis detergens	5 mL to 10 mL
salicylic acid	2g
allantoin	0.5 g
triclosan	0.3 g
clioquinol	2g
citric acid solution at 40% qs	pH 6.5
non ionic shampoo qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Evaporate the solvent of the *liquor carbonis deter gens* in water bath, at nearly 70% and reserve. Separately, grind the salicylic acid, the triclosan, the allantoin and the clioquinol. Add the *liquor carbonis detergens* and mix until the formation of a homogeneous paste. Complete the volume with the shampoo. Adjust the pH with the *citric acid solution at 40%*.

Note: *the LCD is a preparation made with standardized extracts of mineral tar (coal-tar) in soap bark tree dye, according to specific monograph, in this Form. It has reducing and anti-itching action.*

PACKING AND STORAGE
- In well closed opaque plastic container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Local irritation and photosensitivity may occur. Keep away from children.

INDICATIONS
- Psoriasis, dandruff, eczema and scalp seborrheic dermatitis. It has reducing and anti-itching action. It may be used in concentrations of 1% to 5% in treatment of eczemas and dermatitis, and in concentrations of 5% to 20% in the treatment of psoriasis.

DIRECTIONS FOR USE
- External use.
  - Apply the shampoo on the previously wetted hair, gently massaging for some minutes. Rinse it off. If necessary, repeat the application.

HEES' LOTION

SYNONYMITY
- Hees' Suspension.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
precipitated sulfur	3g
zinc oxide	5 a
zinc sulfate	3g
sodium borate	5 g
purified water	qs
camphor	0,5 g
ethylic alcohol 96 °GL	33 mL
acetone	33 mL
rose water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Solubilize the sodium borate in sufficient quantity of boiling purified water and let it cool. Grind the sulfur, the zinc oxide and the zinc sulfate and then add the ethylic alcohol. Add the sodium borate solution and the acetone, under agitation. Complete the volume with the *rose water* and homogenize.

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
- Siccative drug and antiseptic. Used in the treatment of acne.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, one to two times a day, let it act for some minutes and draw with help of neuter soap.

MODIFIED KUMMERFELD'S LOTION

SYNONYMITY
- Precipitated sulfur lotion.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
precipitated sulfur	6g
carmellose sodium	0,5 g
camphorated alcohol	10 mL
ethylic alcohol 96 °GL	10 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Disperse the carmellose sodium in 60 mL of water and let it hydrate, in rest, for 12 hours. Separately, disperse the precipitated sulfur in ethylic alcohol and add the *camphorated alcohol*. Pour the sulfur dispersion and *camphorated alcohol* on the carmellose sodium dispersion. Complete the volume with water and homogenize.

PACKING AND STORAGE
- In well closed glass container amber, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
- Anti-seborrheic. Use in the treatment of acne and seborrhea.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, at night.

PINKY LOTION

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
precipitated sulfur	10 g
resorcinol	2g
lactic acid	1 mL
glycerol	1 mL
bentonite	5g
carbolic acid	20 mg
camphorated alcohol	10 mL
sodium metabisulfite	0,2 g
purified water qsp	100 mL

Note: *calamine lotion may be used as vehicle instead of the purified water, and, in this case, the addition of bentonite is not necessary.*

DIRECTIONS FOR THE PREPARATION
- Grind the precipitated sulfur in mortar. Dissolve the resorcinol and the carbolic acid in the *camphorated alcohol*. Dissolve the sodium metabisulfite apart in qs of water and add the bentonite for dispersion. Mix the two phases, add the lactic acid and the glycerol, homogenizing. Add this mixture gradually to the mortar containing the sulfur and homogenize. Transfer to a proper container, complete the volume with water and homogenize.

PACKING AND STORAGE
- In amber glass container, in fresh place, sheltered from light, moisture and heat.

WARNINGS
- Agitate before using. Keep away from children. Avoid contact with eyes and mucous membranes.

INDICATIONS
- Anti-seborrheic. Use in the treatment of acne and seborrhea.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected parts, one to two times a day. Remove with the help of neuter soap.

LOTIOALBA

SYNONYMITY
- White lotion.

PHARMACEUTICAL FORM
- Suspension.

FORMULA

Component	Quantity
zinc sulfate	4g
potassium or sodium sulfide	4g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the zinc sulfate, dissolve in 45 mL of water and filter. Grind the potassium sulfide, dissolve in 45 mL of water and filter. Pour the potassium sulfide on the zinc sulfate, under agitation. Complete the volume with water.

Note: *a milky white zinc sulfide precipitate is formed.*

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
- Keratolytic and anti-seborrheic. Used in the treatment of acne.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, one to two times a day.

OCULAR LUBRICANT, SALVE

PHARMACEUTICAL FORM
- Ophthalmic salve.

FORMULA

Component	Quantity
liquid petrolatum	42,5 g
lanolin	2,5 g
white petrolatum qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Fuse the white petrolatum and the lanolin and homogenize. Add the liquid petrolatum, under agitation, until reaching room temperature. Sterilize by dry heat, in stove at 150°C, for 60 minutes. Put in previously sterilized ophthalmic tubes, in laminar flow *cabin*.

Note: *the ophthalmic salve must be a sterile product manipulated in laminar flow cabin, properly adorned. The preparation of ophthalmic salve must follow the Good Practices of Manipulation for sterile products.*

The liquid petrolatum suffers decomposition when exposed to heating and light. The lanolin suffers auto-oxidation during its storage. To inhibit this process, the butyl-hydroxytoluene may be incorporated to the Formulation as antioxidant, in the concentrations of 0.01% to 0.03%. Excessive exposure to heat may cause darkening and develop a strong rancidness odor. The lanolin may be sterilized by the dry heat method, since there is temperature control. The sterile ophthalmic salve containing lanolin may also be sterilized by filtration or with exposure to gamma radiation. The white petrolatum is a stable raw material due to the non-reactivate nature of its hydrocarbons' composition.

PACKING AND STORAGE
- In perfectly closed tube with ophthalmic nozzle, at room temperature.

WARNINGS
- Stop using in case of change in the salve's color or odor. Avoid contact of the bottle with the ocular surface. Do not use with contact lenses. Keep away from children.

INDICATIONS
- Protection and ocular lubrication in: exposure keratitis, decreased cornea sensibility, recurrent cornea erosion, keratitis sicca (for use at night), after foreign body removal, in ophthalmic surgeries to protect the eye not involved in the surgery, in non-ophthalmic surgeries to lubricate and to protect the eyes and for postoperative use, as lubricant.

DIRECTIONS FOR USE
- External use.
  - Apply small quantity in the conjunctival sac, when necessary.

MANNITOL 20%, SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
mannitol	100g
paraben preservative solution	8g
purified water qsp	500 mL

DIRECTIONS FOR THE PREPARATION
- Grind the mannitol until getting a quite fine powder. Add the *paraben preservative solution,* complete the volume with water and homogenize.

Note: *mannitol at 20% in solution may precipitate in the presence of sodium or potassium chloride.*

PACKING AND STORAGE
- In perfectly closed amber glass bottle. Keep at room temperature, sheltered from light and heat.

WARNINGS
- Keep away from children. Agitate before using.

INDICATIONS
- For bowel emptying, in colonoscopy examinations.

DIRECTIONS FOR USE
- Internal use.
  - Dissolve the mannitol solution in equal parts with water, orange juice or lemon soda. Administered according to medical direction.

MICONAZOLE 2%, LOTION

PHARMACEUTICAL FORM
- Lotion.

FORMULA

Component	Quantity
miconazole nitrate	2g
propylene glycol	10 mL
non-ionic lotion qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Weigh the miconazole nitrate and transfer to a glass mortar. Grind until getting a quite fine powder. Pour the propylene glycol and disperse the powder until getting a homogeneous paste. Add 50 g of the *non ionic lotion* and mix. Complete the desired quantity with the remainder of the lotion and homogenize.

PACKING AND STORAGE
- In perfectly closed plastic bottle. Keep at room temperature, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Antifungal.

DIRECTIONS FOR USE
- External use.
  - Apply two to four drops of the lotion on the affected area, two to three times a day or at the doctor's discretion. The treatment must be maintained until the complete disappearance of the injuries, which generally occurs after two to five weeks of treatment. After the disappearance of the symptoms, the treatment must be maintained for one more week, to avoid recurrences.

NYSTATIN 100 000 UL/G, CREAM

PHARMACEUTICAL FORM.
- Cream-colored

FORMULA

Component	Quantity
nystatin	2000000 OUCH
propylene glycol	10 mL
non-ionic cream I qsp	20 g

Note: *nystatin is a yellow or brown powder constituted by a mixture of two or more substances obtainedfrom Streptomyces noursei.*

DIRECTIONS FOR THE PREPARATION
- Grind the nystatin and disperse in the propylene glycol. Add the *non-ionic cream*/, gradually, mixing throughout until getting a homogeneous cream.

PACKING AND STORAGE
- In perfectly closed plastic pot or tube. Keep at room temperature, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Antifungal. Treatment of the mucocutaneous candidiasis.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected places three to four times a day, after local hygiene.

NYSTATIN 25 000 UL/G, VAGINAL CREAM

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
nystatin	1 250 000
propylene glycol	5 mL
non-ionic cream II qsp	50 g

Note: *the nystatin is a yellow or brown powder constituted by a mixture of two or more substances obtainedfrom the Streptomyces noursei.*

DIRECTIONS FOR THE PREPARATION
- Grind the nystatin and disperse in the propylene glycol. Add the *non-ionic cream*//, gradually, mixing throughout until getting a homogeneous cream.

Note: *adapt the 100 000 UI dose to the vaginal applicator capability available in the pharmacy.*

PACKING AND STORAGE
- In perfectly closed plastic pot or tube. Keep at room temperature, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Antifungal. Vaginal candidiasis treatment (monilliasis).

DIRECTIONS FOR USE
- Vaginal use.
  - Apply the applicator content (approximately 4 g) one to two times a day, for two weeks or at the doctor's discretion. In the recurring affections the applications shall not be interrupted during the menstrual period.

SILVER NITRATE 1%, SOLUTION

PHARMACEUTICAL FORM

- Solution.

FORMULA

Component	Quantity
silver nitrate	0.2 g
purified water qsp	20 mL

DIRECTIONS FOR THE PREPARATION

- Dissolve the silver nitrate in water, under agitation, until completing the volume. Homogenize and filter.

PACKING AND STORAGE

- In perfectly closed non metallic amber glass bottle, with no alkalinity, sheltered from light and at room temperature.

WARNINGS

- It must not be used as ophthalmic solution. The use must be stopped in case of change of color or odor of the solution. Keep away from children.

INDICATIONS

- Astringent, antiseptic and caustic. Use in herpes simplex and genital herpes.

DIRECTIONS FOR USE

- External use.
  - Apply, once a day, on the injuries, with the help of disposable swaps.

SILVER NITRATE 1%, OPHTHALMIC SOLUTION

PHARMACEUTICAL FORM Eye drops.

FORMULA

Component	Quantity
silver nitrate	0,1 g
sterile purified water qsp	10 mL

Note: *silver nitrate is incompatible with the benzalkonium chloride, halogenated acids and their salts, alkalis and phosphates.*

DIRECTIONS FOR THE PREPARATION

- Dissolve the silver nitrate in water, under agitation, until completing the volume and homogenizing. Filter the solution to previously sterilized dropper bottle, using sterilizing filtration system with 0.22 pm porosity membrane.

Note: *the eye drops must be a sterile solution. Proceed to the sterilizing filtration in laminar chapel flow, properly adorned. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE

- In perfectly closed opaque dropper bottle with sealing and no alkalinity. Keep in refrigerator.

WARNINGS

- Reject the solution 30 days after opening the bottle. Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface.

INDICATIONS

- Ophthalmic Antiseptic. Used in the prevention of the neonatal gonococcal ophthalmia.

DIRECTIONS FOR USE

- External use.
  - Wait it to reach the room temperature before using. Apply two drops in each eye, right after birth.

Note: *higher silver nitrate concentrations must be avoided, since they may cause blindness by corneal opacification. The use of silver nitrate, for prevention of neonatal gonococcal ophthalmia was preconized by Crede in 1879, who verified a 10% to 0.5% decrease in the incidence of this illness, with the use of a 2% solution instilled in each eye, right after birth. Except for the 2% to 1% decrease in the silver nitrate concentration, the Crede Method is still a generalized practice required by the sanitary authorities.*

COMPOSED ZINC OXIDE, CREAM

SYNONYMITY
- Cream with vitamins A, D and E and zinc oxide.

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
retinol palmitate	500 000 UI
ergocalciferol	40 000 UI
dextro-alpha-tocopherol	300 UI
zinc oxide	15 g
non-ionic cream I qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, grind the zinc oxide. Incorporate the retinol and the ergocalciferol and homogenize. Slowly add dextro-alpha-tocopherol, with constant agitation and complete with the *nonionic cream I* until full homogenization.

Note: *the Formulation must not be heated during its preparation.*

PACKING AND STORAGE
- In well closed opaque plastic container or lined aluminum tube, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Ammoniac dermatitis, eczemas and rashes.

DIRECTIONS FOR USE
- External use.
  - Apply on the injured region, after cleaning, two times a day or at the doctor's discretion.

PAPAIN 2% TO 10%, GEL

SYNONYMITY
- Papayotin gel, Vegetable pepsin gel.

PHARMACEUTICAL FORM
- Gel.

FORMULA

Component	Quantity
papain	2 gto 10 g
carbomer gel qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Disperse the papain in sufficient quantity of water and incorporate to *carbomer gel* under constant agitation, homogenizing well. If necessary, adjust the pH to 5.0.

Note: *papain is inactivatedfor oxidant agents as iron, oxygen and iodine.*

PACKING AND STORAGE
- In perfectly closed plastic packing. Preserve under refrigeration.

WARNINGS
- Keep away from children.

INDICATIONS
- Ulcer by pressure, diabetic, venous, arterial and bums.

Note: *papain gel may be used in the concentrations of 2% to 10% in accordance with the clinical evaluation, such as compromised structures and tissues, presence of exudates and/or necrotic tissue.*

DIRECTIONS FOR USE
- External use.
  - Apply on the injury and occlude. Remove the following day with physiologic serum and to reapply.

WATER PASTE

PHARMACEUTICAL FORM

- Paste.

FORMULA

Component	Quantity
zinc oxide	25 g
talcum	25 g
glycerol	25 g
lime water	25 g

DIRECTIONS FOR THE PREPARATION

- Grind the zinc oxide until getting fine powder. Add glycerol and keep the trituration until getting a uniform mixture. Add recently prepared *lime water* and mix. Add talcum and mix to get a homogeneous paste.

PACKING AND STORAGE

- In well closed opaque plastic bottle, sheltered from light and at room temperature.

WARNINGS

- Agitate before using. Keep away from children.

INDICATIONS

- In vesicular affections and in the presence of exudation, as antiseptic, cicatrizant and siccative drug.

DIRECTIONS FOR USE

- External use.
  - Apply in the affected areas, two to three times a day or at the doctor's discretion. Do not apply in pilous area.

WATER PASTE WITH CALAMINE

PHARMACEUTICAL FORM

- Paste.

FORMULA

Component	Quantity
zinc oxide	25 g
talcum	25 g
glycerol	20 g
calamine	10g
lime water qsp	100 g

DIRECTIONS FOR THE PREPARATION

- Grind the zinc oxide and the calamine until getting fine powder. Add the glycerol and keep the trituration until getting an uniform mixture. Add the recently prepared *lime water* and homogenize. Add the talcum and homogenize to get a homogeneous paste.

PACKING AND STORAGE

- In well closed opaque plastic bottle, sheltered from light and in room temperature.

WARNINGS

- Agitate before using. Keep away from children.

INDICATIONS

- Minor skin rashes, as light sun burns and insect bites, as antiseptic, cicatrizant and siccative drug.

DIRECTIONS FOR USE

- External use.
  - Apply in the affected areas, two to three times a day or at the doctor's discretion. Do not apply in pilous area.

WATER PASTE WITH SULFUR

PHARMACEUTICAL FORM
- Paste.

FORMULA

Component	Quantity
precipitated sulfur	10 g
water paste qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind the sulfur until fine powder. Add gradually, and grinding, the recently prepared *water paste*, until a homogeneous paste consistency.

Note: *the sulfur percentage shall be decreased if the patient demonstrates to have any dermic intolerance.*

PACKING AND STORAGE
- In well closed opaque plastic bottle, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children. It must not be used in the prolonged form, since it may result in typical contact dermatitis.

INDICATIONS
- As parasiticide – scabies, mainly in case of secondary infection. As keratolytic – psoriasis, seborrhea, erythematosus lupus, eczematous dermatitis, pediculosis injuries, dermatosis.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, one to two times a day, for five minutes. Repeat the treatment after a week.

MENTHOLATED WATER PASTE

PHARMACEUTICAL FORM
- Paste.

FORMULA

Component	Quantity
menthol	0,1 g to 0,5 g
ethylic alcohol 96 °GL	qs
water paste qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, grind the menthol with help of ethylic alcohol. Add the *water paste*, recently prepared, until the consistency of homogeneous paste.

PACKING AND STORAGE
- In well closed opaque plastic bottle, sheltered from light and at room temperature.

WARNINGS
- Agitate before using. Keep away from children.

INDICATIONS
- Antiseptic, siccative, anti-itching and cicatrizant.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, except in pilous zones, two to three times a day or at the doctor's discretion.

LASSAR'S PASTE

SYNONYMITY
- Zinc oxide paste.

PHARMACEUTICAL FORM
- Paste.

FORMULA

Component	Quantity
zinc oxide	25 g
starch	25 g
white petrolatum qsp	100 g

DIRECTIONS FOR PREPARATION
- Grind and sieve the zinc oxide and the starch. Separately, fuse the white petrolatum at 60°C. Gradually incorporate the fused petrolatum to the mixture of powders, until getting homogeneous paste.

PACKING AND STORAGE
- In proper opaque plastic container with wide mouth, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Itching dermatoses, antiseptic, siccative drug and cicatrizant in the treatment of wounds and ulcers.

DIRECTIONS FOR USE
- External use.
  - Apply a fine layer on the affected area one or two times a day or at the doctor's discretion. Use liquid petrolatum to remove it from the skin.

SALICYLATED LASSAR'S PASTE

SYNONYMITY
- Salicylic Zinc paste.

PHARMACEUTICAL FORM
- Paste.

FORMULA

Component	Quantity
salicylic acid	2g
zinc oxide	24.5 g
starch	24.5 g
liquid petrolatum	24.5 g
white petrolatum qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind and sieve the salicylic acid, the zinc oxide and the starch. Add the liquid petrolatum to THE white petrolatum and heat up to 60°C. Under agitation, incorporate the petrolatum mixture to the powders until getting a homogeneous paste.

Note: this Formulation may be preparedfrom the Lassar 's paste, incorporating the salicylic acid gradually, until a homogeneous aspect.

PACKING AND STORAGE
- In proper well closed opaque plastic container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Topical and siccative antiseptic.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, two time a day or more often. It is possible to cover the applying locations with gauze or at the doctor's discretion. Use liquid petrolatum to remove it from the skin.

UNNA'S PASTE (HARD AND SOFT)

SYNONYMITY

- Unna's glue or jelly, hard and soft.

PHARMACEUTICAL FORM

- Paste.

FORMULA

Component	Gar paste quantity	Soft paste quantity
zinc oxide	10g	10g
jelly	30 g	15 g
glycerol	30 mL	25 mL
purified water qsp	100 mL	100 mL

DIRECTIONS FOR THE PREPARATION

- Disperse the jelly in warm water, under heating, add part of the glycerol. Add and slowly mix the oxide from sieved zinc and the remainder of the glycerol.

Note: *the zinc oxide slowly reacts with fatty acids, originating the respective soaps. Prolonged preservation of preparations containing zinc oxide at temperatures above 30°C must be avoided, since it leads to its degradation. Also, exposure to light and air must be avoided, since, in presence of oxygen and water, under the action of light, the zinc oxide degrades, with formation of hydrogen peroxide.*

PACKING AND STORAGE

- In well closed plastic or glass container with wide mouth, resistant to the water bath temperature, sheltered from light, moisture and at room temperature.

WARNINGS

- Keep away from children.

INDICATIONS

- Non infected varicose ulcer, varicose veins and lymphatic edemas.

DIRECTIONS FOR USE

- External use.
  - Before applying Unna's paste, the patient shall lift up the legs at a 45° inclination for 30 minutes. Confection of Unna's boot: wash the affected region (leg or foot), dry and apply small amount of talcum. Apply Unna's paste, previously heated in water bath, and cover with gauze bandaging, starting from distal part towards the proximal part. In general four paste layers are applied, being all of them covered by bandaging. The boot shall be initially replaced each three days and then in larger intervals or at the doctor's discretion. If the conditions of the surrounding skin are not good it is possible to use compression with elastic bandage.

POTASSIUM PERMANGANATE 100 MG, POWDER

PHARMACEUTICAL FORM
- Powder.

FORMULA

Component	Quantity
potassium permanganate	100 mg

DIRECTIONS FOR THE PREPARATION
- Individually weigh the potassium permanganate and transfer to butter paper envelope. Close the envelope and label.

PACKING AND STORAGE
- In butter paper envelope, sheltered from light, moisture and at room temperature.

WARNINGS
- In case the potassium permanganate enter in contact with organic substances or promptly oxidizable substances there is risk of explosion. This product must be used diluted. For external use only. Keep away from children.
- Crystals and concentrated potassium permanganate solutions are caustic. Even the diluted solutions are irritating to tissue and dye the skin brown. In case of accidents of ingestion, poisoning symptoms include nausea, brown vomiting, corrosion, edema, brown color in the buccal mucous membrane, gastrointestinal hemorrhage, hepatic and renal damages and cardiovascular depression.
- Excessive use in the vaginal mucous membrane may change the pH, accelerating the epithelial desquamation and interfering in the vulvovaginal ecosystem, removing the Doederlein bacilli. Vaginal showers must be exclusively used in cases of festering infections.

Note: *the potassium permanganate solutions must be prepared in the moment of use, in concentration of 1/10 000 to 1/40 000, dissolving the content of an envelope in one to four liters of water. The packing must contain the sign of the skull with the crossed shin-bones (%) and the indication "for topical use only*

INDICATIONS
- Exudative dermatites. It has antiseptic action, astringent, siccative and bactericidal.

DIRECTIONS FOR USE
- External use.
  - Dilute the powder in the moment of the use, in one to four liters of water and use as compresses or in bath, at the doctor's discretion.

BENZOYL PEROXIDE, GEL OR LOTION

PHARMACEUTICAL FORM
- Gel or lotion.

FORMULA

Component	Quantity
benzoyl peroxide	5g
benzyl acetone or alcohol	qs
propvlene slvcol	3 mL
carbomer gel qsp	100 g
or *non-ionic lotion* qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the benzoyl peroxide with acetone or benzyl alcohol, until fine powder and complete evaporation of the solvent. Add propylene glycol and homogenize. Add *carbomer gel* or *non-ionic lotion* and homogenize.

PACKING AND STORAGE
- In well closed plastic recipient, sheltered from light, moisture and at room temperature.

WARNINGS
- Keep away from children. It's use is not recommended for children younger than 12 years. The benzoyl peroxide may discolor hairs and stain clothes. Contact sensitization may result in some patients, in addition to redness and desquamation.

INDICATIONS
- Topical treatment of acne.

DIRECTIONS FOR USE
- External use.
  - Apply a fine layer of gel in the affected areas, one to two times a day or at the doctor's discretion. The use of nonalcoholic sun blocker is recommended during the day.

WHITFIELD'S SALVE

PHARMACEUTICAL FORM
- Salve.

FORMULA

Component	Quantity
salicylic acid	3g
benzoic acid	6g
polyethylene glycol salve qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, grind the salicylic acid with the benzoic acid and incorporate them to the *polyethylene glycol salve* until getting homogeneous aspect.

PACKING AND STORAGE
- In proper well closed opaque plastic container or coated aluminum tube, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Chronic plantar dermatophytosis, with hyper-keratosis.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, at night.

SALVE FOR RASHES

SYNONYMITY
- Salve with vitamins A, D and zinc oxide.

PHARMACEUTICAL FORM
- Salve.

FORMULA

Component	Quantity
retinol	100 000 UI
ergocalciferol	40 000 UI
zinc oxide	10g
talcum	5 g
propylene glycol	qs
polyethylene glycol salve qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind the zinc oxide and the talcum in a mortar. Add the propylene glycol in sufficient quantity to moisten the powders and homogenize. Incorporate the mixture to the *polyethylene glycol salve*. Add the retinol and the ergocalciferol and homogenize until getting uniform aspect.

PACKING AND STORAGE
- In proper well closed opaque plastic container or coated aluminum tube, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Siccative and cicatrizant salve, used in the prevention and treatment of rashes and skin eruptions.

DIRECTIONS FOR USE
- External use.
  - Apply on the injured region, after cleaning, when necessary.

SALTS FOR ORAL REHYDRATION

SYNONYMITY
- Oral rehydration sorum (SRO) or oral hydroelectric replacement.

PHARMACEUTICAL FORM
- Powder.

FORMULA

Component	Quantity
sodium chloride	2.6 g
potassium chloride	1.5g
sodium citrate	2.9 g
glucose	13.5 g

DIRECTIONS FOR THE PREPARATION
- Grind each component individually. Mix the powders, sieve the resulting mixture and homogenize. Condition in container for single dose.

Note: *the components are hygroscopic, thus it is necessary to work with relative air humidity between 30% and 45%.*

PACKING AND STORAGE
- In container for single dose. Keep in fresh place, sheltered from heat and moisture.

WARNINGS
- Keep away from children.

INDICATIONS
- Hydroelectric replacement in hypo or normotonic dehydration and maintenance of the hydration.

DIRECTIONS FOR USE
- Internal use.
  - Dissolve the medicamental unit in one liter of water. Administer 100 mL/kg to 150 mL/kg of body weight each four to six hours or at the doctor's discretion. If in the first two hours of treatment, vomiting continue to prevent the patient from administering the solution, see a doctor immediately.

ARTIFICIAL SALIVA, SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
potassium chloride	0.96 g
sodium chloride	0.67 a
hexa-hydrated magnesium chloride	0.04 g
di-hydrated calcium chloride	0.12 g
monobasic potassium phosphate	0.27 g
carmellose sodium	8g
sorbitol solution at 70% (p/p)	24 g
paraben preservative solution	20 g
mint flavorant	qs
citric acid solution (25% to 50%) qs	pH 6.0-7.0
purified water qsp	1000 mL

Note: *fluor salts may be incorporated to the formulation at the concentration of 2 ppm, for prevention of caries.*

DIRECTIONS FOR THE PREPARATION
- Dissolve in a goblet potassium chloride, sodium chloride, hexa-hydrated magnesium chloride, dihydrated calcium chloride and monobasic potassium phosphate in part of the water. Add the sorbitol solution at 70% (p/p) and the specified amount of *paraben preservative solution*. Homogenize. Complete the volume with purified water, homogenize and filter. Gradually disperse the carmellose sodium in the filtered solution. Leave the mixture in rest for around 24 hours. After this period, using a mechanical agitator, promote an effective dispersal of the mixture. Check the pH and, if necessary, adjusts in the from 6.0 to 7.0 range with *citric acid solution 25% to 50% (p/v)*.

PACKING AND STORAGE
- In well closed opaque plastic bottle or bottle spray, sheltered from light and under refrigeration.

WARNINGS
- Keep away from children.

INDICATIONS
- In the treatment of hyposalivation or xerostomia (dry mouth syndrome).

DIRECTIONS FOR USE
- External use.
  - Mouth wash or sprinkle the oral mucous membrane with a small quantity of the product, several times a day, in accordance with the need.

IODINE TANNIC SODIUM GLYCEROPHOSPHATE SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
sodium glycerophosphate	4,22 g
resublimated iodine	6,25 a
tannin	12,5 g
glycerol	10 mL
ethylic alcohol 96 °GL	20 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the resublimated iodine in the alcohol. Grind the sodium glycerophosphate, add the tannin and the glycerol and homogenize. Add the previously heated purified water, mix the two phases and leave in water bath until all free iodine is consumed. During the heating in water bath, keep the volume with addition of purified water. Let it cool, complete the volume and filter.

Note: *the absence of free iodine must be confirmed by starch test. The iodine tannic solution shall be preferably prepared 24 to 48 hours in advance to form the iodine tannic complex.*

PACKING AND STORAGE
- In perfectly closed dropper glass. Keep sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Rhinitis and tonsillitis, tonsils decrease and adenoids.

DIRECTIONS FOR USE
- Internal use.
  - Administer a drop per year of age, two times a day, at the meals or at the doctor's discretion.

IODISED IODINE TANNIC SODIUM GLYCEROPHOSPHATE SOLUTION

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
sodium glycerophosphate	4,22 g
resublimated iodine	5 g
potassium iodide	20 g
tannin	10 g
glycerol	10 mL
ethylic alcohol 96 °GL	20 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the resublimated iodine in alcohol. Grind the sodium glycerophosphate and the potassium iodide, add the tannin and the glycerol and homogenize. Add the previously heated purified water, mix the two phases and leave in water bath until all free iodine is consumed. During the heating in water bath, keep the volume with addition of purified water. Let it cool, complete the volume and filter.

Note: *the absence of free iodine must be confirmed by starch test. The iodine tannic solution shall be preferably prepared 24 to 48 hours in advance to form the iodine tannic complex.*

PACKING AND STORAGE
- In perfectly closed dropper glass. Keep sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Rhinitis and tonsillitis, tonsils decrease and adenoids.

DIRECTIONS FOR USE
- Internal use.
  - Administer a drop per year of age, two times a day, at the meals or at the doctor's discretion.

STRONG LUGOL'S SOLUTION

SYNONYMITY
- strong iodine Solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
resublimated iodine	5 g
potassium iodide	10g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the resublimated iodine and the potassium iodide. Add 10 mL of the water and disperse until complete dissolution. Transfer to a proper container, complete the volume with water, homogenize and filter.

Note: *do not use plastic or metal containers for the preparation and the packaging of the solution. The preparation of the solution must be carried out in chapel with exhaustion. Use individual protection equipment, since the solution may cause metal taste and sensibility in the teeth and gum.*

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Use not recommended for the gestation and breastfeeding period. Stop using if there is change of color or odor in the solution. Keep away from children.

INDICATIONS
- Iodine deficiency; hyperthyroidism (adjuvant); adjuvant, together with a anti-thyroidal drug, in the induction of the thyroid gland involution before the thyroidectomy; thyrotoxic crisis (adjuvant).

DIRECTIONS FOR USE
- Internal use.
  - Adults – hyperthyroidism: 1 mL, three times a day or at the doctor's discretion. The first dose must be ingested one hour after the first dose of the anti-thyroidal medicine. Thyroid involution (pre-surgery): three to five drops, three times a day, for 10 days before the surgery, usually administered concurrently with anti-thyroidal medicine or at the doctor's discretion. Radiation protection: 15 drops a day, for 10 days or at the doctor's discretion. Iodine replacement: 0.3 to 1 mL, three to four times a day or at the doctor's discretion.
  - Children – thyroid involution (pre-surgery): three to five drops, three times a day, for 10 days before the surgery, usually administered concurrently with anti-thyroidal medicine or at the doctor's discretion. Radiation protection: two to four drops a day, for 10 days or at the doctor's discretion.

WEAK LUGOL'S SOLUTION

SYNONYMITY
- Weak iodine solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
resublimated iodine	0.15 g
potassium iodide	0.30 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the resublimated iodine and the potassium iodide. Add 10 mL of water and disperse until complete dissolution. Transfer to a proper container, complete the volume with water, homogenize and filter.

Note: *do not use plastic or metal containers for the preparation and packaging of the solution. The preparation of the solution must be carried out in chapel with exhaustion. Use personal protection equipment because the solution may cause metal taste and sensibility in the teeth and gum.*

PACKING AND STORAGE
- In well closed amber glass container, sheltered from light and at room temperature.

WARNINGS
- Stop using in case of change of color or odor in the solution. Keep away from children.

INDICATIONS
- Local antiseptic. Preventive medicine and treatment caused by iodine deficiency and maternal hypothyroxinemia.

DIRECTIONS FOR USE
- External use.
  - Local antiseptic – apply in the affected areas, when necessary.
- Internal use.
  - Preventive medicine and treatment caused by iodine deficiency: five to 10 drops a day (0.95 mg/of iodine/day to 1.9 mg/of iodine/day) or at the doctor's discretion. Maternal hypothyroxinemia: for pregnant women and breastfeeding women, 15 drops a day.

SCHILLER'S SOLUTION

SYNONYMITY
- Iodine compound solution, iodine solution for Schiller's test.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
resublimated iodine	2g
potassium iodide	4g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Grind the resublimated iodine and the potassium iodide. Add 10 mL of water and disperse until complete dissolution. Transfer to a proper container, complete the volume with water, homogenize and filter.

Note: *do not use plastic or metal containers for the preparation and packaging of the solution. The preparation of the solution must be carried out in chapel with exhaustion. Use personal protection equipment because the solution may cause metal taste and sensibility in the teeth and gum.*

PACKING AND STORAGE
- In perfectly closed amber glass container. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Use in doctor's office. Stop using in case of change of the solution's color or odor.

INDICATIONS
- Schiller's Test.

DIRECTIONS FOR USE
- External use.
  - At the doctor's discretion.

MODIFIED SHOHL'S SOLUTION

SYNONYMITY
- Sodium citrate and citric acid solution.

PHARMACEUTICAL FORM
- Solution.

FORMULA

Component	Quantity
di-hydrated sodium citrate	10 g
mono-hydrated citric acid	6.68 g
paraben preservative solution	2 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Solubilize, separately, each component in sufficient quantity of water. Pour the solutions into graduated container, add the specified quantity of the *paraben preservative solution* and homogenize. Complete the volume with the remaining water, homogenize and filter.

PACKING AND STORAGE
- In perfectly closed amber glass container. Keep in fresh place, sheltered from light and heat.

WARNINGS
- Keep away from children.

INDICATIONS
- Proper systemic alkalinizing when it is desirable to keep the alkaline urine; to relieve chronic metabolic acidosis state, as result of the chronic renal insufficiency or renal tubular acidosis syndrome. It has chelant action that increases the urinary excretion of calcium and lead and, thus, it can also be used in hypercalcemia and in cases of intoxication by lead. It is also used to facilitate the dissolution of renal calculations.

DIRECTIONS FOR USE
- Internal use.
  - Adults – 10 mL to 30 mL diluted in water, after the meals and before sleeping or at the doctor's discretion (maximum dose: 150 mL a day).
  - Children – 5 mL to 15 mL diluted in water, after the meals and before sleeping or at the doctor's discretion.

SILVER SULFADIAZINE 1%, CREAM

SYNONYMITY
- Argentic sulfadiazine cream.

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
silver sulfadiazine	1 g
propylene glycol	5 mL
anionic cream qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Decrease the sulfadiazine silver to fine powder. Add propylene glycol and mix until getting a uniform paste. Add the *anionic cream* and homogenize.

PACKING AND STORAGE
- In proper well closed opaque plastic container or aluminum tube, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.
- Do not use in patients with hypersensitivity to the silver sulfadiazine. It must not be used during pregnancy or in babies younger than two months. There must be discerning administration in patients with glucose-6-phosphate dehydrogenase (6 G-6-PD) deficiency, since hemolysis may result.
- For exclusive use in 2° and 3° degree bums, the drug must be micronized and the preparation must be sterile. In the cases of large burned areas, there may be absorption, being required to monitor the sulfa serum concentrations and the renal function of the patient. Therefore, it must be avoided in patients with renal and hepatic impairment. Leucopenia may result as side effect.

INDICATIONS
- 2° and 3° degree burns, scabs, pyoderma and recuperation of cutaneous tissue in infected varicose ulcers.

DIRECTIONS FOR USE
- External use.
  - Apply small quantity in the affected areas, two to three times a day or at the doctor's discretion.

FERROUS SULFATE, SYRUP

PHARMACEUTICAL FORM

- Syrup.

FORMULA

Component	Quantity
hepta-hydrated ferrous sulfate	4g
citric acid	0.21 g
flavoring agent	qs
purified water	qs
simple syrup qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Separately solubilize the ferrous sulfate and the citric acid in sufficient quantity of water. Pour the solutions into graduated container, add the flavoring agent and homogenize. Complete the volume with *simple syrup*, homogenize and filter.

PACKING AND STORAGE

- In proper well closed amber glass container, sheltered from light and at room temperature.

WARNINGS

- Do not administer in *diabetes mellitus* patients. In that case, replace the simple syrup by dietetic syrup. Keep away from children. It is recommendable to start the therapy with small doses to check if there is no appearance of characteristic iron intolerance symptoms (heartburn, nausea, gastric discomfort, constipation and diarrhea).

INDICATIONS

- Treatment and preventive medicine of ferroprive anemia.

DIRECTIONS FOR USE

- Internal use.
  - Anemia treatment – 500 mg to 1000 mg of ferrous sulfate a day, in fractional doses or at the doctor's discretion.
  - Anemia prevention – 300 mg to 600 mg of ferrous sulfate a day, in fractional doses or at the doctor's discretion. The usual dose is 10 mL, corresponding to 400 mg of ferrous sulfate.

SELENIUM SULFIDE 2,5%, SHAMPOO

PHARMACEUTICAL FORM

- Shampoo.

FORMULA

Component	Quantity
Phase A	
aluminum and magnesium silicate	1 g
purified water	20 g
paraben preservative solution	2g
Phase B	
coconut fatty acid di ethanol amide	5g
sodium lauryl ether sulfate 26-28%	30 g
extract	qs
selenium sulfide	2-5 g
di sodium edetate	0.05 g
purified water qsp	100 g
Phase C	
citric acid solution at 25% qs	pH 5.0-5.5
sodium chloride solution at 20%	qs

DIRECTIONS FOR THE PREPARATION

- Disperse the *paraben preservative solution* in purified water and homogenize. Disperse the aluminum and magnesium silicate in the water, under agitation. Keep this suspension in rest for 24 hours. Prepare Phase B with homogenization of the selenium sulfide and the coconut fatty acid di ethanol amide. Add the other components of Phase B. Add Phase A in Phase B and homogenize. Adjust the pH between 5.0 and 5.5 with the *citric acid solution at 25%*. If necessary, add the solution of sodium chloride to adjust the viscosity.

Note: *when the extract is added in the beginning of the manipulation, there is no alteration in the shampoo's viscosity. However, if it is added at the end of the process, the viscosity may be reduced. The aluminum and magnesium silicate is used as thixotropic suspensor agent.*

PACKING AND STORAGE

- In perfectly closed dark plastic bottle. Keep at room temperature, sheltered from light.

WARNINGS

- Keep away from children.

INDICATIONS

- In the treatment of dandruff, scalp seborrheic dermatitis and versicolor pityriasis.

DIRECTIONS FOR USE

- External use.
  - Dandruff and scalp seborrheic dermatitis – apply the shampoo on the previously water wetted hair, gently massaging for some minutes and rinse it with water. If necessary, repeat the application.
  - Versicolor Pityriasis – apply once a day, 15 minutes before bath, for 20 days. After the treatment exposure to the sun is recommended, to equal the skin shade.

GLYCERIN SUPPOSITORIES

SYNONYMITY
- Glycerinated Suppository.

PHARMACEUTICAL FORM
- Suppository.

FORMULA

Component	Quantity
sodium stearate	9g
glycerol qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, heat the glycerol to 50°C and, under agitation, dissolve the sodium stearate. Pour the mixture still hot in the proper mold. Let it cool and remove the suppositories.

Note: *it is recommended to use previously heated metal molds. Molds for infants (1 g), children (1.5 g to 2 g) and adults (2.5 g to 3 g).*

PACKING AND STORAGE
- In coated paper or blister, well closed, sheltered from light and moisture. Keep at temperature lower than 25°C.

WARNINGS
- The suppository may be moistened with water before insertion, to decrease the initial trend of the base of drawing water from the mucous membranes, irritating the tissues. Keep away from children.

INDICATIONS
- Laxative.

DIRECTIONS FOR USE
- External use.
  - Adults and Children – introduce the suppository in the rectum, until the wish to go to bathroom results.
  - Babies – introduce the suppository in the rectum, by the thinnest part. The glycerol suppository can be left acting from 15 to 30 minutes.
- It is not necessary that the product dissolves completely to produce the desired effect.

MENTHOLATED TALCUM

PHARMACEUTICAL FORM
- Talcum.

FORMULA

Component	Quantity
menthol	1 g
talcum qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Sieve the talcum. Grind the menthol to fine powder, add the talcum and homogenize.

Note: *the menthol may be ground in sufficient quantity of ethylic alcohol. For that, it is necessary to assure the total evaporation of the ethylic alcohol before the addition of the talcum. It is possible to add 5% to 10% of zinc stearate or magnesium stearate as sliding agent in the Formulation. Those must be sieved by the same sieve size previously used.*

PACKING AND STORAGE
- In proper well closed opaque plastic container, sheltered from light and moisture and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- In the itching dermatoses.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected location, two to three times a day or at the doctor's discretion.

TIABENDAZOLE 5%, CREAM

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
tiabendazole	5g
propylene glycol	10 mL
non-ionic cream qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, grind the tiabendazole to a fine powder, add the propylene glycol and mix until getting homogeneous dispersion. Add the *non-ionic cream* and homogenize.

PACKING AND STORAGE
- In proper well closed opaque plastic container or coated aluminum tube, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Cutaneous Larva migrans, scabies.

DIRECTIONS FOR USE
- External use.
  - Larva migrans treatment: rub the salve in the active extremity of the tracks or tunnels excavated by the parasite, three times a day, for five days or at the doctor's discretion.
  - Scabies treatment: take warm baths at night. Then, quickly dry the skin and apply the salve on the harmed zones and nearby areas, gently rubbing. In the next morning, take another bath and apply the salve again. Repeat the procedure for five consecutive days or at the doctor's discretion. For the treatment, boil the bed clothes, before washing. Treat simultaneously all the sick members of the family.

TIABENDAZOLE 5%, SALVE

PHARMACEUTICAL FORM
- Salve.

FORMULA

Component	Quantity
tiabendazole	5 g
polyethylene glycol salve qsp	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, grind the tiabendazole to a fine powder and incorporate the *polyethylene glycol salve* until getting homogeneous aspect.

PACKING AND STORAGE
- In proper well closed opaque plastic container or coated aluminum tube, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Cutaneous Larva migrans, scabies.

DIRECTIONS FOR USE
- External use.
  - Larva migrans treatment: rub the salve in the active extremity of the tracks or tunnels excavated by the parasite, three times a day, for five days or at the doctor's discretion.
  - Scabies treatment: take warm baths at night. Then, quickly dry the skin and apply the salve on the harmed zones and nearby areas, gently rubbing. In the next morning, take another bath and apply the salve again. Repeat the procedure for five consecutive days or at the doctor's discretion. For the treatment, boil the bed clothes, before washing. Treat simultaneously all the sick members of the family.

UREA 5% TO 10%, CREAM

SYNONYMITY
- Carbamide cream.

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
urea	5 gto 10 g
purified water	2.5 mL to 5 mL
lactic acid 85% qsp	pH 5.0-5.5
anionic cream qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind the urea in a mortar until getting a fine powder. Add water and homogenize well. Gradually incorporate the *anionic cream* homogenizing. Adjust the pH with lactic acid.

Note: *urea in concentrations above 10% presents base pH and it may compromise the stability in non-ionic creams; the use of lactic acid as acidulant is done to avoid ammonia liberation by hydrolysis during the stocking, which easily happens in pH above 6.0.*

PACKING AND STORAGE
- In polypropylene (PP) pot or tube or polyethylene terephthalate pot (PET), sheltered from light and at temperature no higher than 25°C.

WARNINGS
- Keep away from children.

INDICATIONS
- As keratolytic in psoriasis, ichthyosis and hyper-keratoses, as moisturizer in xerodermas. It is also used as keratoplastic in plantar cracks.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected area one or more times a day.

UREA AND SALICYLIC ACID, CREAM

SYNONYMITY
- Cream with carbamide and salicylic acid.

PHARMACEUTICAL FORM
- Cream.

FORMULA

Component	Quantity
urea	5 to 10 g
salicylic acid	1 to 10 g
propylene glycol	qs
purified water	2,5 to 5 mL
anionic base cream qsp	100 g

DIRECTIONS FOR THE PREPARATION
- Grind the urea in a mortar, add the water and homogenize well. Disperse the salicylic acid in the propylene glycol. Gradually incorporate both in the anionic cream, until homogenization.

Note: *the urea in concentrations above 10% presents base pH and it may compromise the stability in non-ionic creams. The salicylic acid must be protectedfrom light and, in concentrations above 2%, it may present incompatibility with non-ionic emulsions.*

PACKING AND STORAGE
- In proper container, sheltered from light and at room temperature.

WARNINGS
- Keep away from children.

INDICATIONS
- Lower concentrations of urea and salicylic acid: as moisturizer in xerodermas;
- Higher concentrations of urea and salicylic acid: as keratolytic in hyper-keratoses.

Note: *in concentrations of salicylic acid above 2%, the Formulation has keratolytic action. The salicylic acid in concentrations higher than 2%, when applied in extensive areas and for a long period may determine salicylism.*

DIRECTIONS FOR USE
- External use.
  - Apply in the affected area one or more times a day.

SALICYLATE VASELINE

SYNONYMITY
- Salicylic acid salve.

PHARMACEUTICAL FORM
- Salve.

FORMULA

Component	1%	2%	5%	10%	20%
salicylic acid	1 g	2g	5g	10 g	20 g
liquid petrolatum	0.3 g	0.7 g	17 g	3.4 g	6.8 g
white petrolatum qsp	100 g	100 g	100 g	100 g	100 g

DIRECTIONS FOR THE PREPARATION
- In proper container, incorporate the salicylic acid to the liquid petrolatum. Add the white petrolatum, mixing until full homogenization.

PACKING AND STORAGE
- In proper well closed opaque plastic container, sheltered from light and moisture and at room temperature.

WARNINGS
- In concentrations above 10% (p/p), use latex gloves in the time of application. Keep away from children.

INDICATIONS
- Hyper-keratoses. Concentrations below 2% (p/p) have essentially keratoplastic action and concentrations above 2% (p/p) have keratolytic action.

DIRECTIONS FOR USE
- External use.
  - Apply in the affected areas, at night, and remove it in the morning. Products containing salicylic acid at 10% (p/p) or 20% (p/p) present strong keratolytic property and their application must be performed with great care, being the use of spatulas or protective gloves recommended.

SILVER VITELLINATE 1%, NASAL SOLUTION

SYNONYMITY
- Argyrol, silver nucleinate, colargol, nargol.

PHARMACEUTICAL FORM
- Nasal topical solution.

FORMULA

Component	Quantity
silver vitellinate	0.15 g
purified water qsp	15 mL

DIRECTIONS FOR THE PREPARATION
- Slowly dissolve the silver vitellinate in sufficient quantity of purified water. Complete the desired volume with the remainder of the water and mix with glass stick or in agitating plate. Put in amber glass with dropper.

Note: *the silver vitellinate solubility in waterish solutions is low, but it comes to be completely dissolved. Exposure to the light must be avoided. During the preparation it is necessary to be careful, since it may stain the skin. The silver vitellinate solutions are incompatible with chlorides, as benzalkonium chloride and sodium chloride.*

PACKING AND STORAGE
- In perfectly closed amber glass. Keep in fresh and dry place, sheltered from light and heat.

WARNINGS
- For nasal topical use. Keep away from children.

INDICATIONS
- Antiseptic.

DIRECTIONS FOR USE
- External use.
  - Pour one to two drops in the nasal cavities up to four times a day or at the doctor's discretion.

SILVER VITELLINATE 2% TO 10%, OPHTHALMIC SOLUTION

SYNONYMITY
- Argyrol, silver nucleinate, colargol, nargol.

PHARMACEUTICAL FORM
- Eye drops.

FORMULA

Component	Quantity
silver vitellinate	0,2 to 1 g
sterile purified water qsp	10 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the silver vitellinate in sterile purified water, with agitation. Filter the solution in previously sterilized dropper bottles, using sterilizing filtration system with 0.45 pm porosity membrane.

Note: *the eye drops must be a sterile solution. Proceed to the sterilizing filtration in laminar flow chapel, properly adorned. The bottle must be the dropper type, to facilitate the administration, and sterile, to not contaminate the solution. The preparation of ophthalmic solutions must follow the Good Practices of Manipulation for sterile products.*

PACKING AND STORAGE
- In perfectly closed milky or opaque dropper bottle, with sealing. Keep at room temperature, sheltered from light.

WARNINGS
- Reject the solution 30 days after opening the bottle. Stop using in case of change in color or odor. Avoid contact of the dropper with fingers and eyelid surface. Keep away from children.

INDICATIONS
- In preoperative procedure of ophthalmic surgeries and as antiseptic for ocular infections and mucous membranes.

Note: *the use of the silver vitellinate in preoperative procedure of ophthalmic surgeries is done due to its capability to color and precipitate mucus filaments, making their removal easier. Silver vitellinate solutions may be added with millesimal sterile adrenalin solution, in equal parts.*

DIRECTIONS FOR USE
- External use.
  - Preoperative procedure: apply two to three drops and then wash with sterile solution for irrigation.
  - Ocular and mucous membranes infections: apply one to three drops each three or four hours or at the doctor's discretion.

8.2 BASES FOR THE PREPARATION OF FORMULATIONS

COLD CREAM

PROPERTIES AND APPLICATION

- A/O type emulsion, i.e., the oily phase is the external or continuous phase and when applied it forms a protective oily film that remains on the skin after the evaporation of the water. The slow evaporation of the water gives the skin a refreshing effect. This cream may be used as vehicle or even pure in products for body and facial massage.

FORMULA

Component	Quantity
Phase A (waterish)	
sodium borate	1 g
paraben preservative solution	3,3 g
purified water qsp	100 g
Phase B (oily)	
white bee wax	15 g
liquid petrolatum	50 g
propylparaben	0,15 g
butyl-hydroxytoluene	0,05 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** at 75°C and **Phase** A **(waterish)** at 80°C. Pour the waterish phase on the oily phase, keeping the temperature. Moderately agitate until an emulsion is formed, avoiding incorporation of air. Reduce the agitation speed and cool to room temperature.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

BASE CONDITIONER

PROPERTIES AND APPLICATION

- O/A cationic emulsion, intended to restore to the hair the properties lost during anionic shampoo washing process or after chemical treatment. It is compatible with silicones, shea butter, hydrolyzed proteins, quatemized polymers, extracts and vegetable oils, among others. It is incompatible with anionic substances.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100 g
Phase B (oily)	
liquid petrolatum	2,0 g
cetostearyl alcohol 30/70	4,0 g
ethoxylated cetostearyl alcohol 20 OE	0,8g
butyl-hydroxytoluene	0,05 g
Phase C (complementary)	
cetyltrimethylammonium chloride at 50%	2,0g

DIRECTIONS FOR THE PREPARATION

- Mix the components of **Phase** A **(waterish)** and heat up to 70°C. Mix the components of **Phase B (oily)** and heat up to 70°C. Add the waterish phase on the oily phase under slow agitation. Add **Phase** C **(complementary)** and keep slow agitation until reaching room temperature. Check the pH and, if necessary, correct to 3.8 – 4.0, with the help of acidulant or alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

NO-RINSE BASE CONDITIONER

PROPERTIES AND APPLICATION

- No-rinse cationic emulsion, intended to restore to the hair the properties lost during anionic shampoo washing process or after chemical treatment.

FORMULA

Component	Quantity
Phase A (waterish)	
purified water qsp	100 g
di sodium edetate	0,1 g
paraben preservative solution	3,3 g
Phase B (oily)	
liquid petrolatum	2,0 g
cetostearyl alcohol 30/70	1,0 g
butyl-hydroxytoluene	0,05 g
behenyltrimethylammonium sulfate	4,0 g

DIRECTIONS FOR THE PREPARATION

- Mix the **Phase** A **(waterish)** components and heat up to 70°C. Mix the **Phase B (oily)** components and heat up to 70°C. Add the waterish phase on the oily phase under slow agitation. Keep slow agitation until reaching room temperature. Check the pH and, if necessary, correct to 3.8-4.0, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

ANIONIC CREAM II

PROPERTIES AND APPLICATION

- Emollient, low irritability and oiliness, O/A anionic cream, with high resistance to active principles requiring vehicles with this character, as hydroquinone, di-hydroxyacetone and resorcinol.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0.1 g
preservative paraben solution	3.3 g
diethanolamine cetyl phosphate	15 g
purified water qsp	100 g
Phase B (oily)	
Capric/Caprylic acid triglyceride	4g
cetostearyl alcohol 30:70	9g
butyl-hydroxytoluene	0.05 g
Phase C (complementary)	
cyclomethicone	2g
imidazolidinyl ure apreservative solution at 50%	0.6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation, add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

ANIONIC CREAM II

PROPERTIES AND APPLICATION

- Emollient, low oiliness, O/A anionic cream, with good resistance to active principles requiring vehicles with this character, as hydroquinone, di-hydroxyacetone and resorcinol.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0,1 g
paraben preserative solution	3,3 g
purified water qsp	100 g
Phase B (oily)	
octyl stearate	6g
cetostearyl alcohol, sodium cetyl stearyl sulfate	15 g
butyl-hydroxytoluene	0,05 g
Phase C (complementary)	
cyclomethicone	2g
imidazolidinyl urea preservative solution at 50%	0,6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

ANIONIC CREAM WITH HYDROXYETHYL CELLULOSE

PROPERTIES AND APPLICATION

- Soft, low oiliness, O/A anionic cream, with high resistance to active principles requiring anionic load vehicles.

FORMULA

Component	Quantity
Phase A (waterish)	
hyetellose (hydroxyethyl cellulose)	0,2 g
di sodium edetate	0,1 g
paraben preservative solution	3,3 g
purified water qsp	100 g
Phase B (oily)	
octyl stearate	6g
anionic auto-emulsioning wax (cetostearyl alcohol,	
sodium cetyl stearyl sulfate 9:1)	15 g
butyl-hydroxytoluene	0,05 g
Phase C (complementary)	
cyclomethicone	2g
imidazolidinyl urea preservative solution at 50%	0,6 g

DIRECTIONS FOR THE PREPARATION

- Mix all the components of **Phase** A **(waterish)** and agitate until full dispersion of the hyetellose. Then, separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70 – 75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

FADE CREAM

PROPERTIES AND APPLICATION

- The fade creams, also called diadermines, are O/A type emulsions containing stearic acid in common concentrations of 15% to 25%, which is partially saponified. The saponification is done with emulsioning alkaline agents such as sodium or potassium hydroxides or carbonates, diluted ammonia solution, triethanolamine, aminomethyl propanol (AMP) at 95% or by the sodium borate.

FORMULA

Component	Quantity
Phase A (waterish)	
triethanolamine or aminometyl propanol at 95%	0.7 g
sorbitol solution 70% (p/p)	3-7g
paraben preservative solution	3.3 g
purified water qsp	100 g
Phase B (oily)	
triple-pressure stearic acid	18 g
liquid petrolatum	2g
lanolin	0.5 g
sorbitan oleate	0.5 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** to 70°C and **Phase** A **(waterish)** to 75°C. Pour the waterish phase on the oily phase under vigorous agitation for 10 minutes, decrease to slow agitation until reaching room temperature.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

NON-IONIC CREAM I

PROPERTIES AND APPLICATION

- Dry O/A non-ionic cream. It has fine appearance and easy adherence to the skin, allowing to convey active principles for use in cosmetics.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100 g
Phase B (oily)	
auto-emulsioning non-ionic wax (cetearyl alcohol, ceteareth 20, mineral oil, lanolin alcohol and vaseline)	15 g
dimethicone	2g
butyl-hydroxytoluene	0.05 g
octyl stearate	2g
Phase C (complementary)	
imidazolidinyl urea preservative solution at 50%	0.06 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70 – 75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

NON-IONIC CREAM II

PROPERTIES AND APPLICATION

- O/A non-ionic cream, highly resistant to the incorporation of several active principles, in which the viscosity is a characteristic to be kept in the end product. Indicated for preparations with ketoconazole and neomycin, among other active principles. It is also compatible with several gynecological use active principles.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100 g
Phase B (oily)	
octyl stearate	6g
auto-emulsioning non-ionic wax (cetearyl alcohol, ceteareth 20, mineral oil, lanolin alcohol and vaseline)	14 g
butyl-hydroxytoluene	0.05 g
Phase C (complementary)	
cyclomethicone	2g
imidazolidinyl urea preservative solution at 50%	0.6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic or amber glass container, sheltered from light and at room temperature.

SILICONE EMULSION

PROPERTIES AND APPLICATION

- Emulsion water in silicone, with non oily sensation. Compatible with several active principles. It assures low irritability in sensitive skins.

FORMULA

Component	Quantity
Phase A (waterish)	
paraben preservative solution	3.3 g
sodium chloride	1 g
purified water qsp	100 g
Phase B (oily)	
cyclomethicone	4.3 g
dimethicone copolyol and cyclomethicone	14.3 g

DIRECTIONS FOR THE PREPARATION

- In proper container add **Phase** A **(waterish)** on **Phase B (oily),** under vigorous agitation in electromechanical agitator, until full homogenization.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

CREAMY GEL

PROPERTIES AND APPLICATION

- Non-ionic creamy gel, indicated for all skin types. It does not change the viscosity in presence of ethylic alcohol and glycols.

FORMULA

Component	Quantity
polyacrylamide, isoalkanes C13-14 and ethoxylated lauryl alcohol 7 OE	4 g
paraben preservative solution	3.3 g
imidazolidinyl urea preservative solution at 50%	0.6 g
purified water qsp	100 g

DIRECTIONS FOR THE PREPARATION

- In proper container, disperse the polyacrylamide compound in the water and add the other components, under agitation.

PACKING AND STORAGE

- In proper opaque plastic container sheltered from light and at room temperature.

CARBOMER GEL

PROPERTIES AND APPLICATION

- Non-ionic waterish gel, colorless, stable at pH 5.5 – 7.3.

FORMULA

Component	Quantity
Phase A	
carbomer 980	1 g
purified water qsp	100 g
Phase B	
di sodium edetate	0.05 g
propylene glycol	5%
imidazolidinyl urea preservative solution at 50%	0.5 g
Phase C	
triethanolamine solution at 50% qs	pH 6.5 -7.0

DIRECTIONS FOR THE PREPARATION

- In proper container, solubilize the disodium edetate, the propylene glycol and the *imidazolidinyl urea preservative solution* in the purified water. Add the carbomer and keep in contact until it is totally wet. Disperse the carbomer with the help of a electromechanical agitator until total absence of granulates. Start the neutralization with the triethanolamine solution, adjusting the pH between 6.5 and 7.0.

PACKING AND STORAGE

- In proper opaque plastic container sheltered from light and at room temperature.

HIGH VISCOSITY HYDROXYETHYL CELLULOSE GEL

PROPERTIES AND APPLICATION

- Transparent, colorless or lightly yellowed non-ionic waterish gel, stable in the 2.0 to 12.0 pH range. Vehicle for very reactive or easily oxidizable substances. Used as vehicle in products with 30% to 50% of active principles in gel. Associations of acids may also be incorporated with hydroquinone in high concentrations (more than 10% each).

FORMULA

Component	Quantity
Phase A	
hyetellose (hydroxyethyl cellulose)	2-5 g
sorbitol	3g
Phase B	
di sodium edetate	0,1 g
paraben preserative solution	3,3 g
imidazolidinyl urea preservative solution at 50%	0.6 g

DIRECTIONS FOR THE PREPARATION

- Mix **Phase** A components. Slowly agitate until full dispersion of the hyetellose and total absence of granulates. Add **Phase B** components one by one under slow agitation (end pH between 5.0 and 6.0).

PACKING AND STORAGE

- In proper opaque plastic container sheltered from light and at room temperature.

TOOTH GEL

PROPERTIES AND APPLICATION

- Gel for oral hygiene.

FORMULA

Component	Quantity
microcrystalline cellulose	0,5 g
carmellose sodium (high viscosity)	2g
glycerol	20 g
sodium saccharin	0,1 g
sodium lauryl sulfate	2g
paraben preservative solution	3,3 g
purified water qsp	100 g

DIRECTIONS FOR THE PREPARATION

- Disperse the microcrystalline cellulose and the carmellose sodium in glycerol. Solubilize the sodium saccharin apart and the *paraben preservative solution* in part of the water and gradually add the sodium lauryl sulfate, under gentle agitation. Pour this solution on the previous dispersion and add the remainder of the water, under moderate agitation. Leave it in rest until getting homogeneous gel and foam stabilization.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

HYDROXYETHYL CELLULOSE FLUID GEL

PROPERTIES AND APPLICATION

- Transparent, colorless or lightly yellowed non-ionic waterish gel, stable in the 2.0 to 12.0 pH range. Vehicle for very reactive or easily oxidizable substances.

FORMULA

Component	Quantity
Phase A	
hyetellose (hydroxyethyl cellulose)	1 g
purified water qsp	100 g
Phase B	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
imidazolidinyl urea preservative solution at 50%	0.6 g

DIRECTIONS FOR THE PREPARATION

- Mix Phase A components. Slowly agitate until full dispersion of the hyetellose and total absence of granulates. Add Phase B components one by one, under slow agitation (end pH between 5.0 and 6.0).

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

HYDROALCOHOLIC GEL

PROPERTIES AND APPLICATION

- Alcoholic Gel indicated as a basis for getting transparent or translucent gels, for incorporation of lipid soluble active principles or active principles with solubility problems. Used for aftershave, depilation or antiseptic gel products.

FORMULA

Component	Quantity
Phase A	
di sodium edetate	0,1 g
glycerol	5g
paraben preservative solution	3,3 a
ethylic alcohol at 70% qsp	100 g
Phase B	
carbomer 980	1 g
Phase C	
triethanolamine solution at 50%	0,6 g

DIRECTIONS FOR THE PREPARATION

- In proper container disperse Phase B in the previously mixed Phase A components, waiting the time necessary for full dispersion of the carbomer (approximately 24 hours). Agitate again until total granulates absence. Start neutralization with the triethanolamine solution (Phase C), adjusting the pH between 5.5 and 6.5.

PACKING AND STORAGE

- In proper narrow mouth container (PET bottle – polyethylene terephthalate or PE bottle – polyethylene), sheltered from light and at room temperature.

ANIONIC LOTION

PROPERTIES AND APPLICATION

- Emollient, low oiliness, anionic A/O emulsion, with high resistance to active principles requiring vehicles with this ionic character, as hydroquinone, di-hydroxyacetone and resorcinol.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0,1 g
paraben preservative solution	3,3 g
Propylene glycol	10 g
purified water qsp	100 g
Phase B (oily)	
Octyl stearate	6g
auto-emulsioning non-ionic wax (cetearyl alcohol, ceteareth 20, mineral oil, lanolin alcohol and vaseline)	10 g
Butyl-hydroxytoluene	0,05 g
Phase C (complementary)	
Cyclomethicone	2g
Imidazolidinyl urea preservative solution at 50%	0,6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

NON-IONIC LOTION I

PROPERTIES AND APPLICATION

- Moisturizing, highly emollient, humectants, non-ionic O/A creamy emulsion, resistant to the incorporation of active principles.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
ethoxylated methyl glucose 20 OE	5 g
purified water qsp	100 g
Phase B (oily)	
almond oil	3 g
auto-emulsioning non-ionic wax	9g
(cetearyl alcohol, ceteareth 20, mineral oil, lanolin alcohol and vaseline) butyl-hy droxytoluene	0.05 g
cyclomethicone and dimethicone	2g
ethoxylated cetostearyl alcohol 20 OE	0.5 g
Phase C (complementary)	
cyclomethicone	2-5 g
imidazolidinyl urea preservative solution at 50%	0.6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

NON-IONIC LOTION II

PROPERTIES AND APPLICATION

- Low oiliness, soft, non-ionic O/A emulsion with good resistance to active principles requiring nonionic load vehicles.

FORMULA

Component	Quantity
Phase A (waterish)	
di sodium edetate	0,1 g
paraben preservative solution	3,3 g
purified water qsp	100 g
Phase B (oily)	
octyl stearate	5 g
auto-emulsioning non-ionic wax	10 g
(cetearyl alcohol, ceteareth 20, mineral oil, lanolin alcohol and vaseline)	
butyl-hy droxytoluene	0,05 g
Phase C (complementary)	
cyclomethicone	2g
imidazolidinyl urea preservative solution at 50%	0,6 g

DIRECTIONS FOR THE PREPARATION

- Separately heat **Phase B (oily)** and **Phase** A **(waterish)** to temperature around 70-75°C. Under slow agitation, add the waterish phase to the oily phase. Keep slow agitation until reaching approximately 40°C and add **Phase** C **(complementary).** Check the pH and, if necessary, correct to 5.5 – 6.5, with the help of acidulant and alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

TOOTH PASTE

PROPERTIES AND APPLICATION

- Paste for oral hygiene.

FORMULA

Component	Quantity
Phase A	
microcrystalline cellulose	0.37 g
sorbitol	7,41 g
Phase B	
sodium saccharin	0,1 g
carmellose sodium (high viscosity)	1,48 g
glycerol	20 g
paraben preservative solution	3,3 g
purified water qsp	100 g
Phase C	
colloidal silicon dioxide (mesh 200)	1,48 g
carbonate of calcium (mesh 50)	28 g
Phase D	
compoundfragrance	qs
Phase E	
sodium lauryl sulfate	2g

DIRECTIONS FOR THE PREPARATION

- Mix **Phase** A components in mechanical agitator using rod with propeller. Leave it in rest. Heat part of the water separately and add to **Phase B** mixture until full dispersion of the constituents; then, let it cool in rest for hydration. After the cooling, Pour **Phase** A in **Phase B** and add the remainder of the water. Separately, mix **Phase** C in mechanical agitator. Slowly pour **Phase** C on the previous mixture under constant agitation. Add **Phase D** and homogenize. Gradually add **Phase** E with moderate agitation, until full homogenization.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

HYDROPHILIC PETROLATUM

PROPERTIES AND APPLICATION

- This salve is considered an absorption base because it has the capability of absorbing additional water. It is oily and difficult to remove from clothes. The Formulation's emulsioning capability is due to the cholesterol.

FORMULA

Component	Quantity
cholesterol	3g
stearyl alcohol	3g
white bee wax	8g
white petrolatum qsp	100 g

DIRECTIONS FOR THE PREPARATION

- Fuse the stearyl alcohol, the white bee wax and the white petrolatum at 75°C. Add the cholesterol, draw from the heating and agitate until solidification.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

LANOLIN SALVE AND VASELINE

PROPERTIES AND APPLICATION

- This salve is considered an absorption base because it has the capability of absorbing additional water. It is oily and difficult to remove from clothes. It has emulsioning capability due to the lanolin present in the Formulation.

FORMULA

Component	Quantity
lanolin	30 g
butyl-hydroxytoluene	0.02 g
liquid petrolatum	qs
white petrolatum qsp	100 g

DIRECTIONS FOR THE PREPARATION

- In proper container, mix the lanolin and the white petrolatum. Add the butyl-hydroxytoluene, previously solubilized in petrolatum, to the mixture, under agitation until full homogenization.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

POLYETHYLENE GLYCOL SALVE

PROPERTIES AND APPLICATION

- This salve is considered a hydro soluble base. It is chemically inert and it is formed by a mixture of different molecular weight polyethylene glycols. It is anhydrous, non-occlusive, easy to remove from clothes and considered less fatty than other salves. It may draw water from the corneal stratum and therefore it is not indicated in patients with extensive bums. Addition of a large quantity of water is not recommended, being more often used for incorporation of solid substances.

FORMULA

Component	Quantity
macrogol 400 (polyethylene glycol 400)	33.3 g
macrogol 4000 (polyethylene glycol 4000)	33.3 g
propylene glycol	33.3 g

Note: *it is possible to add cetyl alcohol at 1% to improve the salve's spreading characteristics.*

DIRECTIONS FOR THE PREPARATION

- Heat the substances until total fusion of the components at approximately 65°C and mix until solidification.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

BASE SHAMPOO I (WITHOUT AMIDE)

PROPERTIES AND APPLICATION

- Product indicated for hair and scalp washing. Base vehicle for incorporation of medicamental active principles.

FORMULA

Component	Quantity
Phase A	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100g
Phase B	
Sodium Lauryl ether sulfate	35 g
cocamidopropyl betaine	4g
Phase C	
Lauryl glucoside	5g
Phase D	
sodium chloride solution at 25%	4g

DIRECTIONS FOR THE PREPARATION

- Mix Phase A components and agitate until full solubilization of the disodium edetate. Add Phase components B on Phase A with slow agitation. Separately heat Phase C to temperature around 50°C and, after the fusion, add to the previous mixture. Add Phase D component with slow agitation. Check the pH and, if necessary, correct to pH 5.5 – 6.5 with the acidifying or alkalinizing solutions, described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

BASE SHAMPOO II

PROPERTIES AND APPLICATION

- Product indicated for hair and scalp washing. Base vehicle for incorporation of medicamental active principles.

FORMULA

Component	Quantity
Phase A	
di sodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100g
Phase B	
Sodium Lauryl ether sulfate (solution of 26% to 28%)	30 g
Phase C	
Coconut fatty acid di ethanol amide	4g
Phase D	
cocamidopropyl betaine	4g

DIRECTIONS FOR THE PREPARATION

- Mix Phase A components and agitate until full solubilization of the disodium edetate. Add Phase B component on Phase A with slow agitation. Separately heat Phase C to temperature around 50°C and, after the fusion, add to the previous mixture. Add Phase D component with slow agitation. Check the pH and, if necessary, correct to pH 5.5 – 6.5 with the acidifying or alkalinizing solutions, described in *Auxiliary Solutions*.

Note: *transparent, colorless or lightly yellowed shampoo.*

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

BASE SHAMPOO III

PROPERTIES AND APPLICATION

- Product indicated for hair and scalp washing. Base shampoo for incorporation of cationic active principles. Low viscosity shampoo; it is possible to add non-ionic thickeners, derived from corn glucose.

FORMULA

Component	Quantity
lauryl glucoside	5g
decyl glucoside	5g
coconut fatty acid di ethanol amide	5g
cocamidopropyl betaine	25 g
di sodium edetate	0.1 g
benzalkonium chloride	0.2 g
purified water qsp	100 g

DIRECTIONS FOR THE PREPARATION

- In proper container, homogenize the components in the flowing order: lauryl glucoside, decyl glucoside, disodium edetate, benzalkonium chloride and part of the water. Add the coconut fatty acid di ethanol amide and the cocamidopropyl betaine, complete the volume with water and homogenize. Adjust the pH between 7.0 and 7.5, with the help of the acidulant solutions described in *Auxiliary Solutions*.

PACKING AND STORAGE

- In proper opaque plastic container sheltered from light and at room temperature.

PEARLY SHAMPOO

PROPERTIES AND APPLICATION

- Product indicated for hair and scalp washing. Base vehicle for incorporation of medicamental active principles.

FORMULA

Component	Quantity
Phase A	
disodium edetate	0.1 g
paraben preservative solution	3.3 g
purified water qsp	100 g
Phase B	
sodium lauryl ether sulfate (26% to 28% solution)	30 g
Phase C	
coconut fatty acid diethanolamide	4g
Phase D	
cocamidopropyl betaine	4g

DIRECTIONS FOR THE PREPARATION

- Mix **Phase** A components and agitate until full solubilization of the disodium edetate. Add **Phase B** component on **Phase** A with slow agitation. Separately heat the **Phase** C to temperature around 50°C and, after the fusion, add to the previous mixture. Add **Phase D** component with slow agitation. After the mixture of the previous phases add **Phase** E and slowly agitate. Check the pH and, if necessary, correct to pH 5.5 – 6.5 with the acidifying or alkalinizing solutions described in *Auxiliary Solutions*.

Note: *pearly shampoo, white*.

PACKING AND STORAGE

- In proper opaque plastic container, sheltered from light and at room temperature.

DIETETIC SYRUP (WITHOUT SUGAR)

PROPERTIES AND APPLICATION

- Vehicle for liquid products containing hydrosoluble drugs. It makes possible the correction of unpleasant tastes of formulations. Indicated for diabetic or overweighed patients.

FORMULA

Component	*Quantity*
carmellose	2g
paraben preservative solution	2-5 g
sodium saccharin	0.1 g
sodium cyclamate	50 mg
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- Gradually add the carmellose in part of the water until dissolution. Add the saccharine and the sodium cyclamate and homogenize. Add the specified quantity of the *paraben preservative solution* and homogenize. Complete the desired volume with the remainder of the water, homogenize and filter.

PACKING AND STORAGE

- In proper amber glass container, sheltered from light and at room temperature.

SIMPLE SYRUP

PROPERTIES AND APPLICATION

- Vehicle for liquid products containing hydrosoluble drugs. It makes possible the correction of unpleasant tastes of formulations. The syrup is a pharmaceutical form prepared with sugar and water, in which the sugar is near to saturation, composing a hypertonic solution.

FORMULA

Component	Quantity
sucrose	85 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- In proper container dissolve the sucrose in 50 mL of water in water bath, with constant agitation. Cool, complete the volume with purified water, homogenize and filter.

Note: *the water bath temperature must not exceed 80°C.*

PACKING AND STORAGE

- In proper amber glass container, sheltered from light and at room temperature.

8.3 AUXILIARY SOLUTIONS

ROSE WATER

APPLICATION
- Adjuvant.

FORMULA

Component	Quantity
essential rose oil	4 drops
purified water qsp	1000 mL

DIRECTIONS FOR THE PREPARATION
- In proper container add 800 mL of water and four drops of essential rose oil. Agitate, complete the volume and filter.

PACKING AND STORAGE
- In proper well closed amber glass container, sheltered from light and at room temperature.

COMPOUND AROMA

APPLICATION

- Flavoring solution for mouth wash and tooth paste. FORMULA

Component	Quantity
vanilla aroma	0.1 mL
lemon aroma	0.005 mL
anis aroma	0.01 mL
eucalyptus oil	0.01 mL
carnation oil	0.01 mL
propylene glycol	0.2 mL
ethylic alcohol 96 °GL qsp	1 mL

DIRECTIONS FOR THE PREPARATION

- In proper container, solubilize the extracts in the alcohol and homogenize

PACKING AND STORAGE

- In proper amber glass container, sheltered from light and at room temperature.

MINT FLAVORANT

APPLICATION
- Flavorant solution.

FORMULA

Component	Quantity
mint flavorant	0.1 g
ethylic alcohol 96 °GL	0.2 g
glycerol	0.4 g
polysorbate 20	0.01 g
purified water qsp	1 g

DIRECTIONS FOR THE PREPARATION
- In proper container, solubilize the colorants in part of the water. Solubilize the extract in ethylic alcohol and add to the previous solution. Add the glycerol and homogenize. Complete the volume with water and homogenize.

PACKING AND STORAGE
- In proper amber glass container, sheltered from light and at room temperature.

IMIDAZOLIDINYL UREA PRESERVATIVE SOLUTION AT 50%

APPLICATION
- Preservative solution.

FORMULA

Component	Quantity
imidazolidinyl urea	50 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Dissolve the imidazolidinyl urea in the water, under agitation. Transfer to proper container and complete the volume.

PACKING AND STORAGE
- In proper amber glass container, sheltered from light and at room temperature.

PARABEN PRESERVATIVE SOLUTION

APPLICATION
- Preservative solution.

FORMULA

Component	Quantity
methylparaben	6g
propylparaben	3g
propylene glycol	91 g

DIRECTIONS FOR THE PREPARATION

In proper container, under agitation, heat the components even completes solubilization.

PACKING AND STORAGE
- In proper opaque plastic container or Amber glass, sheltered from light and at room temperature.

CITRIC ACID SOLUTION 25% TO 50%

APPLICATION
- Acidifying solution.

FORMULA

Component	Quantity
citric acid	25 to 50 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Mix the components and agitate until complete dissolution, transfer to proper container and complete the volume.

PACKING AND STORAGE
- In proper amber glass container, sheltered from light and at room temperature.

HYDROCHLORIC ACID SOLUTION 0.1 M

APPLICATION
- Acidifying solution.

FORMULA

Component	Quantity
hydrochloric acid at 37% (p/p)	0.84 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Transfer 40 mL of water to 100 mL volumetric flask and slowly pour the hydrochloric acid. Agitate, let it cool, complete the volume and homogenize.

PACKING AND STORAGE
- In proper glass container and at room temperature.

HYDROCHLORIC ACID SOLUTION 2 M

APPLICATION
- Acidifying solution.

FORMULA

Component	Quantity
hydrochloric acid at 37% (p/p)	16.8 mL
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- Transfer 40 mL of water to 100 mL volumetric flask and slowly pour the hydrochloric acid. Agitate, let it cool, complete the volume and homogenize.

PACKING AND STORAGE
- In proper glass container and at room temperature.

SODIUM CHLORIDE SOLUTION AT 25%

APPLICATION

- As thickeners for shampoos and liquid soaps.

FORMULA

Component	Quantity
sodium chloride	25 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- In proper container dissolve the sodium chloride in water, complete the volume with the same solvent and homogenize.

PACKING AND STORAGE

- In proper amber glass container, sheltered from light and at room temperature.

SODIUM HYDROXIDE SOLUTION 0.1 M

APPLICATION
- Alkalinizing solution.

FORMULA

Component	Quantity
sodium hydroxide	0.4 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container dissolve the sodium hydroxide in water, complete the volume in volumetric flask and homogenize.

PACKING AND STORAGE
- In proper plastic container and at room temperature.

SODIUM HYDROXIDE SOLUTION 1 M

APPLICATION
- Alkalinizing solution.

FORMULA

Component	Quantity
sodium hydroxide	4g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container dissolve the sodium hydroxide in water, complete the volume in volumetric flask and homogenize.

PACKING AND STORAGE
- In proper plastic container and at room temperature.

SODIUM HYDROXIDE SOLUTION 10%

APPLICATION
- Alkalinizing solution.

FORMULA

Component	Quantity
sodium hydroxide	10 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION
- In proper container dissolves the sodium hydroxide in water, slowly, complete the volume in volumetric flask after cooling the solution to room temperature and homogenizing.

PACKING AND STORAGE
- In proper plastic container and at room temperature.

TRIETHANOLAMINE SOLUTION AT 50%

APPLICATION

- Emulsifying agent of O/A type emulsions and alkaline solution for adjusting pH.

FORMULA

Component	Quantity
triethanolamine	50 g
purified water qsp	100 mL

DIRECTIONS FOR THE PREPARATION

- In proper container mix the water and the triethanolamine, under agitation.

PACKING AND STORAGE

- In proper opaque plastic container or Amber glass, sheltered from light and at room temperature.

ATTACHMENT A – Alcoholometry.

Alcoholometry is the determination of the alcoholic degree of water and ethylic alcohol mixtures.

ETHYLIC ALCOHOL, ETHANOL
- Formula and molecular mass – C**2**H**6**O – 46.07.
- Specification – contains, at least, 96% (v/v).
- Description – limpid, colorless, volatile liquid with a characteristic odor.
- Physical characteristics – boiling point of approximately 78°C. Density from 0.803 to 0.808.
- Preservation – in well closed containers.
- Storage – protect from heat.
- Safety – toxic and flammable.

CENTESIMAL ALCOHOLOMETER
- The centesimal alcoholometer is intended to determinate the alcoholic degree or the actual power of the water and alcohol mixtures, indicating only the alcohol concentration in volume.
- The instrument that determines the alcoholic degree is called densimeter and it immediately indicates the volume of ethylic alcohol contained in 100 volumes of a mixture exclusively made of ethylic alcohol and water.
- The alcoholometer determinations are right only for this mixture, at 20°C temperature, in which the instrument was calibrated. If the temperature during the test is lower or higher than 20°C corrections on the alcoholometer indications in function of the temperature must be performed **(Table** B.l – **Actual power of Spirituous Liquids).**

GAY LUSSAC (°GL = % Volume)
- It is the unit that determines the quantity of ethylic alcohol, in millilitres, contained in 100 millilitres of a hydro-alcoholic mixture.
- INPM (% P = Alcohol Percentage in Weight or Alcoholic Degree INPM)
- INPM represents the quantity in grams of ethylic alcohol contained in 100 grams of a hydro-alcoholic mixture.

PROCEDURE FOR DETERMINATION OF THE ALCOHOLIC DEGREE
- Transfer the ethylic alcohol to be analyzed to a proper volumetric container;
- Let the ethylic alcohol in rest until full elimination of blisters;
- Determine the ethylic alcohol temperature with help of calibrated thermometer (apparent temperature);
- Immerse the rigorously clean and dry alcoholometer, previously drenched in the ethylic alcohol in test, in the liquid;
- The alcoholometer shall float freely, without touching the bottom of the container or adhere to the walls;
- When the alcoholometer reaches the balance position, check the rod projection point and read the number of the graduation in the bottom part of the meniscus. This reading determines the apparent alcoholic degree contained in the sample, in hundredths and in volume;
- Refer to **Table B.l – Actual power of the spirituous liquid**, **ATTACHMENT B**, to proceed to the correction of the reading obtained, in function of the temperature.

Observations
- The reading shall be done in all neuter alcohol batches acquired and in each disinfectant alcohol or diluted alcohol preparation;

- The alcoholic graduation of the ethylic alcohol shall be, at least, 94.7 °GL or 94.7% (v/v) at 15°C;
- The centesimal alcoholometer is calibrated at 20°C and in the Brazilian Pharmacopeia there is indication of the ethanolic titles at 15°C. Therefore it is necessary to proceed to the conversion through **Table B.l – Actual power of the spirituous liquids (ATTACHMENT B)**

ALCOHOLOMETRIC TABLE

- It is the table indicating the relation between centesimal alcoholometer degree, alcoholic mixture density and ponderal title.
- In the first column of **Table 1** the values for ethylic alcohol hundredths or centesimal degree in volume (°GL) are included; in the second column there are the values for density at 15°C of the water and ethylic alcohol mixture and in the third string the ponderal titles or absolute alcohol hundredths in weight are registered.

Table A.1 – Values for centesimal alcoholometer degree from 100 to 2, in volume (°GL), the respective density of the alcoholic mixture at 15°C and the ponderal title.

Centesimal degree, or absolute alcohol hundredths in volume	Density of the water and absolute alcohol mixture at 15°C	Ponderal title or absolute alcohol hundredths in weight	Centesimal degree, or absolute alcohol hundredths in volume	Density of the water and absolute alcohol mixture at 15°C	Ponderal title or absolute alcohol hundredths in weight
100C	0,79 433	100,000	50C	0,93 437	42,506
99C	0,79 926	98,389	49C	0,93 629	41,571
98C	0,80 390	96,833	48C	0,93 817	40,641
97C	0,80 829	95,324	47C	0,94 002	39,716
96C	0,81 246	93,859	46C	0,94 183	38,796
95C	0,81 641	92,430	45C	0,94 361	37,881
94C	0,82 020	91,035	44C	0,94 535	36,905
93C	0,82 385	89,666	43C	0,94 705	36,066
92C	0,82 738	88,325	42C	0,94 872	35,165
91C	0,83 081	87,004	41C	0,95 036	34,269
90C	0,83 415	85,703	40C	0,95 196	33,371
89C	0,83 741	84,421	39C	0,95 350	32,490
88C	0,84 060	83,156	38C	0,95 499	31,607
87C	0,84 372	81,907	37C	0,95 645	30,728
86C	0,84 678	80,673	36C	0,95 786	2:9,854
85C	0,84 979	79,452	35C	0,95 923	28,983
84C	0,85 275	78,245	34C	0,95 055	28,116
83C	0,85 567	71,050	33C	0,96 183	27,253
82C	0,85 854	75,867	32C	0,96 307	26,393
81C	0,86 137	74,696	31C	0,96 428	25,536
80C	0,86 416	73,535	30C	0,96 545	24,683
79C	0,86 692	72,385	29C	0,96 659	23,832
78C	0,86 965	71,244	28C	0,96 769	22,984
77C	0,87 234	70,114	27C	0,96 876	22,138
76C	0,87 500	68,993	26C	0,96 981	21,295
75C	0,87 763	67,881	25C	0,97 084	20,455
74C	0,88 022	66779	24C	0,97 185	19,616
73C	0,88 278	65,686	23C	0,97 286	18,719
72C	0,88 531	64,601	22C	0,97 387	17,944
71C	0,88 781	63,524	21C	0,97 487	17,111
70C	0,89 029	62,455	20C	0,97 587	16,279
69C	0,89 274	61,394	19C	0,97 688	15,449
68C	0,89 516	60,340	18C	0,97 790	14,621
67C	0,89 755	59,295	17C	0,97 892	13,794
66C	0,89 991	58,257	16C	0,97 995	12,969
65C	0,90 224	57,226	15C	0,98 100	12,145
64C	0,90 454	56,202	14C	0,98 206	11,324
63C	0,90 682	55,185	13C	0,98 314	10,503
62C	0,90 907	54,174	12C	0,98 424	9,684
61C	0,91 130	53,170	11C	0,98 537	8,867
60C	0,91 351	52,172	10C	0,98 652	8,042
59C	0,91 569	51,180	9C	0,98 710	7,237
58C	0,91 784	50,313	8C	0,98 891	6,426
57C	0,91 997	49,215	7C	0,99 016	5,615
56C	0,92 209	48,241	6C	0,99 145	4,813
55C	0,92 420	47,271	5C	0,99 271	4,000
54C	0,92 630	46,307	4C	0,99 413	3,196
53C	0,92 837	45,348	3C	0,99 552	2,394
52C	0,93 042	44,394	2C	0,99 695	1,593

ATTACHMENT B – Actual power of the spirituous liquids.

The actual power of an alcohol is the degree indicated by the centesimal alcoholometer at 15°C. The power is said apparent when the temperature is above or below 15°C. To convert apparent power into actual power, Actual power of the Spirituous Liquids **(Table B.l)** is used.

The first horizontal line of **Table B.l** indicates the apparent power, that is, the apparent centesimal alcohol volume marked by the alcoholometer.

The first vertical line from the left indicates the apparent temperature within 30°C and 10°C. The intersection of the vertical (apparent temperature) and horizontal (apparent alcoholic degree) lines will give us the actual power or the actual centesimal volume (°GL) of the alcohol in analysis.

Example

- Neuter alcohol with apparent temperature of 21°C and apparent alcoholic degree equal to 96 °GL will have an actual centesimal volume of 94.7 °GL at 15°C in accordance with **Table B.l.** This number indicates that the mixture in test contains 94.7 hundredths of absolute alcohol in volume and 5.3 volumes of water.

Table B.l — Actual Power of Spirituous Liquids.

Temp, ºC	56c	57c	58c	59c	60c	61c	62c	63c	64c	65c	66c	67c	68c	69c	70c
30º	50,6	51,6	52,6	53,6	54,7	55,7	56,7	57,8	58,8	59,9	60,9	61,9	63,0	64,0	65,0
29º	51,0	52,0	53,0	54,0	55,0	56,0	57,1	58,1	59,2	60,2	61,2	62,3	63,3	64,3	65,4
28º	51,3	52,3	53,3	54,4	55,4	56,4	57,5	58,5	59,5	60,6	61,6	62,6	63,7	64,7	65,7
27º	51,7	52,7	53,7	54,8	55,8	56,8	57,8	58,9	59,9	60,9	61,9	63,0	64,0	65,0	66,0
26º	52,0	53,0	54,0	55,1	56,1	57,1	58,1	59,2	60,2	61,3	62,3	63,3	64,3	65,3	66,4
25º	52,4	53,4	54,4	55,5	56,5	57,5	58,5	59,5	60,6	61,6	62,6	63,7	64,7	65,7	66,7
24º	52,8	53,8	54,8	55,8	56,8	57,8	58,9	59,9	61,0	62,0	63,0	64,0	65,0	66,0	67,1
23º	53,1	54,1	55,1	56,1	57,1	58,1	59,2	60,2	61,3	62,3	63,3	64,3	65,4	66,4	67,4
22º	53,5	54,5	55,5	56,5	57,5	58,5	59,5	60,6	61,6	62,7	63,7	64,7	65,7	66,7	67,8
21º	53,9	54,9	55,9	56,9	57,9	58,9	59,9	61,0	62,0	63,0	64,0	65,0	66,0	67,0	68,1
20º	54,2	55,2	56,2	57,2	58,2	59,2	60,3	61,3	62,3	63,3	64,3	65,4	66,4	67,4	68,4
19º	54,6	55,6	56,6	57,6	58,6	59,6	60,6	61,6	62,7	63,7	64,7	65,7	66,7	67,7	68,7
18º	54,9	55,9	56,9	57,9	58,9	59,9	61,0	62,0	63,0	64,0	65,0	66,0	67,0	68,0	69,0
17º	55,3	56,3	57,3	58,3	59,3	60,3	61,3	62,2	63,3	64,3	65,3	66,3	67,3	68,3	69,3
16º	55,6	56,6	57,6	58,6	59,6	60,6	61,7	62,7	63,7	64,7	65,7	66,7	67,7	68,7	69,7
15º	56,0	57,0	58,0	59,0	60,0	61,0	62,0	63,0	64,0	65,0	66,0	67,0	68,0	69,0	70,0
14º	56,3	57,3	58,3	59,3	60,3	61,3	62,3	63,3	64,3	65,3	66,3	67,3	68,3	69,3	70,3
13º	56,7	57,7	58,7	59,7	60,7	61,7	62,7	63,7	64,7	65,7	66,7	67,7	68,7	69,6	70,6
12º	57,0	58,0	59,0	60,0	61,0	62,0	63,0	64,0	65,0	66,0	67,0	68,0	69,0	70,0	71,0
11º	57,4	58,4	59,4	60,4	61,4	62,4	63,4	64,4	65,4	66,4	67,3	68,3	69,3	70,3	71,3
10º	57,8	58,8	59,7	60,7	61,7	62,7	63,7	64,7	65,7	66,7	67,6	68,6	69,6	70,6	71,6
	71c	72c	73c	74c	75c	76c	77c	78c	79c	80c	81c	82c	83c	84c	85c
30º	66,1	67,1	68,2	69,2	70,3	71,3	72,3	73,3	74,4	75,4	76,4	77,5	78,6	79,6	80,6
29º	66,4	67,4	68,5	69,5	70,6	71,6	72,6	73,7	74,7	75,7	76,7	77,8	78,9	79,9	80,9
28º	66,8	67,8	68,8	69,9	70,9	71,9	73,0	74,0	75,0	76,0	77,1	78,1	79,2	80,2	81,2
27º	67,1	68,1	69,2	70,2	71,2	72,2	73,3	74,3	75,3	76,3	77,4	78,4	79,5	80,5	81,5
26º	67,4	68,4	69,5	70,5	71,5	72,5	73,6	74,6	75,6	76,7	77,7	78,7	79,8	80,8	81,8
25º	67,8	68,8	69,8	70,8	71,8	72,8	73,9	74,9	76,0	77,0	78,0	79,0	80,1	81,1	82,1
24º	68,1	69,1	70,1	71,2	72,2	73,2	74,2	75,5	76,6	77,6	78,6	79,6	80,7	81,7	82,7
23º	68,4	69,4	70,5	71,5	72,5	73,5	74,5	75,2	76,3	77,3	78,3	79,3	80,4	81,4	81,4
22º	68,8	69,8	70,8	71,8	72,8	73,8	74,8	75,9	76,9	77,9	78,9	79,9	81,0	82,0	83,0
21º	69,1	70,1	71,1	72,1	73,1	74,1	75,2	76,2	77,2	78,2	79,2	80,2	81,3	82,3	83,3
20º	69,4	70,4	71,4	72,4	73,4	74,4	75,5	76,5	77,5	78,5	79,5	80,5	81,6	82,6	83,6
19º	69,7	70,7	71,7	72,7	73,7	74,7	75,8	76,8	77,8	78,8	79,8	80,8	81,9	82,9	83,9
18º	70,0	71,0	72,0	73,0	74,0	75,1	76,1	77,1	78,1	79,1	80,1	81,1	82,1	83,1	84,1
17º	70,3	71,3	72,3	73,3	74,3	75,4	76,4	77,4	78,4	79,4	80,4	81,4	82,4	83,4	84,4
16º	70,7	71,7	72,7	73,7	74,7	75,7	76,7	77,7	78,7	79,7	80,7	81,7	82,7	83,7	84,7
15º	71,0	72,0	73,0	74,0	75,0	76,0	77,0	78,0	79,0	80,0	81,0	82,0	83,0	84,0	85
14º	71,3	72,3	73,3	74,3	75,3	76,3	77,3	78,3	79,3	80,3	81,3	82,3	83,3	84,3	85,3
13º	71,6	72,6	73,6	74,6	75,6	76,6	77,6	78,6	79,6	80,6	81,6	82,6	83,6	84,6	85,5
12º	72,0	72,9	73,9	74,9	75,9	76,9	77,9	78,9	79,9	80,9	81,9	82,9	83,9	84,8	85,8
11º	72,3	73,2	74,2	75,2	76,2	77,2	78,2	79,2	80,2	81,2	82,2	83,1	84,1	85,1	86,1
10º	72,6	73,5	74,5	75,5	76,5	77,5	78,5	79,5	80,5	81,5	82,4	83,4	84,4	85,4	86,4
	86c	87c	88c	89c	90c	91c	92c	93c	94c	95c	96c	97c	98c	99c	100c
30º	81,7	82,7	83,8	84,9	86	87,1	88,2	89,3	90,4	91,5	92,7	93,8	95	96,1	97,7
29º	82	83	84,1	85,1	86,2	87,3	88,4	89,5	90,6	91,7	92,9	94,1	95,2	96,3	97,5
28º	82,3	83,3	84,4	85,4	86,5	87,6	88,7	89,8	90,9	92	93,2	94,3	95,4	96,5	97,7
27º	82,6	83,6	84,7	85,7	86,7	87,9	89	90,1	91,1	92,2	93,4	94,5	95,6	96,7	97,9
26º	82,9	83,9	84,9	86	87,1	88,2	89,2	90,3	91,4	92,5	93,6	94,7	95,8	96,9	98,1
25º	83,2	84,3	85,2	86,3	87,4	88,4	89,5	90,6	91,6	92,7	93,8	94,9	96	97,1	98,2
24º	83,5	84,5	85,5	86,5	87,6	88,7	89,7	90,8	91,9	93	94,1	95,2	96,2	97,3	98,4
23º	83,8	84,8	85,8	86,8	87,9	89	90	91,1	92,1	93,2	94,3	95,4	96,5	97,5	98,6
22º	84	85	86,1	87,1	88,2	89,2	90,2	91,3	92,4	93,4	94,5	95,6	96,7	97,7	98,8
21º	84,3	85,3	86,4	87,4	88,4	89,5	90,5	91,6	92,6	93,7	94,7	95,8	96,9	97,9	99
20º	84,6	85,6	86,6	87,7	88,7	89,7	90,8	91,8	92,9	93,9	95	96	97,1	98,1	99,1
19º	84,9	85,9	86,9	87,9	88,9	90	91,1	92,1	93,1	94,1	95,2	96,2	97,3	98,3	99,3
18º	85,2	86,2	87,2	88,2	89,2	90,2	91,3	92,3	93,3	94,3	95,4	96,4	97,4	98,5	99,5
17º	85,4	86,4	87,4	88,4	89,5	90,5	91,5	92,6	93,6	94,6	95,6	96,6	97,6	98,7	99,7
16º	85,7	86,7	87,7	88,7	89,7	90,8	91,8	92,8	93,8	94,8	95,8	96,7	97,8	98,8	99,8
15º	86	57	88	89	90	91	92	93	94	95	96	97	98	99	100
14º	86,3	87,3	88,2	89,2	90,2	91,2	92,2	93,2	94,2	95,2	96,2	97,2	98,2	99,2	
13º	86,5	87,5	88,5	89,5	90,5	91,5	92,5	93,5	94,4	95,4	96,4	97,4	98,4	99,3	
12º	86,8	87,8	88,7	89,7	90,7	91,7	92,7	93,7	94,7	95,6	96,6	97,6	98,5	99,5	
11º	87,1	88	89	90	91	92	92,9	93,9	94,9	95,8	96,8	97,8	98,7	99,7	
10º	87,4	88,3	89,3	90,2	91,2	92,2	93,2	94,2	95,1	95	97	98	98,9	99,9	

ATTACHMENT C – Relation of active pharmaceutical inputs DCB and substances used in preparations included in the Brazilian Pharmacopeia National Form, 2nd edition.

Table C.l – Active principles and adjuvants quoted in the Brazilian Pharmacopeia National Form, 2nd edition.

Name of the substance	N. DCB	CAS	Other names
acetanilide	00050	103-84-4	
aluminum acetate	00054	139-12-8	
acetylcysteine	00067	616-91-1	
acetone	00078	67-64-1	
acetic acid	00086	64-19-7	glacial acetic acid;
ascorbic acid	00104	50-81-7	vitamin C
benzoic acid	00115	65-85-0	
boric acid	00116	10043-35-3	
citric acid	00134	77-92-9	citric acid anhydrous
mono-hydrated citric acid	09852	5949-29-1	monohydrated citric acid; citric acidmonohydrate
hydrochloric acid	00150	7647-01-0	
stearic acid	00182	57-11-4	
folic acid	00194		
lactic acid	00274	50-21-5	
salicylic acid	00340	69-72-7	
tartaric acid	00350	87-69-4	
water for injection	09320		sterile water
purified water	00445	7732-18-5	water
ultra-purified water	09880	7732-18-5	
allantoin	00453	97-59-6	
mineral tar	00465	[Ref. 2]	black coal tar, coal-tar
benzyl alcohol	00471	100-51-6	
cetearyl alcohol		8038-54-8	
cetyl alcohol	00472	36653-82-4	
cetostearyl alcohol	00473	67762-27-0	
lanolin alcohol		8027-33-6	
stearyl alcohol	00474	112-92-5	
ethylic alcohol	00475	64-17-5	ethylic alcohol 96 °GL, ethanol
isopropyl alcohol	00476	67-63-0	isopropanol 99,8%
starch	00657	9005-25-8	
aspartame	00900	22839-47-0	
benzoin		119-53-9	hydroxyphenylacetophenone; benzoin; *a*-hydroxybenzyl phenyl ketone
bentonite	01123	1302-78-9	
benzyl benzoate	01155	120-51-4	
sodium benzoate	01157	532-32-1	
sodium bicarbonate	01249	144-55-8	
sodium borate	00117	1330-43-4	
butyl-hydroxytoluene	01627	128-37-0	butyl hydroxytoluene; BHT
butylparaben	01628	94-26-8	butyl paraben
calamine	01646	8011-96-9	
camphor	01677	76-22-2	2-bomanone; camphor
carbomer 980	09941	139637-85-7	
calcium carbonate	01748	471-34-1	
carmellose	01775	9000-11-7	carboxymethylcellulose

Name of the substance	N. DCB	CAS	Other names
carmellose calcium	01776	9050-04-8	carmellose; carboxymethylcellulose calcium; carmellose calcium; calcium carboxymethyl cellulose
carmellose sodium	01777	9004-32-4	carboxymethyl amide sodium; carboxymethylcellulose sodium; carmellose sodium; sodium carboxymethyl starch
microcrystalline cellulose	09371	9004-34-6	
yellow bee wax	09855	8012-89-3	
white bee wax	09854	8012-89-3	
ethoxylated cetostearyl alcohol wax, sorbitan stearate and ethoxylated sorbitan monooleate		8036-11-1	emulgade wax; mixture of fatty alcohols with non-ionic emulsioning agent; eumulgadewax
sodium cetearyl sulfate		59186-41-3	
cetete	01943	68439-49-6	ethoxylated cetostearyl alcohol
ketoconazole	01956	65277-42-1	
cetomacrogol 1000	01959	9004-95-9; 68439-49-6	polyethylene glycol; eumulgin b2; cetostearyl alcohol 20 moles eo; cremophor a25; ethoxylated alcohol c(16- 18); polyethylene glycol ac 617
ketoprofen	01960	22071-15-4	
sodium cyclamate	01995	139-05-9	
cyclomethicone	02023	69430-24-6	
potassium citrate	02181	866-84-2	
mono-hydrated potassium citrate	09373	6100-05-6	potassium citrate
sodium citrate	02182	68-04-2	
di-hydrated sodium citrate	02183	6132-04-3	
clioquinol	02235	130-26-7	vioform
ammonium chloride	02362	12125-02-9	
benzalkonium chloride	02364	8001-54-5	benzalkonium chloride
di-hydrated calcium chloride	02370	10035-04-8	di-hydrated calcium chloride
cetyl pyridine chloride	02376	123-03-5	
hexa-hydrated magnesium chloride	02400	7791-18-6	
potassium chloride	02415	7447-40-7	
sodium chloride	02421	7647-14-5	
lidocaine hydrochloride	05314	73-78-9	
chlorobetanidine		51-13-8	ammonium behenyl trimethyl sulfate;
cocamidopropyl betaine	02543	61789-40-4	
cholesterol	02571	57-88-5	
dextro-alpha-tocopherol	08716	59-02-9	tocopherol
diethanolamine		8033-73-6	DEA; DEA cetyl phosphate;
cocamide diethanolamine	09697	68603-42-9	coconut fatty acid diethanolamine
dimethicone	03064	9006-65-9	
dimethiconol		31692-79-2	
silicon dioxide	09428	7631-86-9	fumed silica, pyrogenic silica, colloidal silicon dioxide
titanium dioxide	03108	13463-67-7	
dipropylene glycol	03130	110-98-5	
disodium edetate	00168	139-33-3	EDTA;
sulfur	09432	7704-34-9	sulfur
ergocalciferol	03477	50-14-6	calciferol, vitamin D
macrogol stearate 2000	09330	9004-99-3	polyethylene glycol monostearate; polyethylene glycol stearate; peg stearate
macrogol stearate 400	05475	9004-99-3	

Name of the substance	N. DCB	CAS	Other names
magnesium stearate	03577	557-04-0	
octyl stearate	03578	22047-49-0	
sodium stearate	03579	822-16-2	
sorbitan stearate	03580	1338-41-6	sorbitan monostearate; span 60;
zinc stearate	10665	557-05-1	zinc stearate
ethylic ether	03663	60-29-7	ethyl ether
ethylparaben	03694	120-47-8	ethylparaben
carbolic acid	03968	108-95-2	phenol
phenoxy ethanol	03991	122-99-6	
monobasic potassium phosphate	00206	7778-77-0	dihydrogen potassium phosphate
jelly	04413	9000-70-8	
sodium glycerophosphate	04468	1334-74-3	
glycerol	04469	56-81-5	
glucose	04485	50-99-7	
aluminum hydroxide	04694	21645-51-2	
calcium hydroxide	04696	1305-62-0	
magnesium hydroxide	04697	1309-42-8	
potassium hydroxide	04698	1310-58-3	
hydroxypropyl methyl cellulose phthalate		9050-31-1	
hyetellose	04723	9004-62-0	hydroxy ethyl cellulose
sodium hypochlorite	04731	7681-52-9	
sodium hypophosphite	04733	7681-53-0	
hyprolose	4735		hydroxypropyl cellulose
imidazolidinyl urea	04827	39236-46-9	
potassium iodide	04965	7681-11-0	
iodine	04983	7553-56-2	metal iodine; resublimated iodine
povidone iodine	04990	25655-41-8	
isoalkanes C13-14		246538-79-4	isopar m ,c1 3-14 isoparaffm
ammonium lactate	05138	52003-58-4	
anhydrous lanolin	05161	8006-54-0	lanolin anhydrous; lanolin
sodium lauryl ether sulfate	05177	1335-72-4	
lauryl polyglucose		167817-58-5	
sodium lauryl sulfate	05178	151-41-7	sodium lauryl sulfate
lauromacrogol 400	05183	9002-92-0	ethoxylated lauryl alcohol 7 oe
Liquor Carbonis Detergens			LCD *(liquor carbonis detergens)*
menthol	05643	89-78-1	menthol
methylglucose distearate		119831-19-5	ethoxylated metylglucose 20 oe
methylparaben	05809	99-76-3	methylparaben
methylparaben sodic	09516	5026-62-0	sodium methylparaben
isopropyl myristate	05994	110-27-0	isopropyl myristate
glyceryl monostearate	06068	31566-31-1	cutina kd 16; glyceryl stearate se
neomycin	06282	1404-04-2	
silver nitrate	06427	7761-88-8	
polyethylene glycol oelate		9007-68-5	peg-6 oleate
sorbitan oelate	06586	1338-43-8	
triethanolamine oelate		2717-15-9	triethanolamine oleate
avocado oil		8024-32-6	
castor oil	09505	8001-79-4	
calcium oxide	06726	1305-78-8	
zinc oxide	06730	1314-13-2	
retinol palmitate	07695	79-81-2	vitamin A (palmitate)
papain	06821	9001-73-4	

Name of the substance	N. DCB	CAS	Other names
potassium permanganate	07000	7722-64-7	
benzoyl peroxide	07003	94-36-0	
hydrogen peroxide	07004	7722-84-1	peroxide
white petrolatum	09104	308069-07-0	solid vaseline
liquid petrolatum	09388	8012-95-1	liquid vaseline; mineral oil
pyroxylin	07215	9004-70-0	elastic collodion
polyacrylamide	07254	9003-05-8	
polysorbate 20	07272	9005-64-5	
polysorbate 80	07275	9005-65-6	
propylene glycol	07455	57-55-6	
propylparaben	07461	94-13-3	sodium propylparaben
resorcinol	07690	108-46-3	resorcin
retinol	07693	68-26-8	vitamin A
sodium saccharin	07851	128-44-9	saccharine sodic anhydrous; saccharin sodium
sucrose	07854	57-50-1	sucrose
sorbitan sesquioleate	07965	8007-43-0	
aluminum and magnesium silicate	07993	12511-31-8	
sorbitol	08061	50-70-4	
silver sulfadiazine	08118	22199-08-2	
cupric sulfate	08158	7758-98-7	copper sulfate II;
zinc sulfate	08174	7733-02-0	
hepta-hydrated zinc sulfate	09533	7446-20-0	
mono-hydrated zinc sulfate	08175	7446-19-7	hydrated zinc sulfate; monohydrate zinc sulfate
hepta-hydrated ferrous sulfate	08177	7782-63-0	
potassium sulfrde	08181	1312-73-8	
selenium sulfrde	08182	7488-56-4	
sodium sulfrde	09843	1313-82-2	
talcum	08264	14807-96-6	talc
tannin	09688	1401-55-4	tannic acid
tiabendazol	08493	148-79-8	tiabendazole
thiosulfate sodium	08650	7772-98-7	sodium hyposulfrte
triclosan	08881	3380-34-5	
urea	01711	57-13-6	
silver vitellinate	09183	9015-51-4	argirol

Index

C

D

E

F

G

M

N

O

P

R

S

T

U

V

W

Z