**Annex 4a: QIS-RI-FPP**

**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**

|  |  |
| --- | --- |
| **A1. Reference Institution (RI)** | |
|  | |
| **A2. Product registration/authorization number assigned by the RI** | |
|  | |
|  | |
| **Information as currently approved by the RI** | |
| **A3**. Proprietary name of finished pharmaceutical product (FPP) in the RI country/region | |
|  | |
| **A4**. Innovator or multisource (generic) FPP | |
|  | |
| **A5**. Name of the holder of the RI 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) | |
|  | |
| **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**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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) | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **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) | | | | | |
|  | | |  | | | |  | | | | | |
|  | | |  | | | |  | | | | | |
|  | | |  | | | |  | | | | | |
| **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 | | |  | | | |  | | | | | |
|  | | |  | | | |  | | | | | |
|  | | |  | | | |  | | | | | |
| **B4**. API container closure system and re-test period | | | | | | | | | | | | |
| Container closure system | | | Storage statement | | | | Re-test periodb | | | | | |
|  | | |  | | | |  | | | | | |
|  | | |  | | | |  | | | | | |
| 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>* | | | | | | | | | | | | |
|  |  | | | |  | | |  | |  | |  |
|  |  | | | |  | | |  | |  | |  |
|  |  | | | |  | | |  | |  | |  |
|  |  | | | |  | | |  | |  | |  |
| 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): | | | | | | | | | | | | |
| **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 | |  | | | |  | | | | |  | |
|  | |  | | | |  | | | | |  | |
|  | |  | | | |  | | | | |  | |
|  | |  | | | |  | | | | |  | |
| **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 | | | |
|  | | | |  | | | | |  | | | |
|  | | | |  | | | | |  | | | |
|  | | | |  | | | | |  | | | |
| **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 | | | |
|  | | | |  | | | | |  | | | |
|  | | | |  | | | | |  | | | |
|  | | | |  | | | | |  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |
|  |  | |  |
| 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 organisation |
|  |  | |  |
| **Change history to QIS-RI (crp) and Product information** | | | |
| Date of revision (reported variationa) | | Description of revision/variation | |
|  | | | |
|  | | | |
|  | | | |
|  | | | |
| 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. | | | |