Annex 4a: QIS-RI-FPP

Quality Information Summary Of The Finished Pharmaceutical Product Approved By The Reference Institution (RI) (QIS-RI-FPP(crp))

A. 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)	

B. 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 period[b]			
[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 variation[a])	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.