**Quality Overall Summary (QOS)** **for Veterinary Biological Products**

**GENERAL INSTRUCTIONS**

Quality overall summary (QOS) template should be completed for veterinary biological product (VBP) containing active substances. All sections and fields in the QOS template that would be applicable should be completed.

It is understood that certain sections and fields may not apply and should be indicated as such by reporting “not applicable” in the appropriate area with an accompanying explanatory note.

The use of tables to summarize the information is encouraged, where possible. The tables included in the template may need to be expanded or duplicated (e.g. for multiple strengths), as necessary.

These tables are included as illustrative examples of how to summarize information. Other approaches to summarize the information can be used if they fulfill the same purpose.

Please state the exact location (Annex number) of any appended documents in the relevant sections of the form.

See the “Guideline on submission of documentation for registration of veterinary biological for general and detailed instructions on the completion of this template.

Should you have any questions regarding this form, please contact the Rwanda Food and Drugs Authority (Rwanda FDA).

**2.3 S ACTIVE SUBSTANCE (NAME, MANUFACTURER)**

**2.3. S.1. General information**

2.3.S.1.1 Nomenclature

* Biological name (including strain and/ or clone designation)
* Chemical name.
* The name(s) or designation of the strain of organism used to produce the active immunogenic substance

2.3.S.1.2 Structure

* Structural formula
* Schematic amino acids sequence/molecular formula
* Relative molecular mass

2.3.S.1.3 General properties

* Physicochemical Characterization
* Biological Activity

**2.3.S.2 Manufacture**

2.3.S.2.1 Manufacturer(s)

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

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

1. Manufacturing authorization for the production of API(s) and, where available, certificate of GMP compliance (GMP information should be provided in Module 1).

2.3. S.2.2. Description of the manufacturing process and process controls

* 1. Flow diagram of manufacturing process
  2. Narrative description of the manufacturing process (es)

2.3.S.2.3 Control of materials

1. Source, history and generation of cell substrate
2. Cell Banking system, characterization and testing

2.3.S.2.4 Control of Critical Steps and Intermediates

2.3.S.2.5 Process Validation and/or evaluation

1. Validation summaries of each unit operation, hold times, sanitary processing, and virus validation
2. Outline Validation strategy and scale used to complete studies
3. Reference analytical procedures used for analysis

2.3.S.2.6 Manufacturing Process Development

1. Development program outline, scale(s) and tools used (design of experiment, FMEA, statistical evaluations)
2. Process description and batch information from development scale(s)

**2.3.S.3 Characterization of Veterinary Biological active substance**

3.2.S.3.1 Elucidation of Structure and other characteristics

3.2.S.3.2 Impurities

**2.3. S.4. Control of Active Substance**

2.3.S.4.1 Specification

2.3.S.4.2 Analytical Procedures

2.3.S.4.3 Validation of Analytical Procedures

2.3.S.4.4 Batch Analysis

2.3.S.4.5 Justification of Specification

**2.3.S.5 Reference Standard**

**2.3.S.6 Container Closure system**

**2.3.S.7 Stability**

2.3.S.7.1 Stability Summary and Conclusions

2.3.S.7.2 Post-approval Stability Protocol and Stability Commitment

2.3.S.7.3 Stability Data

**2.3.P FINISHED VETERINARY BIOLOGICAL PRODUCT (NAME, MANUFACTURER)**

**2.3.P.1 Description and Composition**

1. Description of the finished veterinary biological product.
2. Composition of the finished veterinary biological product.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Component and quality standard (and grade, if applicable) | Function | Strength (label claim) | | | | | |
|  | |  | |  | |
| Quant. per unit or  per mL | % | Quant. per unit or  per mL | % | Quantity per  unit or  per mL | % |
| Complete with appropriate titles | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Subtotal 1 |  |  |  |  |  |  |  |
| complete with the appropriate title | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Subtotal 2 |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |

1. Description of accompanying reconstitution diluents (s) if any.
2. Type of container and closure used for the dosage form and accompanying reconstitution diluent, if applicable

**2.3. P.2. Pharmaceutical development**

3.2.P.2.1 Active Substance

3.2.P.2.2 Drug Product

3.2P.2.3 Development of the manufacturing process

3.2.P.2.4 Container closure system

3.2.P.2.5 Microbiological Attributes

3.2.P.2.6 Compatibility

**2.3.P.3 Manufacture processes of the biological product**

2.3.P.3.1 Manufacturer(s)

Name, address and responsibility (e.g. fabrication, packaging, labelling, and 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 |
|  |  |
|  |  |
|  |  |

Manufacturing authorization, marketing authorization and, where available, certificate of GMP (GMP information should be provided in Module 1).

2.3.P.3.2 Batch formula

List of all components of the finished drug product to be used in the manufacturing process and their amounts on a per batch basis.

2.3.P.3.3 Description of the manufacturing process

1. Flow diagram of the manufacturing process
2. Narrative description of the manufacturing process

2.3.P.3.4 Control of critical and intermediate steps

Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:

|  |  |
| --- | --- |
| **Step** | **Controls (parameters/limits/frequency of testing)** |
|  |  |
|  |  |
|  |  |

2.3.P.3.5 Validation and/or evaluation of the processes

2.3.P.3.6 Description of the batch identification system

**2.3.P.4 Control of excipients**

2.3.P.4.1 Specifications

Summary of the specifications

2.3.P.4.2 Analytical Procedures

Summary of the analytical procedures for supplementary tests

2.3.P.4.3 Validation of Analytical Procedures

Summary of the validation information for the analytical procedures for supplementary tests (where applicable)

2.3.P.4.4 Justification of Specifications

Justification of the specifications (e.g., evolution of tests, analytical procedures and acceptance criteria, exclusion of certain tests, differences from officially recognized compendia standard(s)).

2.3.P.4.5 Excipients of Human or Animal Origin

For Finished biological products using excipients without risk of transmitting agents of animal spongiform encephalopathies, a letter of attestation confirming this can be found in:

CEP(s) demonstrating TSE-compliance can be found in:

2.3.P.4.6 Novel Excipients

**2.3.P.5 Control of the finished biological product**

2.3.P.5.1 Specifications of the biological product

2.3.P.5.2 Analytical Procedures of the biological product

(a) Summary or references to analytical procedures

2.3.P.5.3 Validation of Analytical Procedures

(a) Summary or references to the validation information

2.3.P.5.4 Batch analysis

(a) Description of the lots:

|  |  |  |  |
| --- | --- | --- | --- |
| **Strength and Batch Number** | **Bact Size** | **Date and site of production** | **Use (e.g clinica, compatibility studies)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

2.3.P.5.5 Characterization and/or determination of impurities

2.3.P.5.6 Justification of specifications

**2.3.P.6 Reference standards and materials**

Information on the reference standards and/or materials used for testing the finished biological product should be provided.

**2.3.P.7 Container Closure System**

Description of the container closure systems, including unit count or fill size, container size or volume:

|  |  |  |  |
| --- | --- | --- | --- |
| **Description (including materials of construction)** | **Strength/concentration** | **Unit count or fill size** | **Container size (e.g. 1mL, 2 mL, 5 mL. etc. )** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.3.P.8 Stability of the Drug Product**

3.2.P.8.1 Protocols and results of the stability study that justify the proposed validity period

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Storage conditions (◦C, % RH)** | **Strength and batch number** | **Batch Size** | **Container Closure System** | **Completed (and**  **proposed) test**  **intervals** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Proposed storage statement and shelf-life (and in-use storage conditions and in-use period, if applicable):

|  |  |  |
| --- | --- | --- |
| **Container Closure System** | **Storage staitement** | **Shelf - Life** |
|  |  |  |
|  |  |  |
|  |  |  |

2.3.P.8.2 Post-approval stability program

Stability protocol for Primary stability batches, Commitment batches and Ongoing batches

2.3.P.8.3 Stability data

1. The actual stability results should be provided in Module 3.
2. Summary of analytical procedures and validation information for those procedures not previously summarized in 3.2.P.5 (e.g. analytical procedures used only for stability studies):
3. Data to support freeze thaw cycles recommended

2.3.P.8.4 Shipping

The procedures used to guarantee the cold chain.