Application for

Active Pharmaceutical Ingredient Master File (APIMF) Procedure

Please complete each section of this application form electronically.

# Application details

|  |  |
| --- | --- |
| Active pharmaceutical ingredient  *International Nonproprietary Name, including salts/counter ion, solvated state* |  |
| **APIMF manufacturer’s internal API code (if applicable)** |  |
| **APIMF version number**  **Applicant’s part version number and date (yyyy-mm-dd)**  **Restricted part version number and date (yyyy-mm-dd)** | Open part:  Restricted part: |
| **Associated WHO finished pharmaceutical product (FPP) application** | FPP applicant company name:  FPP description and strength:  WHO code for FPP (if known at the time of submission): |
| **APIMF holder company**  **Company name**  **Corporate address**  **Phone**  **Fax**  **Email** |  |
| **Agent's name (if applicable)[[1]](#footnote-1)** |  |
| **Contact person responsible for this application** | Title (*Ms, Mr Dr*):  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** |  |

|  |  |
| --- | --- |
| API manufacturing site(s) address. The steps undertaken at the site:  *Repeat section, as needed* |  |
| **Manufacturer’s name** |  |
| **Unit** |  |
| **Building/PO Box number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Phone** |  |
| **Fax** |  |
| **Email** |  |
| **GPS (WGS 84) of site (place to be specified if not main entrance) expressed to 1/10th of a second accuracy** |  |
| **API intermediate manufacturing site(s) address**  **The steps undertaken at the site:**  ***Repeat, as needed*** |  |
| **Manufacturer’s name** |  |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Phone** |  |
| **Fax** |  |
| **Email** |  |
| **GPS (WGS 84) of site (place to be specified if not main entrance) expressed to 1/10th of a second accuracy** |  |
| **Sterility status** | Sterile  Non-sterile |
| **Quality standard claimed for the API**  *e.g. pharmacopoeial (state which), or in-house* |  |
| **Elemental impurities approach based on ICHQ3D** | Option 1: No risk assessment summary is provided  Option 2. Risk assessment summary is provided |
| **Nitrosamines Risk- Assessment** | A nitrosamine Risk Assessment Report is provided. |
| **Other relevant Information**  *e.g. polymorphic form, manufacturing route identifier (e.g. process I), grade (e.g. particle size)* |  |

# Previous acceptance of APIMF

If the APIMF document (current version) is lodged with other medicines regulatory agencies please list each separately in the table below.

|  |  |  |
| --- | --- | --- |
| Agency |  |  |
| **Date of submission** |  |  |
| **Agency’s code for APIMF (if applicable)** |  |  |
| Is this active substance master file (ASMF)/Drug master file (DMF) identical to the ASMF/DMF filed in the above mentioned country or jurisdiction? |  |  |
| If not, ensure that the difference are described in the ASMF/DMF. |  |  |

# Submission declarations

I, the undersigned, on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*company name*),

Declare that the information contained in this application form and in the submitted documents is accurate.

Confirm that information in the application form and the submitted documents does not contain intentionally misleading information, nor has information been withheld that might affect the assessment of compliance with WHO requirements.

Confirm that the submitted APIMF meets the documentation requirements specified on the website of the Prequalification Team: medicines.

Confirm that the sites of manufacture specified in the submitted APIMF are operating in compliance with ICHQ7 GMP.[[2]](#footnote-2)

Confirm that the API manufacturer has undertaken review of their API intermediate suppliers to determine that they are operating in compliance with ICHQ7 GMP.2

Agree to permit WHO inspectors to undertake an on-site inspection at any time, either announced or unannounced, to confirm that the API manufacturing site; and or any associated intermediate, testing or contract manufacturing site, is manufacturing in compliance with WHO GMP.

I confirm that changes to the contact person for this application will be communicated to PQTm in a timely manner.

I confirm that a risk assessment for the presence of nitrosamines has been conducted for this API and that the risk assessment outcome has been integrated into the relevant CTD sections and the risk assessment report appended to the APIMF. In case a risk of presence of nitrosamines has been identified, I confirm confirmatory testing has been undertaken. In case the presence of nitrosamines has been confirmed, risk mitigation measures have been undertaken.

Name:

Signature: Date:

Position within company:

# Application Checklist

To ensure a complete application, please use this checklist to verify that all required information has been prepared for submission.

|  |  |
| --- | --- |
| Item | Submitted  *(Yes / Not applicable)* |
| 1. A cover letter (paper copy) |  |
| 1. A clearly labelled CD or DVD containing: |  |
| * the cover letter (Word or text-selectable PDF) |  |
| * the APIMF application form (Word)   AND   * the signed APIMF application form (PDF) |  |
| * the signed Letter of Access (PDF) |  |
| * the APIMF correctly formatted (Module 3, see documentation requirements section) |  |
| * the Module 2 (see documentation requirements section) |  |

The cover letter and CD/DVD should be sent to:

World Health Organization  
WHO Prequalification Team: medicines  
MHP/RPQ/PQT Room 613  
20 Avenue Appia  
1211 Geneva 27  
Switzerland

Or

Via a secure link to an online document repository.  The link should be sent in an email  to the following email address: [APIassessment@who.int](mailto:APIassessment@who.int)  The Subject line of the emails should clearly indicate the application and the specific medicine procedure referred to. The date of receipt will be the date the file is successfully downloaded. If you have any questions regarding this please contact Dr Matthias Stahl, [stahlm@who.int](mailto:stahlm@who.int)

1. If an agent is making this application on behalf of the manufacturer then a relevant letter of authorization from the API manufacturer should be attached to this application form. [↑](#footnote-ref-1)
2. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. See: [www.ich.org/](http://www.ich.org/). [↑](#footnote-ref-2)