Annex IVa of the Guideline on Reliance: Quality Information Summary Of The Finished Pharmaceutical Product Approved By The Reference Institution (RI) (QIS-RI-FPP(crp))

1. **Pharmaceutical product subject to RI collaborative procedure**

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| **A1. Reference Institution (RI)** |
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| **A2. Product registration/authorization number assigned by the RI** |
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| **Information as currently approved by the RI** |
| **A3**. Proprietary name of finished pharmaceutical product (FPP) in the RI country/region |
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| **A4**. Innovator or multisource (generic) FPP |
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| **A5**. Name of the holder of the RI marketing authorization and official address |
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| **A6**. International Nonproprietary Name (INN) of active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, solvate, etc.) |
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| **A7**. Dosage form and strength |
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| **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) |
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| **A9**. Primary and secondary packaging material(s) and pack size(s) (all pack types) |
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| **A10.** Storage conditions (as in Product information) |
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| **A11.** Shelf life of FPP (including in-use periods, where applicable) |
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| **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 RI, 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 that is considered confidential**

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| **Information as currently approved by the RI** |
| **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). |
| **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. colorants, coatings, capsule shells, imprinting inks): |
| **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 RI 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. |
| **B9**. List of variations pending in the RI up to the date of verification |
| Variation number | Variation | Type of variation according to RI regulations |
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| **B10**. Discussion of differences between national application and data approved by the RI |
| Deviation reference no. | Data submitted for national registration which deviates from data approved by the RI 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 RI |
| Date of completion by the applicant | Name of person representing the applicant who completed the QIS-RI | Position in the organization |
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| Date of verification by the RI *Part B10 is exempted from verification* | Person representing the RI who verified the QIS-RI information | Position in the organization |
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| **Change history to QIS-RI (crp) and Product information** |
| Date of revision (reported variationa) | Description of revision/variation |
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| a Variations approved by the RI after national registration of the FPP and affecting only the QIS-RI and/or Product information should be reported in the change history. |