Quality Information Summary (QIS) of the Finished Pharmaceutical Product (FPP) Approved by the Reference Stringent Regulatory Authority (SRA)

(QIS-SRA)

**FOREWORD**

Reference WHO guideline: [Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities](http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex5.pdf?ua=1). Technical Report Series 986, Annex 5, 2014.

The QIS-SRA template should be completed so that it provides a condensed summary of key information of the finished pharmaceutical product (FPP) as approved by the reference stringent regulatory authority (SRA). It should be submitted in Word format together with the application for prequalification of an FPP approved by an SRA, according to the requirements of the above guideline.

The QIS-SRA should be revised (using track change mode) and resubmitted in Word format:

* whenever any administrative changes are necessary (e.g. change of contact person), or
* whenever any variations to the FPP that affect the QIS-SRA have been approved by the reference SRA, together with the regulatory letter of approval of the variation(s).

For FPPs that were prequalified according to the SRA route before implementation of the QIS-SRA, the QIS-SRA template should be completed in full whenever variations that affect the QIS-SRA have been approved by the reference SRA, and submitted together with the regulatory letter of approval of the variations.

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

**A. Information (as currently approved by the reference SRA, where relevant) that may be published on the WHO medicines prequalification website**

|  |  |  |
| --- | --- | --- |
| A1. Product reference number (WHO number) | | A2. Innovator or multisource (generic) FPP? |
|  | |  |
| A3. Reference stringent regulatory authority | | A4. Date of initial approval by reference SRA |
|  | |  |
| A5. Name of the holder of the Marketing Authorization and official address | | |
|  | | |
| A6. Name of the applicant for prequalification and official address (**provide only if different from the MAH**)[[1]](#footnote-1) | | |
|  | | |
| A7. Proprietary name of finished pharmaceutical product (FPP) in the reference SRA country/region | | |
|  | | |
| A8. INN of active pharmaceutical ingredient(s) [API(s)], including form (salt, hydrate, solvate, etc.) | | |
|  | | |
| A9. Dosage form and strength | | |
|  | | |
| A10. Product description (as in Product Information, e.g. White, film-coated, capsule shaped tablets, debossed with ‘X’ and score line on one side and plain on other side.) | | |
|  | | |
| A11. Primary and secondary packaging material(s) and pack size(s) (all pack types) | | |
|  | | |
| A12. Storage conditions (as in Product Information) | | |
|  | | |
| A13. Shelf-life of FPP (including in-use periods, where applicable) | | |
|  | | |
| A14. Names of all approved manufacturers of FPP, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, primary packaging site and release testing (indicate function of each site) | | |
|  | | |
| A15. Names of all approved API manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (indicate function of each site) | | |
|  | | |
| A16. Storage conditions and duration over which stability, as reported to the reference SRA, was established (e.g. 30±2°C/75±5%RH for 24 months, 40±2°C/75±5%RH for 6 months): | | |
| Long term (real time in months) |  | |
| Intermediate (duration in months) |  | |
| Accelerated (duration in months) |  | |

1. **Information (as currently approved by the reference SRA, where applicable) that will not be made publicly available**

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| --- | --- | --- | --- | --- | --- |
| **B1. Composition (formulation) information** | | | | | |
| Component and quality standard (and grade, if applicable) | Function | Unit composition | | Batch composition (largest approved size) | |
| Quantity per unit or per ml | % | Theoretical quantity / batch | % |
| <complete with appropriate title 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 |  |  |  |  |  |
| Batch size in number of units, where applicable | | | |  | |
| Additionally approved batch sizes — in number of units or kg, where applicable (add as many rows as necessary) | | | |  | |
|  | |
|  | |
| Composition of all components purchased as mixtures (e.g. colorants, coatings, capsule shells, imprinting inks): | | | | | |

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| --- | --- | --- | --- |
| B2. FPP specifications | | | |
| Standard (e.g. Ph.Int., BP, USP, in-house)) | | |  |
| Specification reference number and version / effective date | | |  |
| Test | Acceptance criteria (release) | Acceptance criteria (shelf-life) | Analytical procedure (type/source/version) |
| Description |  |  |  |
| Identification |  |  |  |
| Impurities |  |  |  |
| Assay |  |  |  |
| etc. |  |  |  |
|  |  |  |  |
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| --- | --- | --- |
| B3. Pharmacokinetic / safety / efficacy related information used for SRA approval of multisource products. Indicate: | | |
| **Type of study** | “X” in appropriate box | Comparator product |
| Bioequivalence |  |  |
| BCS-based biowaiver |  |  |
| Other (specify) |  |  |
| No study |  |  |
| Notes / clarifications |  | |

|  |  |
| --- | --- |
| B4. Contact information for communication with WHO | |
| Contact person and postal address |  |
| (International code) Telephone number |  |
| (International code) Fax number |  |
| Email address |  |

**Change history to QIS-SRA and product information**

**Date of preparation of original QIS-SRA: ……………………**

|  |  |
| --- | --- |
| Date of revision  (reported variation\*) | Revision/variation description |
|  |  |
|  |  |
|  |  |
|  |  |

\* Variations approved by the SRA after prequalification of the FPP affecting only the QIS-SRA, Product Information and/or FPP QC test procedures should be reported in the change history.

1. The MAH and Applicant for prequalification must be of the same group of companies – evidence thereof to be provided by the applicant. [↑](#footnote-ref-1)