# Appendix 4

## Quality information summary of the finished pharmaceutical product or vaccine approved by the reference SRA (QIS- SRA (crp))

### Foreword

*Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities*

The WHO *Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities* define a template for a simplified quality information summary (QIS) to outline the key quality parameters of a product approved by a stringent regulatory authority (reference SRA) for WHO prequalification. It was realized that this simplified QIS can be a useful instrument for sharing (under appropriate conditions of confidentiality) the essential quality parameters characterizing each medicine approved by SRAs in order to accelerate national decisions on registration. However, experience with the pilot-testing of the reference SRA *Collaborative procedure* revealed that the simplified WHO QIS does not contain certain data which would facilitate verification of “sameness” of the product for the purpose of the collaborative registration of reference SRA-approved medicines. Therefore the information content of the template was extended to the form of the “QIS-SRA (crp)”.

The QIS-SRA (crp) template should be completed by the applicant and verified by the reference SRA, ideally in the initial stage of the collaborative process, when the applicant (market authorization holder (MAH)) requests the reference SRA’s cooperation and grants consent to information sharing. Should data in the application for national registration deviate from data approved by the reference SRA, these should be clearly indicated and summarized in section B10. The QIS-SRA (crp) should be submitted as a part of the application for national registration together with other documents stipulated in the collaborative procedure for products approved by reference SRA. A copy should also be provided in Word format.

Whenever any variation to the approved product that affects the QIS- SRA (crp) has been approved by the reference SRA, the QIS-SRA (crp) should be revised (using track-changes mode) and resubmitted to the relevant regulatory authorities in Word format together with the regulatory letter or other relevant document confirming approval of the variation under consideration.

**Information as currently approved by the reference SRA**

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The QIS-SRA (crp) is specifically designed for the purpose of the SRA collaborative procedure and should not be confused with other formats of QIS that are used for the purpose of WHO prequalification.

When completing the QIS-SRA (crp) template, this covering *Foreword*

should be deleted.

### QUALITY INFORMATION SUMMARY OF THE FINISHED PHARMACEUTICAL PRODUCT OR VACCINE APPROVED BY THE REFERENCE SRA (QIS-SRA(crp))

#### Pharmaceutical product or vaccine subject to reference SRA collaborative procedure

**A1 Reference SRA**

**A2. Product registration/authorization number assigned by the reference SRA**

**A3.** Proprietary name of finished pharmaceutical product (FPP) in the reference SRA country/region

**A4.** Innovator or multisource (generic) FPP

**A5.** Name of the holder of the reference SRA marketing authorization and official address

**A6.** International Nonproprietary Name (INN) of active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, solvate, etc.)

**A7.** Dosage form and strength

**A8.** 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)

**A9.** Primary and secondary packaging material(s) and pack size(s) (all pack types)

**A10.** Storage conditions (as in Product information)

**A11.** Shelf life of FPP (including in-use periods, where applicable)

**A12.** 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)

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| **A13.** FPP 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) |  |

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1. **Information that is considered confidential**

**Information as currently approved by the reference SRA**

**B1.** 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)

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| --- | --- | --- |
| **B2.** Active pharmaceutical ingredient master file/drug master file (APIMF/DMF version number(s) and date(s), if relevant | | |
| Name of API | API manufacturer | APIMF/DMF version number(s) and date(s) |
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| **B3.** API specifications of the FPP manufacturer | | |
| Standard (e.g. BP, Ph.Eur., Ph.Int., USP, in-house)a | |  |
| Specification reference number and version | |  |
| Test | Acceptance criteria | Analytical procedure (type/source/version) |
| Description |  |  |
| Identification |  |  |
| Impurities |  |  |
| Assay |  |  |
| Others, please specify |  |  |
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| --- | --- | --- |
| **B4.** API container closure system and re-test period | | |
| Container closure system | Storage statement | Re-test periodb |
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a BP: British Pharmacopoeia; Ph.Eur: European Pharmacopoeia; Ph.Int.: The International Pharmacopoeia; USP: United States Pharmacopeia.

b Indicate if a shelf life is proposed in lieu of a retest period (e.g. in the case of labile APIs).

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| **B5.** FPP composition (formulation) information | | | | | |
| Component and quality standard | 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, contents of capsule, powder for injection>*

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| Subtotal 1 |  |  |  |  |  |

<*complete with appropriate title, e.g. film-coating*>

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

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| --- | --- | --- | --- |
| **B6.** FPP manufacture | | | |
| Master production document reference number and version | |  | |
| **B7.** FPP specifications | | | |
| Standard (e.g. BP, Ph.Int., USP, in-house)a | | |  |
| Specification reference number and version/ effective date | | |  |
| Test | Acceptance criteria (release) | Acceptance criteria (shelf life) | Analytical procedure (type/source/version) |
| Description |  |  |  |
| Identification |  |  |  |
| Impurities |  |  |  |
| Assay |  |  |  |
| Others, please specify |  |  |  |
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| **B8.** Pharmacokinetic/safety/efficacy-related information used for reference 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 |  | | |

a BP: British Pharmacopoeia; Ph.Eur: European Pharmacopoeia; Ph.Int.: The International Pharmacopoeia; USP: United States Pharmacopeia.

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| **B9.** List of variations pending in the reference SRA up to the date of verification | | |
| Variation number | Variation | Type of variation according to reference SRA regulations |
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| **B10.** Discussion of differences between national application and data approved by the reference SRA | | |
| Deviation reference no. | Data submitted for national registration which deviates from data approved by the reference SRA presented above.  Mention also deviations in content of Product information, especially those related to indications, contraindications and posology. | Explanatory note |
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| **C1.** Confirmation of content and verification by the reference SRA | | |
| Date of completion by the applicant | Name of person representing the applicant who completed the QIS-SRA | Position in the organization |
|  |  |  |
| Date of verification by the reference SRA *Part B10 is exempted from verification* | Person representing the reference SRA who verified the QIS-SRA information | Position in the organization |
|  |  |  |

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#### Change history to QIS-SRA (crp) and Product information

Description of revision/variation

Date of revision (reported variationa)

a Variations approved by the reference SRA **after** national registration of the FPP and affecting **only** the QIS-SRA and/or Product information should be reported in the change history.