**WHO CRP - Abridged Assessment Report Template**

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

**< Active Ingredient >**

**<Applicant Name>**

**<Dossier Reference Number>**

|  |  |  |
| --- | --- | --- |
| **Lead assessor** |  | |
| **Other assessors** | Name | Responsibility |
|  |  |
|  |  |
|  |  |
| **Rapporteur** |  | |
| **Co-rapporteur** |  | |
| **Application received on (date)** |  | |
| **Application number** |  | |
| **Type of review** |  | |
| **WHO Product Reference Number** |  | |
| **Start of the procedure**  **(MedNet access granted)** |  | |
| **End of the procedure** |  | |
| **Total regulatory time (number of working 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 |  |

# 1. MODULE 1

**1.1 Legal Documents**

1. Presence of Conformation of WHO Prequalification (CPQ) letter

Yes  No

2. Presence of the GMP certificate for all manufacturing sites

Yes  No

3. Presence of manufacturing license

Yes  No

4. Presence of Certificate of Pharmaceutical Product (CPP)

Yes  No

5. Presence of European Certificate of Suitability (CEP)

Yes  No  Not Applicable

6. Presence of letter of authorization or agency agreement

Yes  No

7. 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 Has the product been rejected, suspended, deferred or withdrawn from any market?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 Inspection reports**

1. Presence of inspection reports

Yes  No

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

**General comments on the administrative information**

Click or tap here to enter text.

## **2. Product details**

|  |  |
| --- | --- |
| **Dossier aspects to verify** | |
| Proprietary product name |  |
| International Nonproprietary Name (INN) of the active pharmaceutical ingredient (API) or drug substance, strength, pharmaceutical form |  |
| Applicant |  |
| Date of application |  |
| Application number (assigned by NRA) |  |
| Type of product/registration |  |
| Reference authority |  |
| Declaration from the applicant |  |

## **3. Product quality**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Dossier aspects to verify** | **WHO Prequalification Team (PQT) or reference SRA submission** | | | | | **NRA submission** | | | | **Comments** |
| Name and complete address of the applicant |  | | | | |  | | | |  |
| Name(s) and complete address (including specific blocks/units) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)] or biological drug products(s) (DP(s)), including the final product release if different from the manufacturer |  | | | | |  | | | |  |
| **Drug substance or active pharmaceutical ingredient (name, manufacturer)** | | | | | | | | | | |
| Name of API/drug substance |  | | | | |  | | | |  |
| General properties that may affect the  performance of the finished product (for example, polymorphism, solubility in physiological media) |  | | | | |  | | | |  |
| Name and address(es) (including specific blocks/units) of the manufacturer(s) of the API(s)/drug substance |  | | | | |  | | | |  |
| Control of the API/drug substance (including the specification reference number, version and date – the copy of the specification may be included as an attachment to the report) |  | | | | |  | | | |  |
| Analytical procedures (including the analytical procedure reference number, version and date – the copy of the analytical procedure may be included  as an attachment to the report) |  | | | | |  | | | |  |
| Container closure system |  | | | | |  | | | |  |
| Stability summary and conclusions (including storage statement and re‑test period) |  | | | | |  | | | |  |
| **Finished pharmaceutical product (FPP)/ drug product (DP)** | | | | | | | | | | |
| Description |  | | | | |  | | | |  |
| Composition | Component  and quality  standard | Function | | Quantity  per unit  (mg) | % | Component  and quality  standard | Function | Quantity  per unit  (mg) | % |  |
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| Total |  | |  |  | Total |  |  |  |
| Manufacturer (name, address (including  specific block/unit) and responsibility) |  | | | | |  | | | |  |
| Commercial batch size and  batch formula | Proposed commercial  batch size(s) (for  example, number of  dosage units) | |  | | | Proposed commercial  batch size(s) (for  example, number of  dosage units) | |  | |  |
| Component and  quality standard (and  grade, if applicable) | | Quantity per  batch (kg/ batch) | | | Component and quality standard (and  grade, if applicable) | | Quantity per  batch (kg/  batch) | |
|  | |  | | |  | |  | |
|  | |  | | |  | |  | |
|  | |  | | |  | |  | |
|  | |  | | |  | |  | |
| Total | | Total | | | Total | | Total | |
| Narrative description of the manufacturing process (no need to compare the whole manufacturing process – one can just look at the blank master production document reference number, version and date, together with information on the site) |  | | | | |  | | | |  |
| Control of FPP/DP (state the specification reference number, version and date – a copy of the specification may be included as an attachment to the report) |  | | | | |  | | | |  |
| Analytical procedures (including the analytical procedure reference number, version and date– a copy of the analytical procedure may be included as an attachment to the report) |  | | | | |  | | | |  |
| Container closure system (including pack sizes, container size or volume) |  | | | | |  | | | |  |
| Stability summary and conclusions (including the storage statement and shelf-life) |  | | | | |  | | | |  |
| Lot/batch-release documents |  | | | | |  | | | |  |
| Assessor’s comments on the product quality |  | | | | |  | | | |  |

## **4. Product information**

### **4.1 Information for health-care professionals and corresponding sections of the patient information leaflet**

|  |  |
| --- | --- |
| **Dossier aspects to verify** | **Comments** |
| Is the information for the health-care professionals provided as approved by the reference SRA or PQT? |  |
| Is the information for the patient/user (PIL) provided as approved by reference the SRA or PQT? |  |
| Does the information contradict national therapeutic guidelines? |  |
| Assessor’s comments on the product information |  |

### **4.2 Labelling**

The following minimum information appears on the label:

|  |  |
| --- | --- |
| **Dossier aspects to verify** | **Comments** |
| Is the labelling of outer packaging (as final packaging or mock-up presentation) provided as approved by the reference SRA or PQT? |  |
| Additional information on outer packaging as per national requirements |  |
| Is the labelling of internal packaging (as final packaging or mock-up presentation) provided as approved by the reference SRA or PQT? |  |
| Additional information on internal packaging as per national requirements |  |
| Assessor’s comments on the product labelling |  |

## **5. Applicant commitments to the WHO Prequalification team or reference stringent regulatory authority**

State any commitments by the applicant to WHO or to the reference SRA that may require follow up.

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

## **6. General national regulatory authority review comments**

Click or tap here to enter text.

## **7. Assessment of 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.

## **8. Overall Recommendation**

Click or tap here to enter text.