**Full API Assessment Report Template**

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

**< Active Ingredient >**

**<Applicant Name>**

**<Dossier Reference Number>**

|  |  |  |
| --- | --- | --- |
| **Lead assessor** |  | |
| **Other assessors** | Name | Assessor’s responsibility |
|  |  |
|  |  |
|  |  |
| **Rapporteur** |  | |
| **Co-rapporteur** |  | |
| **Application received on (date)** |  | |
| **Application number** |  | |
| **Type of review** |  | |
| **Start of the procedure** |  | |
| **End of the procedure** |  | |
| **Total regulatory time (days)** |  | |
| **Date of report** |  | |

# Executive Summary

|  |  |
| --- | --- |
| **Finished Pharmaceutical Product (FPP)** | |
| Name |  |
| Strength |  |
| Dosage form |  |
| Category for distribution |  |
| Therapeutic class or indication |  |
| Mode of administration |  |
| Shelf life |  |
| **Active Pharmaceutical Ingredient/s (API/s)** (Add more rows if there are more than one API) | |
| International non-proprietary name (INN) |  |
| CAS registry number |  |
| **Applicant** | |
| Applicant name and address |  |
| Local authorized agent information |  |

**MODULE 1**

**1.1 Legal Documents**

1. Presence of the GMP certificate for all manufacturing sites

Yes  No

2. Presence of manufacturing license

Yes  No

3. Presence of Certificate of Pharmaceutical Product (CPP)

Yes  No

4. Presence of letter of authorization or agency agreement

Yes  No

5. Presence of Local Authorized Agent information

Yes  No

**Remark:** Click or tap here to enter text.

**1.2 Registration Status in other Countries**

1. Has the product been registered in other countries?

Yes  No

2. In how many countries has the product been registered? Click or tap here to enter text.

3. List any five countries where the product has been registered.

Click or tap here to enter text.

4. Has the product been rejected, suspended, deferred or withdrawn from any market?

Yes  No

If yes, provide reason(s): Click or tap here to enter text.

**1.3 Product Labeling and Prescribing Information**

1. Presence of product labelling samples for

1.1 Tertiary Packaging (Unit carton)  Yes  No

1.2 Secondary Packaging (Inner label)  Yes  No

1.3 Primary packaging (Blister/strips/vial/ampoule)  Yes  No

2. Presence of the below information in the primary (immediate) packaging of the product

Brand name where appropriate

International non-proprietary name/generic name

Pharmaceutical form, quantity of active ingredient per dosage unit

Total contents of container

Date of manufacture

Date of expiry

Batch number

Specific storage conditions

Name and full location address of manufacturer

**Remark:** Click or tap here to enter text.

3. Presence of Summary Product Characteristics (SmPC) sample

Yes  No

4. Presence of Patient Information Leaflet (PIL) sample

Yes  No  Not Applicable

**1.4 Samples**

1. Presence of product sample  Yes  No

2. Number of samples received Click or tap here to enter text.

**Remark:** Click or tap here to enter text.

3. Sample received on Click or tap to enter a date.

4. Samples had at least 60% of their shelf life remaining at the time of reception

Yes  No  Not Applicable

5. Presence of Certificate of Analysis (COA) of the sample from the manufacturer

Yes  No  Not Applicable

**Remark:** Click or tap here to enter text.

6. Sample sent to quality control laboratory on Click or tap to enter a date.

7. Quality Control results received on Click or tap to enter a date.

8. Results of product quality control tests

Product passed  Product failed

**Remark:** Click or tap here to enter text.

**1.5 Inspection reports**

1. Presence of inspection reports

Yes  No  Not Applicable

**Remark:** Click or tap here to enter text.

**MODULE 3**

# 1. Assessment of Active Pharmaceutical Ingredient (API) Section

# 3.2.S.1 General information

## 3.2.S.1.1 Nomenclature

|  |  |
| --- | --- |
| International non-proprietary name (INN): |  |
| Compendial name: |  |
| Chemical name: |  |
| Other non-proprietary names: |  |
| Chemical Abstracts Service (CAS) Number: |  |

## 3.2.S.1.2 Structure

|  |  |
| --- | --- |
| Structural formula (including relative and absolute stereochemistry, salt form and solvate moieties): |  |
| Molecular formula: |  |
| Molecular mass: |  |

## 3.2.S.1.3 General Properties

|  |  |
| --- | --- |
| Physical description |  |
| Solubility over the physiological pH range (e.g., pH 1.2-6.8): |  |
| Solubilities in relevant solvents: |  |
| Hygroscopicity: |  |
| Polymorphism: |  |
| pH/Pka values |  |
| Partition coefficient |  |
| Melting point |  |
| Other *(refractive index, optical rotation, Molar absorptivity, etc.)* |  |

# 3.2.S.2 Manufacture

## 3.2.S.2.1 Manufacturer(s)

Name, address (including unit/plot/block), and responsibility (e.g. fabrication, packaging, labelling, testing, storage, sterilization) of each manufacturing facility(ies) (including manufacturer(s) of the intermediates, if sourced from a third party):

| Name and Address | Responsibility | APIMF/CEP number (if applicable) |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

## 3.2.S.2.2 Description of manufacturing process and process controls

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.3.1 Elucidation of structure and other characteristics

List of studies performed to elucidate the structure (e.g., IR, UV, NMR, MS, elemental analysis) including a brief summary of results and conclusion:

Click or tap here to enter text.

Discussion relating to the characterisation of the drug substance (e.g., potential isomerism and identification of stereochemistry, polymorphism, particle size distribution):

Click or tap here to enter text.

## 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) |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

(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.4.1 Specification

API specifications *of the FPP manufacturer*:

|  |  |  |
| --- | --- | --- |
| Standard (e.g. Ph.Int., Ph.Eur., BP, USP, House) | |  |
| Specification reference number and version | |  |
| Test | Acceptance criteria | Analytical procedure (Type/Source/Version) |
| Description |  |  |
| Identification |  |  |
| Impurities |  |  |
| Assay |  |  |

(Add rows if required)

**Remark**

Click or tap here to enter text.

## 3.2.S.4.2 Analytical Procedures and 3.2.S.4.3 Validation of Analytical Procedures

(Add columns if required)

|  |  |
| --- | --- |
| **Analytical Procedure** | Insert Method Description or “N/A” |
| Method Type: |  |
| Routine System Suitability Tests and Acceptance criteria |  |
| Specificity |  |
| Linearity |  |
| Accuracy |  |
| Precision: |  |
| - Repeatability |  |
| - Intermediate precision |  |
| Range (specify) |  |
| Detection limit (specify) |  |
| Quantitation limit (specify) |  |
| Robustness |  |
| Solution stability |  |

+ indicates that the parameter is acceptably tested and validated

- indicates that the parameter is not tested

? indicates that questions remain before the parameter is judged to be acceptable

**Remark**

Click or tap here to enter text.

## 3.2.S.4.4 Batch analyses

Summary of batches:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Batch Number | Batch Size | Manufacturing Site | Manufacturing Date | Use (e.g. comparative bioavailability or biowaiver, stability) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

(Add rows if required)

Summary of batch analyses results and conformance to proposed specifications:

(Add columns if required)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | Acceptance Criteria |  | Results |  |
| <batch x> | <batch y> | <batch z> |
| Description |  |  |  |  |
| Identification |  |  |  |  |
| Impurities |  |  |  |  |
| Assay |  |  |  |  |

(Add rows if required)

**Remark**

Click or tap here to enter text.

## 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.

## 3.2.S.5 Reference Standards or Materials

Summarize source of reference standards or reference materials (e.g., in-house, USP, BP, Ph.Eur., JP) for drug substance and impurity(ies):

Click or tap here to enter text.

Discuss characterization and evaluation of non-official (e.g. not from an officially recognized pharmacopoeia) primary reference standards or reference materials

Click or tap here to enter text.

Summarize description of the process controls of the secondary reference standard (comparative certificate of analysis and IR spectra against primary standard)

Click or tap here to enter text.

# 3.2.S.6 Container Closure System

Description of the container closure system(s) for the shipment and storage of the API (including the identity of materials of construction of each primary packaging component and a brief summary of the specifications):

|  |  |  |
| --- | --- | --- |
| Packaging component | Materials of construction | Specifications (list parameters e.g. identification (IR)) |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

Discussion of the suitability of the container closure system (e.g., choice of materials, protection from moisture and light, compatibility of the materials of construction with the drug substance and in view of the API stability results):

Click or tap here to enter text.

# 3.2.S.7 Stability

*Check according to WHO guideline stability testing of active pharmaceutical ingredients and finished pharmaceutical products (WHO Technical Report Series, No953 Annex 2)*

## 3.2.S.7.1 Stability summary and conclusions

|  |  |  |
| --- | --- | --- |
| **Container Closure System** | **Storage Conditions** | **Retest period** |
|  |  |  |

Summary of accelerated and long-term testing parameters (e.g. studies conducted):

|  |  |  |  |
| --- | --- | --- | --- |
| Type of test  (Accelerated/ Intermediate/Long term) | Storage condition  (◦C, % RH) | Batch number | Completed (and proposed) testing intervals |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Summary of the stability results observed for the above accelerated, intermediate (if applicable) and long-term studies:

|  |  |  |  |
| --- | --- | --- | --- |
| Test | Acceptance criteria | Results | Remark |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

(Add rows if required)

Summary of stress testing studies (e.g., heat, humidity, oxidation, photolysis, acid/base) conducted:

Click or tap here to enter text.

\* Is the proposed re-test period and storage condition supported by the stability data?

Yes  No

## 3.2.S.7.2 Post-approval stability protocol and stability commitment

Summary of post-approval stability protocol and stability commitment:

Click or tap here to enter text.

## 3.2.S.7.3 Stability data

Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (e.g. analytical procedures used only for stability studies):

Click or tap here to enter text.

**Remark**

Click or tap here to enter text.

*Note: For multiple APIs, this section can be filled for each API.*

# 2. Assessment of Finished Pharmaceutical Product (FPP) Section

# 3.2.P.1 Description and Composition of the FPP

Summary of the description of the dosage form:

Click or tap here to enter text.

Composition of the dosage form i.e. list of all components of the FPP and their amounts on a per unit basis and percentage basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

|  |  |  |  |
| --- | --- | --- | --- |
| Component and quality standard (and grade, if applicable) | Function | Quant. per unit | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total |  |  |  |

Type of container and closure used for the dosage form and accompanying reconstitution diluent, if applicable:

Click or tap here to enter text.

# 3.2.P.2 Pharmaceutical Development

\* Availability of the definition of the quality target product profile (QTPP).

Yes  No

**Remark**

Click or tap here to enter text.

Availability of the discussion of the selection criteria for the manufacturing process and the control strategy required to manufacture commercial lots meeting the QTPP in consistent manner.

**Remark**

Click or tap here to enter text.

## 3.2.P.2.1 Components of the FPP

### 3.2.P.2.1.1 Drug Substance

Discussion of the relevant physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the drug substance that can influence the performance of the FPP:

Click or tap here to enter text.

Discussion on the compatibility of the drug substance with excipients listed in 3.2.P.1:

Click or tap here to enter text.

Discussion on the compatibility of APIs with each other for fixed-dose combinations:

Click or tap here to enter text.

### 3.2.P.2.1.2 Excipients

Discussion on the critical functionality and acceptability of the choice of excipients listed in 2.3.P.1 (e.g. their concentrations, their characteristics that can influence the FPP performance):

Click or tap here to enter text.

## 3.2.P.2.2 Finished Pharmaceutical Product

### 3.2.P.2.2.1 Formulation Development

Summary and discussion on the development of the FPP (e.g. route of administration, usage, optimization of the formulation, etc.):

Click or tap here to enter text.

### 3.2.P.2.2.2 Overages

Justification of overages in the formulation(s) described in 2.3.P.1 including the step(s) where the loss occurs, and reasons for the loss:

Click or tap here to enter text.

### 3.2.P.2.2.3 Physicochemical and Biological Properties

Discussion of the parameters relevant to the performance of the FPP (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties):

Click or tap here to enter text.

## 3.2.P.2.3 Manufacturing Process Development

Summary and discussion of the development of the manufacturing process of the FPP (e.g. optimization of the process, selection of the method of sterilization):

Click or tap here to enter text.

Summary and discussion of the differences in the manufacturing process(es) for the batches used in the comparative bioavailability or biowaiver studies and the process described in 2.3.P.3.3:

Click or tap here to enter text.

Summary of the discussion of the results from comparative in vitro studies (e.g., dissolution) or comparative in vivo studies (e.g., bioequivalence), when appropriate.

Click or tap here to enter text.

## 3.2.P.2.4 Container Closure System

Brief description of the container closure system:

Click or tap here to enter text.

Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP):

Click or tap here to enter text.

For a device accompanying a multi-dose container, a summary of the study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume):

Click or tap here to enter text.

## 3.2.P.2.5 Microbiological Attributes

Brief summary and discussion of the microbiological control strategy and microbial testing (including integrity of the container system in case of sterile products, amount of antimicrobial preservative included if any):

Click or tap here to enter text.

## 3.2.P.2.6 Compatibility

Discussion of any compatibility studies (e.g., to support in-use periods with reconstitution diluents or dosage devices, co-administered FPPs):

Click or tap here to enter text.

# 3.2.P.3 Manufacture

## 3.2.P.3.1 Manufacturer(s)

Name, address and responsibility (e.g. fabrication, packaging, labelling, testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

|  |  |
| --- | --- |
| Name and address  (include block(s)/unit(s)) | Responsibility |
|  |  |
|  |  |
|  |  |
|  |  |

## 3.2.P.3.2 Batch Formula

List of all components of the FPP to be used in the manufacturing process and their amounts on a per batch basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

|  |  |  |  |
| --- | --- | --- | --- |
| Component and quality standard (and grade, if applicable) | Quant. per batch  (e.g. kg/batch) | Quant. per batch  (e.g. kg/batch) | Quant. per batch  (e.g. kg/batch) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total |  |  |  |

## 3.2.P.3.3 Description of Manufacturing Process and Process Controls

Summary of the manufacturing process and process controls (e.g. flow diagrams, narrative description of the manufacturing process, and justification of reprocessing materials):

Click or tap here to enter text.

## 3.2.P.3.4 Controls of Critical Steps and Intermediates

Summary and discussion of controls performed at the critical steps and intermediates, and data used to support controls:

|  |  |
| --- | --- |
| Step  (e.g. granulation, compression, coating) | Controls |
|  |  |
|  |  |

(Add rows if required)

## 3.2.P.3.5 Process Validation and/or Evaluation

Summary of the process validation and/or evaluation studies conducted (including product quality review(s) where relevant) and/or a summary of the proposed process validation protocol for the critical steps or critical assays used in the manufacturing process (e.g. protocol number, parameters, results):

Click or tap here to enter text.

# 3.2.P.4 Control of Excipients

## 3.2.P.4.1 Specifications

Remarks on the specifications provided from the applicant or the FPP manufacturer for all excipients, including those that may not be added to every batch, those that do not appear in the final FPP, and any others used in the manufacturing process.

Click or tap here to enter text.

## 3.2.P.4.2 Analytical Procedures

Remark on the procedures used for testing the excipients, where appropriate.

Click or tap here to enter text.

## 3.2.P.4.3 Validation of Analytical Procedures

Remark on the analytical validation information, including experimental data, for the analytical procedures used for testing the excipients, where appropriate.

Click or tap here to enter text.

## 3.2.P.4.4 Justification of Specifications

Remark on the justification for the proposed excipient specification, where appropriate.

Click or tap here to enter text.

## 3.2.P.4.5 Excipients of Human or Animal Origin

Remark on the excipients of human or animal origin, availability of information regarding adventitious agents.

Click or tap here to enter text.

\* Availability of a letter of attestation for excipients of animal origin.

Yes  No

**Remark**

Click or tap here to enter text.

## 3.2.P.4.6 Novel Excipients

Remark on the details of manufacture, characterization, and controls, with cross references to supporting safety data according to the API and/or FPP format.

Click or tap here to enter text.

# 3.2.P.5 Control of FPP

## 3.2.P.5.1 Specification(s) for the FPP

|  |  |  |
| --- | --- | --- |
| Standard (e.g. Ph.Int., Ph.Eur., BP, USP, House) | |  |
| Specification reference number and version | |  |
| Test | Acceptance criteria | Analytical procedure (Type/Source/Version) |
| Description |  |  |
| Identification |  |  |
| Impurities |  |  |
| Assay |  |  |

(Add rows if required)

**Remark**

Click or tap here to enter text.

## 3.2.P.5.2 Analytical Procedures and 3.2.P.5.3 Validation of Analytical Procedures

(Add columns if required)

|  |  |
| --- | --- |
| **Analytical Procedure** | Insert Method Description or “N/A” |
| Method Type: |  |
| Routine System Suitability Tests and Acceptance criteria |  |
| Specificity |  |
| Linearity |  |
| Accuracy |  |
| Precision: |  |
| - Repeatability |  |
| - Intermediate precision |  |
| Range (specify) |  |
| Detection limit (specify) |  |
| Quantitation limit (specify) |  |
| Robustness |  |
| Solution stability |  |

+ indicates that the parameter is acceptably tested and validated

- indicates that the parameter is not tested

? indicates that questions remain before the parameter is judged to be acceptable

**Remark**

Click or tap here to enter text.

## 3.2.P.5.4 Batch Analyses

Summary of batches

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Batch Number | Batch Size | Manufacturing Site | Manufacturing Date | Use (e.g. comparative bioavailability or biowaiver, stability) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

(Add rows if required)

Summary of batch analyses results and conformance to proposed specifications:

(Add columns if required)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | Acceptance Criteria |  | Results |  |
| <batch x> | <batch y> | <batch z> |
| Description |  |  |  |  |
| Identification |  |  |  |  |
| Impurities |  |  |  |  |
| Assay |  |  |  |  |

(Add rows if required)

**Remark**

Click or tap here to enter text.

## 3.2.P.5.5 Characterization of Impurities

Identification of potential and actual impurities in the FPP and not present in the drug substance:

|  |  |
| --- | --- |
| Degradation product (chemical name or descriptor) | Origin |
|  |  |
|  |  |

(Add rows if required)

|  |  |
| --- | --- |
| Process-related impurity (compound name) | Step used in the FPP manufacturing process |
|  |  |
|  |  |

(Add rows if required)

Discussion of potential mutagenic impurities (including a summary of risk assessment for the potential presence of Nitrosamine impurities taking into consideration the manufacturing process and controls for the FPP, the excipients, the container closure system and the potential for degradation):

Click or tap here to enter text.

Discussion of the ICH Q3D risk assessment:

Click or tap here to enter text.

## 3.2.P.5.6 Justification of Specification

Discussion on the justification of the FPP specification(s) and acceptability of the proposed specification and the claimed standard

Click or tap here to enter text.

# 3.2.P.6 Reference Standards

Summarize source of reference standards or reference materials (e.g., in-house, USP, BP, Ph.Eur., JP) for drug substance and impurity(ies):

Click or tap here to enter text.

Discuss characterization and evaluation of non-official (e.g. not from an officially recognized pharmacopoeia) primary reference standards or reference materials

Click or tap here to enter text.

Summarize description of the process controls of the secondary reference standard (comparative certificate of analysis and IR spectra against primary standard)

Click or tap here to enter text.

# 3.2.P.7 Container Closure System

Summary of the container closure system(s) for the storage of the FPP, including unit count or fill size, container size or volume:

Click or tap here to enter text.

Summary of the specifications for each primary and functional secondary (e.g. foil pouches) packaging components:

|  |  |  |
| --- | --- | --- |
| Packaging component | Materials of construction | Specifications (list parameters e.g. identification (IR)) |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

Click or tap here to enter text.

# 3.2.P.8 Stability

## 3.2.P.8.1 Stability Summary and Conclusions

Summary of batches placed on stability:

|  |  |  |
| --- | --- | --- |
| Batch information (number of batches of each strength, batch size) | Container closure | Duration of study and storage conditions |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

(Add rows if required)

Summary of stress testing studies (e.g. photostability studies, cyclic studies, freeze-thaw studies) conducted:

Click or tap here to enter text.

Summary of accelerated and long-term testing parameters (e.g. studies conducted):

|  |  |  |  |
| --- | --- | --- | --- |
| Type of test  (Accelerated/ Intermediate/Long term) | Storage condition  (◦C, % RH) | Batch number | Completed (and proposed) testing intervals |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

(Add rows if required)

Summary of the stability results observed for the above accelerated, intermediate (if applicable) and long-term studies:

|  |  |  |  |
| --- | --- | --- | --- |
| Test | Acceptance criteria | Results | Remark |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

(Add rows if required)

Summary of stress testing studies (e.g., heat, humidity, oxidation, photolysis, acid/base) conducted:

Click or tap here to enter text.

Proposed shelf-life and storage conditions:

|  |  |  |
| --- | --- | --- |
| **Container Closure System** | **Storage Conditions** | **Shelf-life** |
|  |  |  |

\* Is the shelf-life supported by the stability data?

Yes  No

## 3.2.P.8.2 Post-approval stability protocol and stability commitment

\* Availability of the post-approval stability protocol and stability commitment

Primary stability study commitment

Commitment stability studies

Ongoing stability studies

Summary of post-approval stability protocol and stability commitment:

Click or tap here to enter text.

## 3.2.P.8.3 Stability data

Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (e.g. analytical procedures used only for stability studies):

Click or tap here to enter text.

Bracketing and matrixing design and justification for *Commitment* and/or *Ongoing stability batches*, if applicable:

Click or tap here to enter text.

**Remark**

Click or tap here to enter text.

# 3. Assessment of Regional Information Section

## 3.2.R.1 Production Documentation

### 2.3.R.1.1 Executed Production Documents

**\*** Availability of executed production documents in English, where relevant.

Yes  No

**Remark**

Click or tap here to enter text.

### 3.2.R.1.2 Master production documents

\* Availability of copies of the FPP master production documents for each proposed strength, commercial batch size and manufacturing site.

Yes  No

**Remark**

Click or tap here to enter text.

## 3.2.R.2 Analytical procedures and validation information

\* Availability of summary of the analytical procedures and validation information from sections

**3.2.S.4.2, 3.2.S4.3, 2.3.S.4.4, 2.3.S.7.3, 3.2.P.5.2 and 3.2.P.5.3**, where relevant.

Yes  No

**Remark**

Click or tap here to enter text.

# 4. Literature References

\* Availability of references to the scientific literature relating to both the API and FPP, where appropriate.

Yes  No

**Remark**

Click or tap here to enter text.

# 5. Overall Conclusion on the Quality

Click or tap here to enter text.

# 6. Assessment of the Responses to the List of Questions

## For the list of questions issued on choose date

Question 1:

Click or tap here to enter text.

**Summary of Applicant’s Response:**

Click or tap here to enter text.

**Assessment of the Applicant’s Response and Conclusion:**

Click or tap here to enter text.

Question 2:

Click or tap here to enter text.

**Summary of Applicant’s Response:**

Click or tap here to enter text.

**Assessment of the Applicant’s Response and Conclusion:**

Click or tap here to enter text.

## For the list of questions issued on choose date

Question 1:

Click or tap here to enter text.

**Summary of Applicant’s Response:**

Click or tap here to enter text.

**Assessment of the Applicant’s Response and Conclusion:**

Click or tap here to enter text.

Question 2:

Click or tap here to enter text.

**Summary of Applicant’s Response:**

Click or tap here to enter text.

**Assessment of the Applicant’s Response and Conclusion:**

Click or tap here to enter text.

# 7. Overall Recommendation

Click or tap here to enter text.