**WHO CRP - Verification 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 Has the product been rejected, suspended, deferred or withdrawn from any market?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)/  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** | **Comments (including confirmatory**  **statements of sameness)** | | | |
| Marketing status in reference SRA or WHO prequalification status |  | | | |
| Name and complete address of the applicant |  | | | |
| Name and complete address (including specific unit/blocks) of the API/drug substance manufacturer(s) |  | | | |
| Name(s) and complete address(es) (including specific unit/blocks) 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 |  | | | |
| Description (visual appearance) |  | | | |
| Composition | Component and quality standard | Function | Quantity per unit (mg) | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total |  |  |  |
| Specifications for the finished product |  | | | |
| 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

|  |  |
| --- | --- |
| **Dossier aspects to verify** | **Comments** |
| Is the information for the health-care professional provided as approved by the reference SRA or WHO Prequalification Team (PQT)? |  |
| Is the information for the patient/user (patient information leaflet) provided as approved by the reference SRA or PQT? |  |
| The information does not contradict national therapeutic guidelines |  |
| Assessor’s comments on the product information |  |

# 5. Labelling

|  |  |
| --- | --- |
| **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 |  |

# 6. 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.

# 7. General national regulatory authority review comments

Click or tap here to enter text.

# 8. 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.

# 9. Overall Recommendation

Click or tap here to enter text.