Application for Active Pharmaceutical Ingredient

Master File (APIMF)

eCTD Baseline Amendment

Please complete each section of this application form and provide as a signed text selectable Pdf file.

# Application details

|  |  |
| --- | --- |
| 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.* |
|  |  |
| Application Subtype | eCTD Baseline |
| WHO APIMF Number(s) |  |
| API name (INN) |  |
| Applicant’s Document number |  |
|  |  |

# Amendment Change type: 1c (Amin)

## Conditions and documents

|  |  |
| --- | --- |
| The APIMF is already accepted by PQT and there are no on-going applications associated with this APIMF. No changes are made, whether editorial or otherwise, to the details of the currently accepted APIMF. | YES |

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

I declare that:

The submitted APIMF is compiled in compliance with WHO PQT’s eCTD documentation requirements.

There are no changes to accepted APIMF information.

There are no changes to the currently agreed upon API-QIS.

The information submitted is true and correct.

I understand that if unauthorized changes have been submitted this may result in suspension of the APIMF.

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

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

# 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. The APIMF correctly formatted |  |
| 1. A copy of the API-QIS |  |

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.