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

**GENERAL INSTRUCTIONS**

Quality overall summary (QOS) template should be completed for immunological veterinary product (IVP) containing active immunogenic 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 fulfil 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 immunological veterinary product (IVP) 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 IMMUNOGENIC 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 of the immunogenic substance**

**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 Method of manufacture**

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

#### **S.3. Manufacturing Consistency**

Consistency of the manufacturing process for each immunogenic substance component should be demonstrated by providing the manufacturing lot certificates of at least three, preferably consecutive, batches of the active immunogenic substance of a size corresponding to that for routine production.

**2.3. S.4 Reference Standards or Materials (name, manufacturer)**

Source (including lot number) of primary reference standards or reference materials (e.g.Ph.Int., Ph.Eur., BP, USP, in­house). Characterization and evaluation of non­official (e.g. not from an officially recognized pharmacopoeia) primary reference standards or reference materials (e.g. elucidation of structure, certificate of analysis). Description of the process controls of the secondary reference standard (comparative certificate of analysis and IR spectra against a primary standard).

**2.3. S.5 Container closure system of the immunogenic substance**

A brief description of the container and closure system and information on its compatibility with the immunogenic substance.

**2.3. S.6 Stability of the immunogenic substance**

* 1. Stability Studies Protocol, summary, and conclusions
  2. Stability data
  3. Proposed storage and transportation conditions

**2.3. P FINISHED IMMUNOGENIC PRODUCT (NAME, MANUFACTURER)**

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

* Description of the finished immunogenic product.
* Composition of the finished immunogenic 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 |  |  |  |  |  |  |  |

Type of container closure system used for the IVP and accompanying reconstitution diluents, if applicable.

**2.3. P.2 Method of manufacture of the finished immunogenic product**

**2.3.P.2.1 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.2.2 Manufacture Flow Chart**

Flow diagram of the manufacturing process

**2.3.P.2.3 Manufacture process details**

Narrative description of the manufacturing process, including equipment type and working capacity, process parameters:

**2.3.P.2.4 Control of starting materials**

1. Starting material listed in pharmacopeias
2. Starting materials not listed in pharmacopeias
   1. Starting materials of non­biological origin
   2. Starting materials of biological origin

**2.3.P.2.5 Minimizing the risk of TSE**

**2.3.P.2.6. Media preparation**

##### 

##### 2.3.P.2.7. In­process control tests

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

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

**2.3.P.2.8 Process validation**

**2.3. P.3 Control Tests on the finished IVP**

**2.3.P.3.1 Specifications**

Brief information on finished product tests performed on each batch, including the batch release specification.

**2.3.P.3.2 Analytical Methods**

Summary of the analytical procedures to test the finished product specifications.

**2.3.P.3.3 Validation of Analytical Procedures**

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

**2.3. P.4 Batch to Batch Consistency**

1. Description of the lots:

|  |  |  |  |
| --- | --- | --- | --- |
| Strength and  batch number | Batch size | Date and  site of production | Use |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. Summary of Results from the three consecutive batches in tabular form for ease of comparison.

**2.3. P.5 Container Closure System**

1. 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,2ml, 5ml, etc.) |
|  |  |  |  |
|  |  |  |
|  |  |  |

1. Summary of the container and closure system.

**2.3. P.6 Stability of the Finished Immunogenic Product**

**2.3.P.6.1 Protocols and results of the stability study**

Protocol and results that justify the proposed validity period. Summary of stability data.

**2.3.P.6.2 In- use shelf life**

Stability-indicating tests should be provided on at least 2 different batches to support an in­use shelf life.

**2.3.P.6.3 Description of procedures to guarantee cold chain**

**2.3. D INFORMATION ON DILUENT**

For any immunological veterinary product accompanied with reconstitution diluents provide a summary of data to support the quality of reconstitution diluents.