# FOOD AND DRUGS AUTHORITY

# QUALITY INFORMATION SUMMARY (QIS)

**TO BE SUBMITTED AS ELECTRONIC COPIES**

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,
FOOD AND DRUGS AUTHORITY
P.O. BOX CT 2783
CANTONMENT-ACCRA
GHANA.
Fax: +233-302229794, 225502
Telephone: +233-3022333200, 235100
Website: www.fdaghana.gov.gh

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|---|---|
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**QUALITY INFORMATION SUMMARY (QIS)**

**<Product Application number: e.g. AFH0001/18>**

## 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 Prequalification PD. The QIS provides an accurate record of technical data in the PD at the time of prequalification and thereafter serves as an official reference document during the course of GMP inspections, variation assessments and requalification assessments as performed by WHO. 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***

# QUALITY INFORMATION SUMMARY (QIS)

## INTRODUCTION

### (a) 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** | | | |
| **Reference Number(s)** | | | |
| **Strength(s)** | | | |
| **Route of administration** | | | |
| **Proposed indication(s)** | | | |
| | | | |
| **Primary contact person responsible for this application**[1] | Title:<br>First name:<br>Family Name: | | |
| **Contact person's job title** | | | |
| **Contact person's postal address** ***(only complete sections applicable to the contact persons address)*** | | | |
| **Unit** | | | |
| **Building/PO Box number** | | | |
| **Road/Street** | | | |
| **Plant/Zone** | | | |
| **Village/suburb** | | | |
| **Town/City** | | | |
| **District and Mandal** | | | |
| **Province/State** | | | |
| **Postal code** | | | |
| **Country** | | | |
| **Contact person's email address** | | | |
| **Contact person's phone number** | | | |

### (b) Administrative Summary:

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

1 *Please note that the contact listed in this form will be the primary contact for email and mail communication for this specific application.*

***Related dossiers (e.g. FPP(s) with the same API(s) submitted to the Prequalification Team: medicines (PQTm) by the applicant):***

| Reference number (e.g. HA998) | Prequalified (Y/N) | API, strength, dosage form (eg. Abacavir (as sulphate) 300 mg tablets) | API manufacturer (including address if same supplier as current dossier) |
|---|---|---|---|
| | | | |
| | | | |

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

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

| | |
|---|---|
| **Name of API:** | |
| **Name of API manufacturer:** | |
| □ | Confirmation of API prequalification document |
| □ | Certificate of suitability to the European Pharmacopoeia (CEP) |
| □ | Full details in the PD<br>Document version number/identifier of current module 3.2.S: _____ |

**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, 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) – <u>for API option 4 only</u>***

**(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)***

**(c) 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))**

**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):**

| Component and quality standard (and grade, if applicable | Function | Quantity per unit / % |
|---|---|---|
| | | |
| | | |

(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:**

**(i) Summary of batch numbers:**

| **Batch number(s) of the FPPs used in** | | | |
|---|---|---|---|
| **Bioequivalence or biowaiver** | <e.g. bioequivalence batch A12345> <e.g. biowaiver batch X12345> | | |
| **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 | | | | | | | | |

| 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 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**<br><br>**(including materials of construction)** | **Strength** | **Unit count or fill size**<br><br>**(e.g. 60s, 100s etc.)** | **Container size**<br><br>**(e.g. 5 ml, 100 ml etc.)** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

**2.3.P.8 Stability**

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

**(a) 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) (◦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***

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

## WRITTEN COMMITMENTS OF THE MANUFACTURER – FOR WHO USE

Important note: The product information is an essential part of the medicinal product. The SmPC and PIL published with the WHOPAR have been quality assured by WHO experts and reflect the situation at the time of publication of the WHOPAR. These texts, i.e. the SmPC and the PIL are prequalified and should be adhered to. Generally, a deviation from the prequalified product information (especially as to contents) means the product can no longer be considered to be prequalified.

### 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 WHO 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 WHO. The approved stability protocol should be used for commitment batches.

**API option 2 – CEP**

The Applicant provided a commitment in writing (date of letter of commitment) to inform WHO in the event that the CEP is revised or withdrawn, and that revisions to the CEP will be handled as per variation 5 (Annex 3, TRS 981). Note that revisions or withdrawal will require additional consideration of the API data requirements to support the dossier.

**API option 3 – 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 will be investigated. Any confirmed significant change or out-of-specification result will be reported immediately to WHO. The possible impact on batches on the market will be considered in consultation with WHO inspectors.

**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 WHO 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 will immediately be reported to WHO. The approved stability protocol will 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 or out-of-specification result will be reported immediately to WHO.

## 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 and found acceptable). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change or out-of-specification result will be reported immediately to WHO. The possible impact on batches on the market will be considered in consultation with WHO 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 WHO inspection team.

## Change History

***Date of preparation of original QIS:***

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