FIFARMA

Common Technical Document

Mapping to Reliance List

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CMC Module 2/3	Section	Module 1	Module 2	Module 3
Certification of the manufacturing facilities.	1. For the drug substance: Date(s) on which the manufacturing facilities were inspected or certified	EMA Application form Annex 5.9		
	2.For the drug substance: Description of the activities that were done for the inspection or certification of the manufacturing facilities.	EMA Application form Annex 5.9		
	3.For the drug substance: The address(es) of the inspected or certified manufacturing facilities.	EMA Application form Section 2.5.3. Manufacturer(s) of the active substance(s) and site(s) of manufacture and Annex 5.9	2.3.S.2 Manufacture (name, manufacturer)	3.2.S.2.1 Manufacturer(s) (name, manufacturer)
	4.For the finished pharmaceutical product: Date(s) on which the manufacturing facilities were inspected or certified.	"EMA Application form Annex 5.9"		
	5.For the finished pharmaceutical product: Description of the activities that were done for the inspection or certification of the manufacturing facilities.	"EMA Application form Annex 5.9"		
	6.For the finished pharmaceutical product: The address(es) of the inspected or certified manufacturing facilities.	EMA applicatoin form 2.5.2. Manufacturer(s) of the medicinal product and site(s) of manufacture and Annex 5.9	2.3.P.3 Manufacture (name, dosage form)	3.2.P.3.1 Manufacturer(s) (name, dosage form)
Raw materials (e.g., manufacture, quality and stability of the API, excipients).	"1. Description of the analytical methods."		2.3.S.4 Control of drug substance (name, Manufacturer)	3.2.S.4.2 Analytical procedures (name, Manufacturer)
	"2.Description of the container closure system."		2.3.S.6 Container Closure system (name, manufacturer)	3.2.S.6 Container Closure system (name, manufacturer)
	"3.Description of the critical quality attributes (CQA)."			3.2.S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)

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	"4.Description of the manufacturing process."		2.3.S.2 Manufacture (name, manufacturer)	"3.2.S.2.6 Manufacturing process development (name, manufacturer)"
	"5.Description of the storage conditions."		2.3.S.7 Stability (name, manufacturer)	"3.2.S.2.2 Description of manufacturing process and process controls (for biotech) and 3.2.S.7.1 Stability summary and conclusions (name, manufacturer)"
	6.List of intermediate products.			"3.2.S.2.2 Description of manufacturing process and process controls, 3.2.S.2.4 control of critical steps and intermediates. "
	7.List of reference materials.		2.3.S.5 Reference standards or Materials (name, manufacturer)	"3.2.S.5 Reference standards or materials (name, manufacturer)"
Finished pharmaceutical product (e.g., manufacture, quality and stability of the finished dosage form).	"1. Description of the analytical methods."		"2.3.P.5 Control of drug product (name, dosge form)"	"3.2.P.4.2 Analytical procedures (name, dosage form)"
	"2.Description of the container closure system."		"2.3.P.7 Container closure system (name, dosage form)"	"3.2.P.7 Container Closure system (name, dosage form)"
	"3.Description of the critical quality attributes (CQA)."			"3.2.P.3.4 Controls of Critical Steps and Intermediates (name, dosage form)"
	"4.Description of the manufacturing process."		"2.3.P.3 Manufacture (name, dosage form)"	"3.2.P.3.3 Description of Manufacturing process and process controls (name, dosage form)"
	5.List of reference materials.		"2.3.P.6 reference standards of materials (name, dosage form)"	"3.2.P.6 Reference standards or materials (name, dosage form)"

CMC Module 2/3	Section	Module 1	Module 2	Module 3
	"6.Qualitative list of raw materials, including excipients."	"1.3.1 Summary of product characteristics, labelling and packaging leaflet"	"2.3.P.4 Control of excipients (name, dosage form), 2.3.A.3 Excipients"	"3.2.P.4 Control of excipients (name, dosage form)"
	7.Quantitative list of raw materials, including excipients.		"2.3.P.4 Control of excipients (name, dosage form), 2.3.A.3 Excipients"	"3.2.P.4 Control of excipients (name, dosage form)"
Transportation and storage conditions	Description of the atmospheric conditions to be kept when storing finished pharmaceutical product.	"1.3.1 Summary of product characteristics, labelling and packaging leaflet"		
	2.Description of the time in which the finished pharmaceutical product can be stored without compromising its integrity	"1.3.1 Summary of product characteristics, labelling and packaging leaflet"		

CMC Module 2/4	Section	Module 1	Module 2	Module 4
Non Clinical Studies	"1. List of studies performed."		"List of toxicologic studies in 2.6.6.1 Brief Summary"	"4.1 Table of contents of module 4"
	"2.Description of the purpose of each study."		In 2.6.6.8 (for toxicity studies) and 2.6.6.5 (for Carcinogenicity studies)	"Study reports: 4.2.1 - 4.2.3.7.7"
	"3.Description of the study setup."			"Study reports: 4.2.1 - 4.2.3.7.7"
	"4.Description of the models used."		"2.6.4.8 Other Pharmacokinetic studies"	"Study reports: 4.2.1 - 4.2.3.7.7"
	"5.Description of the analytical methods used."		"2.6.5.2 Analytical methods and Validation reports"	"Study reports: 4.2.1 - 4.2.3.7.7"
	"6.Description of granular results."			"Study reports: 4.2.1 - 4.2.3.7.7"
	"7.Description of GLP certifications."		"2.6.6.1 Brief summary, also tables - ask"	"Study reports: 4.2.1 - 4.2.3.7.7"
	"8.Description of overall results."		"2.6.2.1 Brief summary (pharmacology) 2.6.6.1 Brief Summary (toxicology)"	"Study reports: 4.2.1 - 4.2.3.7.7"

CMC Module 2/5	Section	Module 1	Module 2	Module 5
"Therapeutic indication and dose."	"1.Description of the approved dose and its dose modifications if applicable."	1.3.1 SPC, labelling and pckaging leaflet		
	"2.Description of the approved therapeutic indication."	1.3.1 SPC, labelling and pckaging leaflet		
"Clinical studies (e.g., pivotal and supplemental)."	"1.Description of Good Clinical Practices certifications."	Cover Letter	"2.5 Clinical Overview "	"Clinical Study reports 5.3.1 - 5.3.7 and appendices"
	"2.Description of granular results."			"Clinical Study reports 5.3"
	"3.Description of overall results."		Clinical Summary 2.7.1 - 2.7.4.5	"Clinical Study reports 5.3.1 - 5.3.7"
	"4.Description of the analytical methods used."		"Summary of Biopharmaceutical studies and associated analytical methods 2.7.2"	"Reports of Bioanalytical and Analytical methods for human studies 5.3.1.4"
	5.Description of the purpose of each study.		"Summary Tables 2.7.1.1 - 2.7.2.2"	Table 5.1 Listing of clinical studies
	6.Description of the size of studied populations.		"Summary Tables 2.7.1.1 - 2.7.2.3"	"Table 5.1 Listing of clinical studies"
	"7.Description of the study setup."		"Summary Tables 2.7.1.1 - 2.7.2.4"	"Clinical Study reports 5.3.1 - 5.3.6"

CMC Module 2/5	Section	Module 1	Module 2	Module 5
	8.Description of the types of studied populations.		"Summary Tables 2.7.1.1 - 2.7.2.5"	"Clinical Study reports 5.3.1 - 5.3.7"
	9.List of studies performed		"Summary Tables 2.7.1.1 - 2.7.2.6"	Tabular Listing of all clinical studies 5.3
"Effects and precautionary actions in diverse populations."	1.Description of the effects of the finished pharmaceutical product among different types of populations.	1.3.1 SPC, labelling and pckaging leaflet	"Study Populations 2.7.3.3.1 - Comparison of results in Sub-populations 2.7.3.3.1"	"Intrinsic Factor PK study reports 5.3.3.3 - Extrinsic factor PK study reprts 5.3.3.5"
	2.May not be applicable. Description of the precautionary actions when using the finished pharmaceutical product by different types of populations.	1.3.1 SPC, labelling and pckaging leaflet	"2.5.5 (methods to prevent, mitigate, or manage adverse events)"	
Benefit-Risk Assessment.	Description of the context in which the decision was taken.	Assessment report - EPAR, in annex		
	"2.Description of the Quality conclusion."	Assessment report - EPAR, in annex		
	"3.Description of the Non-clinical conclusion."	Assessment report - EPAR, in annex		
	"4.Description of the Clinical conclusion."	Assessment report - EPAR, in annex		
	"5.Description of the identified benefits."	Assessment report - EPAR, in annex		

CMC Module 2/5	Section	Module 1	Module 2	Module 5
	"6.Description of the uncertainties associated with benefits."	Assessment report - EPAR, in annex		
	"7.Description of the identified risks."	Assessment report - EPAR, in annex		
	"8.Description of the uncertainties associated with risks."	Assessment report - EPAR, in annex		
	"9.Description of the conclusion of the Benefit-Risk Assessment."	Assessment report - EPAR, in annex		
	"Assessment of the ethnic factors."	"1.Description of a section dedicated to the assessment of the ethnic factors within the Benefit-Risk Assessment."	"Assessment report (may not be relavant for relying NRAs)"	
	"Other obligations to complete after the recommendation /approval"	"2.Description of the Risk Management Plans."	"1.8 Pharmacovigilance"	
	"3.Description of the post-authorisation commitments."	"In module 1 - fixed component cover"		

Section	Comments
"List of outstanding issues (CMC module 2/5)"	These are in fact the Questions raised on the application - will not be in the CTD or in the assessment report but can be supplied separately