**FOREWORD**

The QIStemplate 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 NDA. 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 consistent with 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.**

**INTRODUCTION**

(a) Summary of product information:

|  |  |
| --- | --- |
| **Non-proprietary name of the finished pharmaceutical product (FPP)** |  |
| **Proprietary name of the finished pharmaceutical product (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** |  |
| **Reference Number(s)** |  |
| **Strength(s)** |  |
| **Route of administration** |  |
| **Proposed indication(s)** |  |
| **Authorised Agent** |  |
| **Contact information** | Name: Phone: Email: Website: |

(b) Administrative Summary:

|  |  |
| --- | --- |
| Applicant’s date of preparation or revision of the QIS |  |
| Internal version and/or date of acceptance | *(NDA use only)* |

Related dossiers (e.g. FPP(s) with the same API(s) submitted to the Pre-qualification Programme by the applicant):

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

**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: |  |
| Name of API manufacturer |  |
|  | Certificate of suitability to the European Pharmacopoeia (CEP)?  |
|  | API prequalified by WHO |
|  | Full details in the PD |

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

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

(a) 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** | **API-PQ number /APIMF/CEP number** **(if applicable)** | **Letter of access provided?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

***2.3.S.2.3 Control of Materials (name, manufacturer)***

**(a) Name of starting material:**

**(b) 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)**

(a) 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)**

**(a) 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)**

(a) Proposed storage conditions and re-tests period:

|  |  |  |
| --- | --- | --- |
| **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)

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

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

**(a) Description of the FPP (in signed specifications):**

**(b) Composition of the FPP:**

(i) 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 |  |  |  |  |  |  |  |

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

 **(c) 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 biowaiver, stability, commercial:**

1. **Summary of batch numbers:**

|  |
| --- |
| **Batch number(s) of the FPPs used in** |
| **Bioequivalence or biowaiver** |  |
| **For proportional strength biowaiver: 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)****or code(s)/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 biowaiver** | **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)**

(a) 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:

<Information on all intended commercial batch sizes should be in the QIS>

(a) 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****(and grade, if applicable)** | **Quantity per batch (e.g. kg/batch)** | **Quantity per batch (e.g. kg/batch)** | **Quantity per batch (e.g. kg/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.3.3 Description of Manufacturing Process and Process Controls

(a) Flow diagram of the manufacturing process:

(b) 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

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

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

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

2.3.P.3.5 Process Validation and/or Evaluation

(a) 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)

(a) Specification(s) for the FPP:

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

2.3.P.7 Container Closure System

(a) 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)** |  |
|  |  |

(b) 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)** |  |
|  |  |
| (c) 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) (⁰C, % 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:

**Change History**

**Date of preparation of original QIS:**

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