Application for Active Pharmaceutical Ingredient

Master File (APIMF) Amendment

Please complete each section of this application form electronically as a Word Document and as a scanned signed Pdf file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

# Application details

|  |  |
| --- | --- |
| WHO APIMF Number |  |
| **API name (INN)** |  |
| **Therapeutic Area** |  |
| **Applicant Company** |  |
| **Applicant’s document number** |  |
| **Amendment application number** | For WHO use only |

# Amendment type:

|  |  |  |
| --- | --- | --- |
| Amendment # | Title | Change category |
| *e.g. 9b* | *More than 10-fold increase in batch size* | *Amin* |
|  |  |  |
|  |  |  |
|  |  |  |

## Amendment application overall change category: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

(being the most severe categories of the amendments applied for).

# Applicant details

|  |  |
| --- | --- |
| Contact person responsible for this application | Title:  First name:  Family name: |
| Contact person's job title |  |
| **Contact person's postal address** | |
| Unit |  |
| Building/PO Box number |  |
| Road/Street |  |
| Plant/Zone |  |
| Village/suburb |  |
| Town/City |  |
| District and Mandal |  |
| Province/State |  |
| Postal code |  |
| Country |  |
| Contact person's email address |  |
| Contact person's phone number |  |

# Summary of amendment change

## For Amendment Types AIN, Amin and Amaj only

* Reproduce section 4 and provide separate summaries for each proposed change.
* The specifics of the change should be described in the table below, but a separate document should be provided discussing and justifying the change in depth.
* If there are no AIN, Amin or Amaj changes please delete this section.

### Amendment title and number

*e.g. 9b – Change in batch size – more than 10-fold increase*

### Conditions and documents

All conditions specified for this category in the amendment guidance has been met  YES

All documents as specified for this category in the amendment guidance has been provided  YES

The supporting document specified for this category are located in: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Summary of current and proposed details:

|  |  |
| --- | --- |
| Current details | Proposed details |
| *Batch size Unit A – 300 kg API output*  *Batch size Unit B – 350 kg API output* | *Batch size Unit A – 300 kg API output*  *Batch size Unit B – 600 kg API output* |

### Justification for change:

### Date of implementation (*for Immediate Notifications only*):

# Summary of amendment change

## Amendment Summary – For Annual Amendments only (AANs)

*If there are no AAN changes please delete this section 4.2*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Amendment category | Pre-change details | Post-change details | Justification for Change | Date of implementation |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Note:**

1. **For APIMFs that have an agreed upon API-QIS, the API-QIS should be revised and submitted with any revised sections highlighted.**
2. **When an Annual notification involves a change in specifications, the signed and dated version of the revised specification should be submitted. In other cases the documentation indicated for AAN’s should be available on request or at the time of inspection, but do not need to be submitted.**

# Summary of Changes Document – (*for replacement CTD subsections provided with application, if applicable*)

Please list the revised sections provided with the amendment.

|  |  |  |  |
| --- | --- | --- | --- |
| Affected CTD subsection | Details in current CTD subsection version | Details in proposed CTD subsection | Justification for Change |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Note:**

1. **For APIMFs that have an agreed upon API-QIS, the API-QIS should be revised and submitted with any revised sections highlighted.**

# Documentation checklist

The following documents have been submitted together with this application form:

|  |  |
| --- | --- |
| Note: All documents must be provided for this application to be valid. |  |
| A completed APIMF amendment form (Word)  and  A signed and completed APIMF amendment form (PDF) | Yes  Yes |
| An amendment summary document introducing, explaining, discussing the proposed changes in (Word or text selectable PDF). | Yes |
| All supporting documents as specified in the *Guidance on Amendments to an APIMF submitted in support of a prequalified product (FPP) or prequalified active pharmaceutical ingredient (API)*. (Word or text selectable PDF). These documents should be presented in a folder entitled “supporting documents”.  For Annual amendment notifications documents discussing and supporting the implemented changes should not be provided, but should be available on request or at the time of inspection, | Yes |
| Replacement subsections for the APIMF resulting from the change in fulfillment of requirements under section 3.2.S of the WHO *Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part*. (refer to APIMF documentation requirements on PQT - Medicines website).  When an Annual notification involves a change in specifications, the signed and dated version of the revised specification should be submitted. In other cases updated sub-sections do not need to be submitted. | Yes |
| API-Quality Information Summary (API-QIS)  For APIMFs that have an agreed upon API-QIS, the QIS should be revised and submitted. All revised details should be highlighted. To assist with rapid identification of changes, all revisions should be made in red font and obsolete information struck through.  If there are no alterations required to the API-QIS then it does not need to be provided.  If there is no agreed API-QIS then this document can be omitted. | Yes  No agreed QIS  No change to QIS |
|  |  |

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

I declare that:

For each change all conditions and documents as stipulated in the *Guidance on Amendments to an APIMF submitted in support of a prequalified product (FPP) or prequalified active pharmaceutical ingredient (API)* for the change requested are fulfilled.

That any sites of manufacture requested in this amendment are operating in compliance with ICHQ7 GMP.[[1]](#footnote-1)

That the API manufacturer of any API intermediate suppliers requested in this amendment, has undertaken a review of the requested intermediate site(s) to confirm they are operating in compliance with ICHQ7 GMP.1

That any changes proposed in this application have been assessed with regard to the risk for the presence of nitrosamines and, unless specifically highlighted in this application, there is no change to this risk profile.

There are no changes being made other than those applied for in this submission.

There are no changes to the revised APIMF subsections other than those stated in the summary of changes document, or

not applicable, there are no changes to APIMF subsections.

The API-QIS has been updated to reflect each change notified in this application, or

There are no changes to the currently agreed upon API-QIS and therefore a copy of the currently agreed API-QIS has not been included in this submission.

The information submitted is true and correct.

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

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

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)