Application for New Version of an Active Pharmaceutical Ingredient Master File (APIMF)

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

# Application details

|  |  |
| --- | --- |
| WHO APIMF Number |  |
| API name (International Nonproprietary Name) |  |
| Therapeutic area |  |
| Applicant company |  |
| Original APIMF open part version number |  |
| Original APIMF restricted part version number |  |
| Proposed APIMF open part version number |  |
| Proposed APIMF restricted part version number |  |
| Amendment application number | *For WHO use only* |

# Amendment type: Please tick one

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Amendment 1a | New APIMF version (editorial changes only) | [ ]  |
| Amendment 1b | New APIMF version (as requested by PQT) | [ ]  |

# Applicant details

Please note that the contact listed in this form will be the primary contact for email and mail communication for this specific application.

|  |  |
| --- | --- |
| Contact person responsible for this application | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

# Summary of editorial changes announced in this application only

*If editorial changes have been made please complete this section..*

Summary of proposed changes:

|  |  |  |  |
| --- | --- | --- | --- |
| Affected CTD subsection | Pre-change details | Post-change details | Justification for Change |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

**Note:** For APIMFs that have an agreed-upon API Quality Information Summary (QIS), the API-QIS should be revised and submitted with any revised sections highlighted.

# History of Changes Document

Please record here all differences between the current and proposed versions of the APIMF. Please include all editorial changes announced in this application, together with any Annual notification (AAN), immediate notification (AIN), minor (Amin) or major (Amaj) changes previously accepted on the current version of the APIMF. For such changes please list the WHO amendment application number associated with the change.

|  |  |  |  |
| --- | --- | --- | --- |
| Affected CTD subsection | Details in Original APIMF version | Details in proposed APIMF version | WHO amendment reference number (if applicable) |
|  |  |  |  |
|  |  |  |  |
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**Note:** For APIMFs that have an agreed upon API-QIS, the API-QIS should be revised and submitted with any revised sections highlighted.

## Documentation checklist

The following documents have been submitted together with this application form:

|  |  |
| --- | --- |
| *Note: All documents must be provided for this application to be valid.* |  |
| A completed revised APIMF application form (Word)andA signed and completed revised APIMF application form (PDF) | *[ ]  Yes**[ ]  Yes* |
| Open and restricted sections of the APIMF revised in fulfillment of the requirements under section 3.2.S of the WHO *Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part.* (Refer to APIMF documentation requirements on website of the Prequalification Team: medicines website.) | *[ ]  Yes**[ ]  not applicable* |
| API-Quality Information Summary (API-QIS) For APIMFs that have an agreed upon API-QIS, the QIS should be revised and submitted. All revised details should be highlighted. To assist with rapid identification of changes, all revisions should be made in red font and obsolete information struck through.If there are no alterations required to the API-QIS then it does not need to be provided.If there is no agreed API-QIS then this document can be omitted. | *[ ]  Yes**[ ]  No agreed QIS**[ ]  No change to QIS* |

# Declarations

## Declaration – only for applications for amendment 1a. (*delete section 6.1 if not applicable*)

I declare that:

[ ]  No changes have been made to any detail of the currently accepted APIMF details and the API continues to be supplied in accordance with these details.

[ ]  No changes have been made to the originally agreed-upon API-QIS and therefore a copy of the currently agreed API-QIS has not been included in this submission.

[ ]  The information submitted is true and correct.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

## Declaration (*Please check all declarations that apply*)

I declare that:

[ ]  For each change, all conditions, as stipulated in the *Guidance on Amendments to an APIMF submitted in support of a prequalified product (FPP) or prequalified active pharmaceutical ingredient (API)* for the change requested, are fulfilled.

[ ]  No changes have been made to the revised APIMF subsections other than those stated in the summary of changes document, or

 [ ]  Not applicable, no changes have been made to APIMF subsections.

[ ]  The API-QIS has been updated to reflect each change notified in this application, or

[ ]  No changes have been made to the currently agreed-upon API-QIS and therefore a copy of the currently agreed API-QIS has not been included in this submission.

[ ]  The information submitted is true and correct.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_