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| **ASSESSMENT OF ELIGIBILITY FOR THE OPTIMIZED ANALYSIS PROCEDURE OF CADIFA APPLICATIONS (ANNEX III of IN 289/2024)** |

This Form must be filled and signed by the responsible official, legal representative, or other authorized official of the active pharmaceutical ingredient dossier (DIFA) Holder.

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| **GENERAL INFORMATION** | |
| API: |  |
| Equivalent Foreign Regulatory Authority (EFRA): |  |
| CEP or CPQ number: |  |

| **Criteria** | **Checklist** |
| --- | --- |
| **General** | |
| Was the submitted regulatory documentation issued by an equivalent EFRA designated by Anvisa? | **No**. The application is not eligible for the temporary optimized analysis procedure.  **Not Applicable**. The regulatory documentation is not mandatory for this EFRA (i.e. EDQM).  Name of the EFRA:  Date of approval:  **Yes.** Inform the name of the EFRA and the date it was approved by Anvisa.  Name of the EFRA:  Date of approval:  If applicable, present a letter authorizing the exchange of regulatory documentation by the EFRA with Anvisa. |
| Does the EFRA’s regulatory documentation meet the following general application criteria?  I – The regulatory documentation refers to an assessment for a definitive regularization of the API (that is, it is not a provisional or conditional approval).  II – The regulatory documentation is complete, in Portuguese, English, or Spanish, and it was not edited or censored. | **Yes.** The application is eligible for the temporary optimized analysis procedure.  **Not Applicable**. The regulatory documentation is not mandatory for this EFRA (i.e. EDQM).  Name of the EFRA:  Date of approval:  **No**. The application is not eligible for the temporary optimized analysis procedure. |
| Was the application for regularization of the API object of this petition denied, rejected, refused, or withdrawn, or is it commercialized with a court order in any country? | **No.** The application is eligible for the temporary optimized analysis procedure.  **Yes**. Inform the country and details on the case:  Subject to assessment by Anvisa of the eligibility for the temporary optimized analysis procedure. |
| Was there a withdrawal of application for marketing authorization for the medicinal product or biological product in any of the EFRAs designated by Anvisa? | **No**. The application is eligible for the temporary optimized analysis procedure.  **Yes**. Inform the EFRA and attach clarifications. Subject to assessment by Anvisa of the eligibility for the temporary optimized analysis procedure.  Country: |
| **Active Pharmaceutical Ingredient Dossier (DIFA)** | |
| Is the DIFA approved by an EFRA? | **No.** The application is not eligible for the temporary optimized analysis procedure.  **Yes.** Inform the name of the EFRA and the date of approval by the EFRA. In addition, inform the Version of the DIFA submitted to the EFRA.  Name of the EFRA:  Date of approval:  Version of the DIFA submitted to the EFRA: |
| Is there a copy attached of:  I – the latest approved version of a valid Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP), issued by EDQM, completed by its holder in the name of the medicinal product marketing authorization/ post-marketing authorization applicant; or  II – the latest approved version of a valid Confirmation of API prequalification (CPQ), issued by the WHO, completed by its holder in the name of the medicinal product marketing authorization/ post-marketing authorization applicant; or  III – equivalent document confirming the approval by an EFRA. | **Yes.** Inform the document version and its respective issuer.  Document version:  Issuer:  **No**. The application is not eligible for the temporary optimized analysis procedure.  **Not applicable.** The API temporary optimized analysis procedure shall not use such documents. |
| Are the quality information of the DIFA submitted to Anvisa (part 3.2.S) identical to the quality information of the DIFA currently approved by the EFRA? | **Yes.** The application is eligible for the temporary optimized analysis procedure.  **No.** In case this option is checked, indicate on the list below the sections with distinct information, if any. For unchecked sections, present Comparative Table (Annex 8 of the [CADIFA’s Application Form](https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/insumos/formularios-e-modelos/formulario-de-peticao-cadifa.docx/view)), for assessment of the eligibility for the temporary optimized analysis procedure. Subject to assessment by Anvisa of the eligibility for the temporary optimized analysis procedure. If eligible, additional assessment may be carried out.  General Information (3.2.S.1)  Nomenclature (3.2.S.1.1)  Structure (3.2.S.1.2)  General Properties (3.2.S.1.3)  Manufacture (3.2.S.2)  Manufacturer(s) (3.2.S.2.1)  Description of the Manufacturing Process and In-process Controls (3.2.S.2.2)  Control of Raw Materials (3.2.S.2.3)  Control of Critical Stages and Intermediates (3.2.S.2.4)  Process Validation (3.2.S.2.5)  Manufacturing Process Development (3.2.S.2.6)  Characterization (3.2.S.3)  Structure Elucidation and Other Characteristics (3.2.S.3.1)  Impurities (3.2.S.3.2)  API Quality Control (3.2.S.4)  Specification (3.2.S.4.1)  Analytical Methods (3.2.S.4.2)  Validation of Analytical Methods (3.2.S.4.3)  Analysis of Batches (3.2.S.4.4)  Justification for Specification (3.2.S.4.5)  Materials and Reference Chemical Substances (3.2.S.5)  Packaging (3.2.S.6)  Stability (3.2.S.7)  Stability Summary (3.2.S.7.1)  Protocols and Post-submission Commitments (3.2.S.7.2)  Stability Data and Reports (3.2.S.7.3) |
| **Conclusion** | |
| In any of the questions in this checklist, was an answer checked indicating the application is not eligible for the temporary optimized analysis procedure? | **Yes.** The process is not eligible for the temporary optimized analysis procedure.  **No.** Answer the next question |
| In any of the questions in this checklist, was an answer checked informing that an additional assessment may be carried out? | **Yes.** Eligibility assessment depends on analysis of the documents attached to this checklist.  **No.** The process is eligible for the temporary optimized analysis procedure. |

I am aware that Anvisa may, in accordance with the technical assessment of the information provided, adopt the ordinary analysis.

I hereby declare that the API approved by the EFRA has the same quality level as the API in this application, including the following:

1. Manufacturing process (including parameters and in-process controls);

2. Manufacturing sites;

3. Specification of raw materials, including the specification of start materials;

4. Suppliers and route for obtention of start materials;

5. Specification and analytical methods of intermediate products;

6. Specification and analytical methods of APIs;

7. API solid phase properties;

8. Packaging;

9. Stability data;

10. Information level (open part) available to the applicants;

11. Any other parameters that may have a potential impact on the API quality.

I hereby declare that the DIFA meets the international quality guidelines adopted by Anvisa, particularly the following:

I – ICH Q1A – Stability Testing of New Drug Substances and Products;

II – ICH Q1B – Stability Testing: Photostability Testing of New Drug Substances and Products;

III – ICH Q1D – Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products;

IV – ICH Q1E – Evaluation for Stability Data;

V – ICH Q2(R1) – Validation of Analytical Procedures;

VI – ICH Q3A(R2) – Impurities in New Drug Substances;

VII – ICH Q3C(R6) – Impurities: Guideline for Residual Solvents;

VIII – ICH Q3D(R1) – Guideline for Elemental Impurities;

IX – ICH Q6A – Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances;

X – ICH Q11 – Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/ Biological Entities); and

XI – ICH M7(R1) – Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.

I hereby declare that the Applicant is a legitimate party of the application with the EFRA and, consequently, with Anvisa.

By completing and signing this form, I authorize Anvisa, if necessary, to contact the EFRA and exchange the information relating to my application.

Date: \_\_/\_\_/\_\_\_\_

Name:

Signature (DIFA Contact): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:

Signature (DIFA Holder Responsible Official/Legal Representative): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_