Application for

Active Pharmaceutical Ingredient Master File (APIMF) Procedure

Please complete each section of this application form electronically.

# Application details

|  |  |
| --- | --- |
| Application subtype | Standard / Abridged |
| Abridged application reference Agency |  |
| 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): |
| Applicant Organisation Name |  |
| Applicant Organisation’s ePQS Account UID1 | If the Account does not yet exist in ePQS, please download a New Account form from the ePQS Portal and append it to this application. |
| Applicant Contact’s Name |  |
| Applicant Contact’s ePQS Contact UID1 | If this Contact does not yet exist in ePQS please download and a New Contact form from tee PQS Portal and append it to this application. |
| Agent's name (if applicable)[[1]](#footnote-2) |  |

# Quality Details & Sites of Manufacture

**Quality Details**

|  |  |
| --- | --- |
| Sterility status | Sterile  Non-sterile |
| 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. |
|  |  |

**Sites of Manufacture**

*Extend table as necessary for each site of API or Intermediate manufacture*

|  |  |
| --- | --- |
| Site activity | API Manufacture/Intermediate manufacture |
| **Manufacturing Site Company Name** |  |
| **Manufacturing Site: City & Country** |  |
| **Manufacturer’s Organisation’s ePQS Account UID1** | If the Account does not yet exist in ePQS, please download a New Account form from the ePQS Portal and append it to this application. |
|  |  |
| **Site activity** | API Manufacture/Intermediate manufacture |
| **Manufacturing Site Company Name** |  |
| **Manufacturing Site: City & Country** |  |
| **Manufacturer’s Organisation’s ePQS Account UID1** | If the Account does not yet exist in ePQS, please download a New Account form from the ePQS Portal and append it to this application. |
|  |  |
| **Site activity** | API Manufacture/Intermediate manufacture |
| **Manufacturing Site Company Name** |  |
| **Manufacturing Site: City & Country** |  |
| **Manufacturer’s Organisation’s ePQS Account UID1** | If the Account does not yet exist in ePQS, please download a New Account form from the ePQS Portal and append it to this application. |
|  |  |
| **Site activity** | API Manufacture/Intermediate manufacture |
| **Manufacturing Site Company Name** |  |
| **Manufacturing Site: City & Country** |  |
| **Manufacturer’s Organisation’s ePQS Account UID1** | If the Account does not yet exist in ePQS, please download a New Account form from the ePQS Portal and append it to this application. |
|  |  |

# Previous acceptance of APIMF

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

|  |  |  |
| --- | --- | --- |
| Agency |  |  |
| **Date of submission** |  |  |
| **Status of APIMF with Agency** |  |  |
| **Agency’s code for APIMF (if applicable)** |  |  |
| **Is the APIMF filed in the above mentioned country or jurisdiction identical to the APIMF submitted?** |  |  |
| **If not, ensure that the differences 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 WHO Prequalification Unit/Medicines Team (PQT/MED).

Confirm that the sites of manufacture specified in the submitted APIMF are operating in compliance with ICHQ7 GMP.[[2]](#footnote-3)

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.

Confirm that changes to the contact person for this application will be communicated to PQT/MED in a timely manner.

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 that confirmatory testing has been undertaken. In case the presence of nitrosamines has been confirmed, risk mitigation measures have been undertaken.

Confirm that any changes to the APIMF details and circumstances pertaining to this API will be notified to PQT/MED in a timely manner.

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 |  |
| 1. A signed APIMF application form (PDF) |  |
| 1. A signed Letter of Access (PDF) |  |
| 1. The APIMF correctly formatted |  |
| 1. Completed forms for each referenced new Site/organization not already in the ePQS database |  |

Please file this application via the ePQS Portal (https://who.my.site.com/ePQS/s/login).

Further information regarding the portal and its use can be located on the PQT website at this address: https://extranet.who.int/prequal/epqs/epqs-portal.

1. *The UID can be located via the ePQS Portal at the top of either the Account or Contact record.*

   *2* 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-2)
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-3)