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.