**FOREWORD**

The QIS template should be completed to provide a condensed summary of the key quality information for product dossiers (PDs) containing APIs of synthetic or semi-synthetic origin and their corresponding products that are filed with the Prequalification Programme.

The QIS constitutes part of the PD. The QIS provides an accurate record of technical data in the PD at the time of Marketing Authorization and thereafter serves as an official reference document during the course of GMP inspections, variation assessments and renewal of Marketing Authorizations by Rwanda FDA. The QIS is a condensed version of the Quality Overall Summary – Product Dossier (QOS-PD) and represents the final, agreed upon key information from the PD review (inter alia identification of the manufacturer(s), API/FPP specifications, stability conclusions and relevant commitments).

The QIS template is structured to permit the rapid assembly of the QIS by copying requisite information from the corresponding portions of the QOS-PD filed with the original PD. It is acknowledged that the numbering of the sections may not be entirely sequential. Those sections not considered necessary to be included in the QIS have been removed (e.g. *2.3.S.5 Reference* *Standards or Materials*) and the remaining sections have retained their numbering to be consistentwith the original PD.

For original PDs, the QIS should be provided in Word format at the time of PD submission. The QIS should be revised and submitted with the change history (see table at the end of the template) each time additional data is provided during the assessment process. If no revision is necessary due to no change in the information, a statement should be made to this effect in the covering letter. For variations and requalification dossiers, the QIS should be completed *in its entirety* (regardless of the proposed change), it should include information on *all strengths*, with any changes highlighted and it should be provided *at the time of filing*.

**When completing the QIS template, this covering *Foreword* should be deleted.**

|  |  |
| --- | --- |
| **Summary of product information:Non-proprietary name(s) of the finished pharmaceutical product(s) (FPP)** |  |
| **Proprietary name(s) of the finished pharmaceutical product(s) (FPP)** |  |
| **International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph)** |  |
| **Applicant name and address** |  |
| **Dosage form** |  |
| **Application Number** |  |
| **Strength** |  |
| **Route of administration** |  |
| **Proposed indication(s)** |  |
|  |  |
| **Local Technical Representative (Agency)** |  |
| LTR Contact person details |  |
| **Local Technical Representative (LTR) contact person** | Surname: First Name: |
| **Physical address details** | |
| **Town/City** |  |
| **Postal code** |  |
| **Country (Within EAC)** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |
|  |  |
| **FPP manufacturer Qualified Person** | Surname: First Name: |
| **FPP manufacturer Qualified person's contact details (including Physical address)** | |
| **Unit /block** |  |
| **Road/Street** |  |
| **Plant** |  |
| **Village/suburb** |  |
| **Town/City** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

1. **Administrative Summary:**

|  |  |
| --- | --- |
| **Applicant’s date of preparation or revision of the QIS** |  |
| **Version and/or date of acceptance** | *(Rwanda FDA use only)* |

**Related dossiers (e.g. FPP(s) with the same API(s) submitted to Rwanda FDA by the applicant):**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Reference** |  | **Marketing** |  | **API, strength, dosage** |  |  | **API manufacturer** |  |
|  | **number** |  | **Authorization** |  | **form** |  |  | (including address) |  |
|  |  |  |  |  |  |  |  |  |
|  | (eg J998) |  | **granted (Y/N)** |  | (e.g. Abacavir (as sulphate) |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  | 300 mg tablets) |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

**2.3.S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API))**

**(NAME, MANUFACTURER)**

**Indicate which option applies for the submission of API information:**

|  |  |
| --- | --- |
| **Name of API Manufacturer:** |  |
| Full details in the PD  Open part DMF version number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Restricted part DMF version number\_\_\_\_\_\_\_\_\_\_\_\_\_  Identifier of current module 3.2.S: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  |  |
|  |  |
|  |  |

|  |  |  |
| --- | --- | --- |
| **Name of API manufacturer:** | |  |
| □ | Full details in the PD  Open part DMF version number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Restricted part DMF version number\_\_\_\_\_\_\_\_\_\_\_\_\_  Identifier of current module 3.2.S: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Option 1. | |
| □ | Certificate of suitability to the European Pharmacopoeia (CEP)  Option 2. | |
| □ | Confirmation of API WHO prequalification document:  Option 3 | |
| □ | Active pharmaceutical ingredient master file (APIMF) procedure:  APIMF number assigned (if known): \_\_\_\_\_\_\_ ; version number(s) including amendments (and/or date(s)) of the open part: \_\_\_\_\_\_\_ ; version number(s) including amendments (and/or date(s)) of the restricted part: : \_\_\_\_\_\_\_.  Option 4. | |

**2.3.S.2 Manufacture (name, manufacturer)**

***2.3.S.2.1 Manufacturer(s) (name, manufacturer)***

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Name and address** |  | **Responsibility** | **API-PQ number** | **Letter of access** |
|  | **(including** |  |  | **/APIMF/CEP** | **provided?** |
|  |  |  |  |  |
|  | **block(s)/unit(s))** |  |  | **number (if** |  |
|  |  |  |  |  |
|  |  |  |  | **applicable)** |  |
|  |  |  |  |  |  |

***2.3.S.2.3 Control of Materials (name, manufacturer) – for API option 4 only***

1. Name of starting material:
2. Name and manufacturing site address of starting material manufacturer(s):

**2.3.S.4 Control of the API (name, manufacturer)**

***2.3.S.4.1 Specification (name, manufacturer)***

1. **API specifications *of the FPP manufacturer*:**

|  |  |  |
| --- | --- | --- |
| **Standard (e.g. Ph.Int., Ph.Eur., BP, USP, in-house)** | |  |
|  |  |  |
| **Specification reference number and version** | |  |
|  |  |  |
| **Test** | **Acceptance criteria** | **Analytical procedure** |
|  |  | **(Type/Source/Version)** |
|  |  |  |
| Description |  |  |
|  |  |  |
| Identification |  |  |
|  |  |  |
| Impurities |  |  |
|  |  |  |
| Assay |  |  |
|  |  |  |
| etc. |  |  |
|  |  |  |
| **2.3.S.6 Container Closure System (name, manufacturer)** | |  |

**Description of the container closure system(s) for the storage and shipment of the API:**

**2.3.S.7 Stability (name, manufacturer)**

***2.3.S.7.1 Stability Summary and Conclusions (name, manufacturer)***

**Proposed storage conditions and re-test period (or shelf-life, as appropriate):**

|  |  |  |
| --- | --- | --- |
| **Container closure system** | **Storage statement** | **Re-test period\*** |
|  |  |  |
|  |  |  |
|  |  |  |

indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile APIs)

**2.3.P DRUG PRODUCT (or FINISHED PHARMACEUTICAL PRODUCT (FPP))**

Indicate which option applies for the submission of FPP information: <check one only>

|  |  |  |
| --- | --- | --- |
| **Name of API:** | |  |
| **Name of API manufacturer:** | |  |
| □ | Full details | |
| □ | WHO collaborative procedure | |
| □ | SRA Abridged procedure | |
| □ | Rwanda FDA Mutual Recognition | |
| □ | EU Article 58 procedure | |

**2.3.P.1 Description and Composition of the FPP**

1. **Description of the FPP:**
2. **Composition of the FPP:**

Composition, 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** | **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 e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection> | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Subtotal 1 |  |  |  |  |  |  |  |
| <complete with appropriate title e.g. Film-coating > | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Subtotal 2 |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |

Composition of all components purchased as mixtures (e.g. colourants, coatings, capsule shells, imprinting inks):

1. **Description of accompanying reconstitution diluent(s), if applicable:**

***2.3.P.2.2.1 Formulation Development***

**b) Information on primary (submission, registration, exhibit) batches including comparative bioavailability or bio waiver, stability, commercial:**

**Summary of batch numbers:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Batch number(s) of the FPPs used in** | | | |
| **Bioequivalence** | <e.g. bioequivalence batch A12345>. | | |
| **Bio waiver** | <e.g.bio waiver batch X12345> | | |
| **For proportional strength bio waiver: the bioequivalence batch of the reference strength** |  | | |
| **Dissolution profile studies** |  | | |
| **Stability studies (primary batches)** | | | |
| ‹packaging configuration I› |  |  |  |
| ‹ packaging configuration II› |  |  |  |
| *‹Add/delete as many rows as necessary›* |  |  |  |
| **Stability studies (production batches)** | | | |
| ‹ packaging configuration I› |  |  |  |
| ‹ packaging configuration II› |  |  |  |
| *(Add/delete as many rows as necessary)* |  |  |  |
| **Validation studies (primary batches)** | | | |
| ‹ packaging configuration I› |  |  |  |
| ‹ packaging configuration II› |  |  |  |
| *(Add/delete as many rows as necessary)* |  |  |  |
| **Validation studies (at least the first three consecutive production batches) version(s) for process validation protocol(s)** |  |  |  |

**Summary of formulations and discussion of any differences:**

| **Component and quality standard (e.g. NF, BP, Ph.Eur, in-house)** | **Relevant batches** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Comparative bioavailability or bio waiver** | | **Stability** | | **Process validation** | | **Commercial (2.3.P.1)** | |
| **<Batch nos. and sizes>** | | **<Batch nos. and sizes>** | | **<Batch nos. and sizes>** | | **<Batch nos. and sizes>** | |
| **Theor.**  **quantity per batch** | **%** | **Theor.**  **quantity per batch** | **%** | **Theor.**  **quantity per batch** | **%** | **Theor.**  **quantity per batch** | **%** |
| <complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection> | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Subtotal 1 |  |  |  |  |  |  |  |  |
| <complete with appropriate title e.g. Film-coating > | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Subtotal 2 |  |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |  |

**2.3.P.3 Manufacture**

***2.3.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** |
|  |  |
|  |  |

***2.3.P.3.2 Batch Formula***

**Largest intended commercial batch size:**

**Other intended commercial batch sizes:**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Strength (label claim)** |  |  |  |  |
|  |  |  |  |  |  |
|  | **Master production document** |  |  |  |  |
|  | **reference number and/or version** |  |  |  |  |
|  |  |  |  |  |  |
|  | **Proposed commercial batch size(s) (e.g.** |  |  |  |  |
|  | **number of dosage units)** |  |  |  |  |
|  |  |  |  |  |  |
|  | **Component and quality standard** | **Quantity per** | **Quantity per** | **Quantity per** |  |
|  | **(and grade, if applicable)** | **batch (e.g.** | **batch (e.g.** | **batch (e.g.** |  |
|  |  |  |  |  |
|  |  | **kg/batch)** | **kg/batch)** | **kg/batch)** |  |
|  |  |  |  |  |  |

<complete with appropriate title e.g. Core tablet, Contents of capsule, Powder for injection>

Subtotal 1

<complete with appropriate title e.g. Film-coating >

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Strength (label claim)** |  |  |  |
|  |  |  |  |  |
|  | **Master production document** |  |  |  |
|  | **reference number and/or version** |  |  |  |
|  |  |  |  |  |
|  | **Proposed commercial batch size(s) (e.g.** |  |  |  |
|  | **number of dosage units)** |  |  |  |
|  |  |  |  |  |
|  | **Component and quality standard** | **Quantity per** | **Quantity per** | **Quantity per** |
|  | **(and grade, if applicable)** | **batch (e.g.** | **batch (e.g.** | **batch (e.g.** |
|  |  |  |  |
|  |  | **kg/batch)** | **kg/batch)** | **kg/batch)** |
|  |  |  |  |  |
| Subtotal 2 | |  |  |  |
|  | |  |  |  |
|  | Total |  |  |  |
|  |  |  |  |  |
| ***2.3.P.3.3 Description of Manufacturing Process and Process Controls*** | | | |  |

1. Flow diagram of the manufacturing process:
2. Narrative description of the manufacturing process, including equipment type and working capacity, process parameters:

***2.3.P.3.4 Controls of Critical Steps and Intermediates***

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Step** |  | **Controls (parameters/limits/frequency of** |
|  | **(e.g. granulation, compression, coating)** |  | **testing)** |
|  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Proposed/validated holding periods for intermediates (including bulk product):

***2.3.P.3.5 Process Validation and/or Evaluation***

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

Document code(s) for the process validation protocol(s) and/or report(s) (including reference number/version/date):

**2.3.P.5 Control of FPP**

***2.3.P.5.1 Specification(s)***

1. **Specification(s) for the FPP:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Standard (e.g. Ph.Int., BP, USP, in-house)** | |  |  |
|  |  |  |  |
| **Specification reference number and version** | |  |  |
|  |  |  |  |
| **Test** | **Acceptance criteria** | **Acceptance criteria** | **Analytical procedure** |
|  | **(release)** | **(shelf-life)** | **(type/source/version)** |
|  |  |  |  |
| Description |  |  |  |
|  |  |  |  |
| Identification |  |  |  |
|  |  |  |  |
| Impurities |  |  |  |
|  |  |  |  |
| Assay |  |  |  |
|  |  |  |  |
| etc. |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.3.P.7 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** | **Unit count or fill size**  **(e.g. 60s, 100s etc.)** | **Container size**  **(e.g. 5 ml, 100 ml etc.)** |
|  |  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |  |
|  |  |  |
|  |  |  |

**2.3.P.8 Stability**

***2.3.P.8.1 Stability Summary and Conclusions***

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

|  |  |  |
| --- | --- | --- |
| **Container closure system** | **Storage statement** | **Shelf-life** |
|  |  |  |
|  |  |  |
|  |  |  |

***2.3.P.8.2 Post-approval Stability Protocol and Stability Commitment***

**a) Stability protocol for *Primary stability batches* (e.g. storage conditions (including tolerances), batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):**

| **Parameter** | **Details** | |
| --- | --- | --- |
| **Storage condition(s) (◦C, % RH)** |  | |
| **Batch number(s) / batch size(s)** | <*primary batches*> | |
| **Tests and acceptance criteria** | Description |  |
| Moisture |  |
| Impurities |  |
| Assay |  |
| etc. |  |
|  |  |
| **Testing frequency** |  | |
| **Container closure system(s)** |  | |
|  |  | |

1. **Stability protocol for *Commitment batches* (e.g. storage conditions (including tolerances), batch numbers (if known) and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Details** | |
|  |  |  |
| Storage condition(s) (◦C, % RH) |  |  |
|  |  |  |
| Batch number(s) / batch size(s) | *<not less than three production batches in each container* | |
|  | *closure system>* | |
|  |  |  |
| Tests and acceptance criteria | Description |  |
|  |  |  |
|  | Moisture |  |
|  |  |  |
|  | Impurities |  |
|  |  |  |
|  | Assay |  |
|  |  |  |
|  | etc. |  |
|  |  |  |
| Testing Frequency |  |  |
|  |  |  |
| Container Closure System(s) |  |  |
|  |  |  |
|  |  |  |

1. **Stability protocol for *Ongoing Batches* (e.g. storage conditions (including tolerances), number of batches per strength and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Details** | |
|  |  |  |
| Storage condition(s) (◦C, % RH) |  |  |
|  |  |  |
| Batch size(s), annual allocation | *<at least one production batch per year (unless none is* | |
|  | *produced that year) in each container closure system >* | |
|  |  |  |
| Tests and acceptance criteria | Description |  |
|  |  |  |
|  | Moisture |  |
|  |  |  |
|  | Impurities |  |
|  |  |  |
|  | Assay |  |
|  |  |  |
|  | etc. |  |
|  |  |  |
| Testing frequency |  |  |
|  |  |  |
| Container closure system(s) |  |  |
|  |  |  |
| ***2.3.P.8.3 Stability Data*** |  |  |

**c) Bracketing and matrixing design for commitment and/or continuing (i.e. ongoing) batches, if applicable:**

**WRITTEN COMMITMENTS OF THE MANUFACTURER – Rwanda FDA use**

**API**

**If applicable (primary stability study commitment):**

The Applicant (or API manufacturer) undertook in writing (date of letter of commitment) to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year) and to report any significant changes or out-of-specification results immediately to Rwanda FDA for the following batches:

<Batch numbers, manufacturing dates, batch size, primary packing materials>

**If applicable (commitment stability studies):**

Since stability data on three production scale batches were not provided with the application, the remaining number of production scale batches should be put on long-term stability testing. Any significant changes or out-of-specification results should be reported immediately to Rwanda FDA. The approved stability protocol should be used for commitment batches.

**API option 1 - full details in the PD (ongoing stability study commitment)**

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends should be investigated. Any confirmed significant change, out-of-specification result, or significant atypical trend should be reported immediately to Rwanda FDA. The possible impact on batches on the market should be considered in consultation with Rwanda FDA inspectors.

**API option 2 - CEP**

The Applicant provided a commitment in writing (date of letter of commitment) to inform Rwanda FDA in the event that the CEP is withdrawn. Note that withdrawal will require additional consideration of the API data requirements to support the dossier.

**FPP**

**If applicable (primary stability study commitment):**

The Applicant undertook in writing (date of letter of commitment) to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year) and to report any out-of-specification results or significant changes immediately to Rwanda FDA for the following batches : <Batch numbers, manufacturing dates, batch size, primary packing materials >

**If applicable (commitment stability studies):**

Since stability data on three production scale batches was not provided with the application, the Applicant undertook in writing, (date of letter of commitment) to put the remaining number <e.g.

additional two (2)> production scale batches of < FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> on long-term stability testing. Any out-of-specification results or significant changes during the study should immediately be reported to Rwanda FDA. The approved stability protocol should be used for commitment batches.

**If applicable (when the proposed largest commercial batch size is 200 000 units (x units) or less)**

The Applicant undertook in writing (date of letter of commitment) to place the first three batches of any production size larger than x units on stability. The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change, out-of-specification result, or significant atypical trend will be reported immediately to Rwanda FDA.

**Ongoing stability study commitment**

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product manufactured in every primary packaging type will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends should be investigated. Any confirmed significant change, out-of-specification result, or significant atypical trend should be reported immediately to Rwanda FDA. The possible impact on batches on the market should be considered in consultation with Rwanda FDA inspectors.

**If applicable (validation of production batches)**

Validation data on production scale batches of not less than three (3) consecutive batches of <FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> was not provided with the application. Therefore, the Applicant submitted a written commitment (date of letter of commitment) that three consecutive production batches would be prospectively validated and a validation report —in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the Rwanda FDA inspection team.

**Change History**

**Date of preparation of original QIS:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Date of revised** |  | **Section (e.g.** |  | **Revision** |
|  | **version** |  | **S.2.1)** |  |
|  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |