**Confidential: This section should not be disclosed to the applicant.**

**APIMF Restricted Part (Closed Part) Assessment Report Template**

**<Product Name (INN and brand name)>**

**< Active Ingredient >**

**<Applicant Name>**

**<Dossier Reference Number>**

|  |  |
| --- | --- |
| **Assessor:** |  |
| **Rapporteur:** |  |
| **Date of start of the assessment:** |  |
| **Date of report:** |  |

**Note:** This Assessment Report solely concerns the ASMF. It should however always be read in conjunction with the assessment report of the applicant’s part of the ASMF and the assessment report(s) of the Finished drug product for which it is associated with.

# **1. General Information**

A. An APIMF in CTD-format has been provided by *Enter the ASMF holder name* for the *Enter the name of the drug substance*

B. Applicant’s Part version: Click or tap here to enter text.

C. Restricted Part version: Click or tap here to enter text.

# **2. Assessment of Active Pharmaceutical Ingredient (API) Section**

## **3.2.S.2 Manufacture**

### **3.2.S.2.2 Description of manufacturing process and process controls (detailed information)**

Flow diagram of the synthetic process(es):

Remark: Click or tap here to enter text.

Summary and discussion on the detailed manufacturing process and process controls:

Click or tap here to enter text.

### **3.2.S.2.3 Control of materials**

| Step/Starting material | Test(s)/ Method(s) | Acceptance criteria |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

Remark: Click or tap here to enter text.

### **3.2.S.2.4 Control of critical steps and intermediates**

| Step/Material | Test(s)/ Method(s) | Acceptance criteria |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

Remark: Click or tap here to enter text.

### **3.2.S.2.5 Process validation and/or evaluation**

Summary of process validation and/or evaluation studies (e.g., for aseptic processing and sterilisation):

Click or tap here to enter text.

### **3.2.S.2.6 Manufacturing process development**

Discussion on significant changes (if any) made to the manufacturing process and/or manufacturing site of the drug substance used in the bioavailability, clinical, scale up and production batches:

Click or tap here to enter text.

## **3.2.S.3 Characterization**

### **3.2.S.3.2 Impurities**

Drug-related impurities (e.g., starting materials, by-products, intermediates, chiral impurities, degradation products):

| Chemical name/Descriptor | Origin | Maximum  Observed Levels | LOQ  (if applicable) | Acceptance Criteria  (if applicable) |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

(Add rows if required)

Applicable thresholds for drug-related impurities as per ICH Q3A guideline:

|  |  |
| --- | --- |
| Maximum daily dose (mg/day): |  |
| Identification Threshold: |  |
| Qualification Threshold: |  |

Process-related impurities (e.g., residual solvents, reagents, elemental impurities):

| Process-related impurity | ICH Q3C/Q3D Class and Concentration Limit | Step Used | Maximum Observed Levels | LOQ  (if applicable) | Acceptance Criteria  (if applicable) |
| --- | --- | --- | --- | --- | --- |
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(Add rows if required)

Impurities for relevant batches (e.g. comparative bioavailability or biowaiver, stability batches)

| Impurity (API related and process related) | Acceptance criteria | Results (include batch number and use) | | |
| --- | --- | --- | --- | --- |
|  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

(Add rows if required)

Discussion of potential mutagenic impurities and control strategy applied as per ICH M7 (including a summary of risk assessment for the potential presence of Nitrosamine impurities taking into consideration the manufacturing process and controls for the drug substance and the potential for degradation):

Click or tap here to enter text.

## **3.2.S.4 Control of the Drug Substance**

### **3.2.S.4.5 Justification of specification**

Discussion on the justification and acceptability of the proposed specification and the claimed standard (e.g., including the tests that are omitted or not routinely performed and the controls for impurities, polymorphs, particle size distribution, as applicable):

Remark: Click or tap here to enter text.