Application for Prequalification of an

Active Pharmaceutical Ingredient (API)

Please complete each section of this application form electronically. Please ensure an electronic and printed version of this application form accompanies your submission for API prequalification.

# 1. Application details

|  |  |
| --- | --- |
| Application subtype | Standard / Abridged / Conversion / Parallel |
| Abridged application reference Agency |  |
| Active pharmaceutical ingredient  *International Nonproprietary Name, including salts/counter ion, solvated state* |  |
| API master file (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: |
| 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)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. |
|  |  |

# 3. 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.** |  |  |

# 4. Evidence of compliance with Good Manufacturing Practices (GMP)

## 4.1 Inspection declarations

(Please select one option only and delete the remaining options.)

**Option 1**

To establish that the indicated site(s) of API manufacture is/are operating in compliance with GMP, \_\_\_\_\_\_\_\_\_\_\_\_ (*company name*) requests that WHO arranges to inspect this/these facility(ies).

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

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

**Option 2**

To demonstrate that the indicated site(s) of API manufacture is/are operating in compliance with GMP, evidence of this compliance has been included with this application. Nonetheless, \_\_\_\_\_\_\_\_\_\_\_\_ (*company name*) acknowledges that WHO may need to inspect this/these facility(ies).

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

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

## 5.2 A summary of the evidence of compliance with GMP submitted with application

(If supporting documentation has been provided, please summarize briefly below.)

|  |  |  |  |
| --- | --- | --- | --- |
| Type of document | Issuing authority | Date of issue | Remark |
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# 6. Declaration

I, the undersigned, on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (company name) declare that the information contained in this application form and in the submitted documents is accurate. I 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.

I confirm that the submitted APIMF meets the documentation requirements specified on PQT/MED website.

Confirm that the sites of manufacturing specified in the submitted APIMF are operating in compliance with ICHQ7 GMP.[[1]](#footnote-1)

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

I confirm that PQT/MED may 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 standards.

I confirm that I understand the obligations and conditions of the API Prequalification procedure as outlined in Annex 4, WHO Technical Report Series, No. 953, 2009.

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:

# 6. Application Checklist

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

|  |  |
| --- | --- |
| Item | *Submitted*  *(Yes / Not applicable)* |
| 1. A cover letter |  |
| 1. A signed API Prequalification application form (PDF) |  |
| 1. The APIMF correctly formatted |  |
| 1. Evidence of compliance with GMP, or a request for inspection by WHO for each manufacturing site (Word or text-selectable PDF) |  |
| 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/MED website at this address: https://extranet.who.int/prequal/epqs/epqs-portal

1. 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-1)