



EVALUATIONS AND REGISTRATION DIVISION

**APPLICANT'S SCREENING CHECKLIST FOR REGISTRATION OF HUMAN
MEDICINES**

Application number		
Date received		
Date of covering letter		
Generic or International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.		
Proprietary Product or Trade name (if relevant)		
Number of binders		
Screener	Name	Signature & date
Reviewer	Name	Signature & date
Conclusion of the assessment.		
Name and complete address of the applicant		
Applicant's contact person name, phone & email (for correspondence)		
Name and complete address of the Principal		
Name and complete address of the manufacturing site (s) for the FPP		
GMP status of the manufacturing site(s)		
Name and complete address of the manufacturing site (s) for the API		
Samples (At least 2 market packs should have been submitted)		
Country (ies) where the medicine has been registered		
Fee		

SECTION	DOCUMENTS	Submitted?		
		Yes	No	Location and any relevant comments
Module 1	Administrative and Regional Information			
1.0	Cover letter			
1.1	Table of contents of the application including Module 1 (Module 1 – 5)			
1.2	Application information:			
1.2.1	Completed, signed and dated MC8 form in duplicate			
1.2.2	Declaration by the applicant			
1.2.3	A screening checklist indicating that all the sections of the application have been completed and the pages thereof			
1.2.4	Proof of payment of the appropriate fees			
1.2.5	Manufacturing and marketing authorisation(s)/international registration status and/or the WHO certificate of pharmaceutical product (CPP)			
1.2.6	Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (including letter of access and any annexes) / Confirmation of API Prequalification Document (CPQ) <i>See further details under 3.2.S</i>			
1.2.7	Proof of compliance with current Good Manufacturing Practices (cGMP) 1.2.7.1 GMP certification for each FPP manufacturing site {inclusive of secondary packer(s)} 1.2.7.2 GMP certification for each API manufacturing site, issued by an NRA			
1.2.8	Biowaiver requests in relation to conducting a comparative bioavailability study A biowaiver application is compulsory when: 1.2.8.1 There is no accompanying BE study conducted using that particular strength of that product 1.2.8.2 The FPP is in a non-solution dosage form (i.e. suspensions, tablets, capsules etc.) 1.2.8.3 Route of administration is non-intravenous			

	1.2.8.4 The drug is meant to act systemically 1.2.8.5 FPP is non-SRA/WHO approved N.B. A biowaiver is not acceptable for FPPs containing BCS class II or IV APIs <u>and</u> where conditions ii to v above are met <u>and</u> where there is no BE study for <u>any</u> other strengths of that product.			
1.3	Product information:			
1.3.1	Summary of product characteristics (SmPC)			
1.3.2	Labelling (primary and secondary packaging)			
1.3.3	Package insert and patient information leaflet			
1.4	Regional summaries:			
1.4.1	Bioequivalence application form (BAF)			
1.4.2	Quality information summary (QIS) The QIS template should be completed to provide a <i>condensed summary</i> of the <i>key quality information</i> for the PD and constitutes part of the submission package. The QIS provides an accurate record of technical data in the PD. The QIS is a condensed version of the QOS-PD and represents the final agreed upon <i>key API and FPP information</i> from the PD assessment (inter alia identification of the manufacturer[s]/site addresses API/FPP specifications, stability conclusions and relevant commitments).			
1.6	Samples (e.g. FPP, device(s), certificates of analysis)			
Module 2	COMMON TECHNICAL DOCUMENT (CTD) SUMMARIES			
2.1	CTD Table of contents (Module 2 – 5)			
2.2	CTD Introduction			
2.3	Quality Overall Summary – product dossier (QOS) (In MS WORD format)			
2.4	Non- clinical overview – <i>Applicable to biologics and/or NCEs</i>			
2.5	Clinical overview			
2.6	Non – clinical written and tabulated summaries – generally not applicable for multisource products <i>Applicable to biologics and/or NCEs</i>			
2.7	Clinical summary – generally not applicable for multisource products			

Module 3	QUALITY			
3.1	Table of contents of Module 3			
3.2.S	ACTIVE PHARMACEUTICAL INGREDIENTS			
	API information submission option chosen by applicant: i. API Master File/ Drug Master File and letter of access ii. Valid *CEP/CPQ duly signed by the holder on behalf of the applicant (including any annexes) iii. Full details in the product dossier <i>Please indicate i., ii or iii under the Yes column with any relevant comments</i>			
NOTE:	*If a valid CEP/CPQ is provided, note that only the following information will be required: 3.2. S.1.3 <i>General properties</i> - discussions on any relevant API properties not controlled by the CEP and Ph.Eur. monograph, e.g. dose solubility, polymorphs 3.2. S.2 – If sterility of the FPP is based upon the sterile manufacture of the API then data on the sterilisation process together with full validation data should be provided (<i>applicable to CPQ option only</i>) 3.2. S.3.1 <i>Elucidation of structure and other characteristics</i> - studies to identify polymorphs and particle size distribution. All 3.2. S.4 sections – the FPP manufacturer should provide this information. 3.2.S.5 Reference standards or materials – information on the FPP manufacturer's standards - 3.2. S.6 <i>Container closure system</i> - specifications and test methods. Exception: where the CEP specifies a re-test period.			

	- 3.2. S.7 Stability - exception: where the CEP specifies a re-test period $\geq$ the re-test period proposed by the applicant or in case of a CPQ , data to support the retest period if either the proposed retest period is longer or the proposed storage conditions are at a higher temperature or humidity to that of the prequalified API			
3.2.S.1	General information			
3.2.S.1.1	Nomenclature			
3.2.S.1.2	Structure			
3.2.S.1.3	Dose/solubility data (across physiological pH range at 37°C) for BCS Class II, Class IV, unclear/ unknown BCS Class APIs used to manufacture oral solid dosage forms.			
	Polymorphism information for BCS Class II, Class IV and unclear/ unknown BCS Class APIs used to manufacture oral solid dosage forms, oral suspensions and for parenteral suspensions administered via non-intravenous routes.			
3.2.S.2	MANUFACTURE			
3.2.S.2.1	Manufacturer and address			
3.2.S.2.2	Description of manufacturing process and process controls			
3.2.S.2.3	Control of raw materials			
3.2.S.2.4	Control of critical steps and intermediates			
3.2.S.2.5	Process validation and/or evaluation for sterile APIs			
3.2.S.2.6	Manufacturing process development			
3.2.S.3	CHARACTERISATION			
3.2.S.3.1	Particle size distribution data for BCS Class II, Class IV and unknown/unclear BCS Class APIs used to manufacture non-solution oral dosage forms. Also critical for APIs used to manufacture creams, ointments, non-IV injections that are suspensions, etc.			
	Confirmation of API polymorphic form produced (e.g., diffractograms) - for APIs of BCS Class II, Class IV and unknown/unclear BCS Class used to			

	manufacture non-solution oral dosage forms. May be critical for APIs used to manufacture non-IV injections that are suspensions			
3.2.S.3.2	Impurities			
3.2.S.4	CONTROL OF API			
3.2.S.4.1	FPP manufacturer's API Specifications			
3.2.S.4.2	FPP manufacturer's API Analytical Procedures			
3.2.S.4.3	FPP manufacturer's API analytical method validation of analytical procedures			
3.2.S.4.4	Batch analysis data for three batches including API batch used to manufacture the clinical batch or bioequivalence batch			
3.2.S.4.5	Justification of specifications			
3.2.S.5	Reference standards			
3.2.S.6	Container closure system			
	Specifications			
	Test Methods			
3.2.S.7	Stability			
3.2.S.7.1	Stability Summary and Conclusions			
3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment			
3.2.S.7.3	Forced degradation studies Critical for NCEs (New Chemical Entities) Non-critical for non-NCEs			
	Accelerated Stability Studies & Real-Time Stability Studies ~ At point of submission, at least 12 months of real time data and 6 months of accelerated data on at least 3 primary batches of the API should be provided			
3.2.P	FINISHED PHARMACEUTICAL PRODUCT (FPP)			
3.2.P.1	Description and Composition of the FPP			
	Section 77A Undesirable Ingredients present in formulation			
3.2.P.2	Pharmaceutical Development			

	<i>For sterile products:</i> <i>Filter-drug product compatibility studies</i> <i>Filter microbial retention studies</i> <i>Filter integrity studies</i>			
3.2.P.3	MANUFACTURE			
3.2.P.3.1	Manufacturer(s) name(s) and physical address(es)			
3.2.P.3.2	Batch Formula			
3.2.P.3.3	Description of manufacturing process and process controls			
3.2.P.3.4	Control of critical steps and intermediates			
3.2.P.3.5	Process validation ~For three consecutive batches At least a process validation study protocol and commitment should be provided <i>For sterile products:</i> <i>Manufacturing process validation</i> <i>Media fill studies</i> <i>Validation of sterilisation of vials, rubber bungs, etc</i>			
3.2.P.4	Control of Excipients			
3.2.P.4.1	Specifications			
3.2.P.4.2	Analytical Procedures Only required if specifications are non-compendial			
3.2.P.4.3	Validation of analytical procedures			
3.2.P.4.4	Justification of specifications			
3.2.P.4.5	Excipients of Human or Animal Origin BSE / TSE free certification			
3.2.P.4.6	Novel excipients Provide information provided as per full API Section			
3.2.P.5	Control of FPP			
3.2.P.5.1	Specification(s) of Finished Pharmaceutical Product (FPP)			
3.2.P.5.2	Analytical Procedures			
3.2.P.5.3	Validation of Analytical Procedures			
3.2.P.5.4	Batch analyses data for at least two batches			
3.2.P.5.5	Characterisation of Impurities			
3.2.P.6	Reference Standards			
3.2.P.7	Container- Closure System			
	Test Methods			
	Specifications			
3.2.P.8	Stability			

3.2.P.8.1	Stability summary and conclusions			
3.2.P.8.2	Post-approval stability protocol and stability commitment			
3.2.P.8.3	Photostability Data			
	Accelerated stability data at 40°C/75%RH (for non-cold chain products) <i>Accelerated conditions will differ for refrigerated items, e.g., 25°C/60%RH</i> At least 6 months of data for at least two batches			
	Long-term stability data at 30°C/65%RH or 30°C/75%RH (for non-cold chain products). <i>Long-term conditions will differ for refrigerated items, e.g., 5±3°C</i> At least 12 months of data for at least two batches			
3.2.R	REGIONAL INFORMATION			
3.2.R.1.1	Executed production document(s) For applications accompanied by clinical data, the executed BMR should be for the batch(es) used in the clinical study			
3.2.R.1.2	Master production documents			
Module 4	NON-CLINICAL DATA			
	i. Critical for NCEs and biologics. ii. Not required for generics			
4.1	Table of contents of Module 4			
4.2	Study reports			
4.3	Literature references			
Module 5	CLINICAL STUDY REPORTS			
5.1	Table of contents of Module 5			
5.2	Tabular listing of all clinical studies			
5.3	Clinical study reports			
5.3.1	Reports of biopharmaceutical studies			
5.3.2	Case report forms and individual patient listings			
5.4	Literature references			