

Section	Section Title	NDA	NDA-V	GDA	GDA-V/CECA	MAV1	MAV1-V	MAV2	MIV1-PI	MIV1-PI-V	MIV1-CMC	MIV1-CMC-V	MIV2-N	MIV2-DnT	PV-EDU/RMP Materials	PV-PBRER/RMP Reports	Reg Cond (non-PV)	DMF	Baseline	Transfer of Application	Other Regulatory Activity	
1	Module 1 Administrative and Prescribing Information																					
1.0	Correspondence																					
1.0.1	Cover Letter	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	P	E
1.0.2	Note to Evaluator	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
1.0.3	Correspondence with HSA	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
1.0.4	Response to Input Request	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.0.5	Meeting Information	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
1.2	Administrative Information																					
1.2.1	Application Forms	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV
1.2.2	Checklists																					
1.2.2.1	Appendix 2a Checklist	E	E	E	E	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.2.2	Appendix 2b Checklist	NV	NV	NV	NV	E	E	E	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.2.3	Appendix 13a/14a Checklist	NV	NV	NV	NV	NV	NV	NV	E	E	W	W	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.2.4	Appendix 13b/14b Checklist	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	E	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.2.5	Appendix 13c/14c Checklist	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	E	NV	NV	NV	NV	NV	NV	XE	NV
1.2.3	Annexes																					
1.2.3.1	Letter of Authorisation from Product Owner	W	W	W	W	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	NV	XE	NV
1.2.3.2	Change in Applicant																					
1.2.3.2.1	Letter of Authorisation from Product Owner to New Registrant	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	P	NV
1.2.3.2.2	Written Confirmation of Hand-over of Dossier	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	P	NV
1.2.3.3	Declaration for Verification or Verification-CECA	NV	E	NV	E	NV	E	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.3.4	Patent Declaration																					
1.2.3.4.1	Patent Declaration Form	E	E	E	E	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.3.4.2	Evidence of Authorisation	E	E	E	E	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.2.4	Table of summary of changes	NV	NV	NV	NV	E	E	E	E	E	E	E	E	E	NV	NV	NV	P	NV	XE	NV	
1.2.A	Additional Administrative Information	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
1.3	Product Information																					
1.3.1	Outer Carton Labels (OCL)																					
1.3.1.1	Approved - OCL	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	NV	NV	NV	NV	NV	XE	NV	

1.3.1.2	Clean Proposed - OCL	W	W	W	W	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.1.3	Annotated - OCL	NV	NV	NV	NV	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.2	Inner/Blister Labels (IBL)																				
1.3.2.1	Approved - IBL	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	NV	NV	NV	NV	NV	XE	NV
1.3.2.2	Clean Proposed - IBL	W	W	W	W	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.2.3	Annotated - IBL	NV	NV	NV	NV	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.3	Package Insert (PI)																				
1.3.3.1	Approved - PI	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	NV	NV	NV	NV	NV	XE	NV
1.3.3.2	Clean Proposed - PI	W	W	W	W	W	W	W	W	W	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.3.3	Annotated - PI	NV	NV	NV	NV	W	W	W	W	W	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.4	Patient Information Leaflet (PIL)																				
1.3.4.1	Approved - PIL	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	XW	NV	NV	NV	NV	NV	XE	NV
1.3.4.2	Clean Proposed - PIL	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.4.3	Annotated - PIL	NV	NV	NV	NV	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.5	Approved Foreign Labelling (SPC/PI/PIL)																				
1.3.5.1	SPC/PI/PIL - Reference Agency	P	E	P	E	P	E	P	P	E	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.5.2	SPC/PI/PIL - Proof of Approval Agency	W	W	W	W	W	W	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.5.3	SPC/PI/PIL - Other Agency	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.3.6	Declarations on Foreign Text/Braille	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.4	Information about the Experts																				
1.4.1	Quality	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.4.2	Nonclinical	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.4.3	Clinical	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.5	Master Files and Certificates of Suitability																				
1.5.1	DMF Acknowledgement Email	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.5.2	Letter of Access																				
1.5.2.1	DMF Letter of Access	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	P	NV	XE	NV
1.5.2.2	PMF Letter of Access	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.5.3	EMA Certificate for Plasma Master File (PMF)	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.5.4	Certificate of Suitability (CEP)	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.6	Environmental Risk Assessment																				
1.6.1	Non-GMO	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.6.2	GMO	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.7	Good Manufacturing Practice																				
1.7.1	GMP Certificates or Proof of GMP Compliance																				
1.7.1.1	Drug Substance Manufacturers	E	E	E	E	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	P	NV	XE	NV
1.7.1.2	Finished Pharmaceutical Product (FPP) Manufacturers	E	E	E	E	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.7.1.3	Batch Releaser	E	E	E	E	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV

1.7.2	Description of Batch Numbering System	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.7.3	HSA GMP Conformity Assessment Application																				
1.7.3.1	Application for GMP Evidence Evaluation	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.7.3.2	Application for Requesting an Overseas GMP Audit	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.7.A	Additional GMP Documents	P	P	P	P	NV	NV	NV	NV	NV	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.8	Information Relating to Pharmacovigilance																				
1.8.1	Singapore-Specific Annex	P	P	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.8.2	Reference RMP	P	P	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.8.3	Educational/RMP Materials																				
1.8.3.1	Clean Proposed - Educational/RMP Materials	P	P	P	P	P	P	P	P	P	NV	NV	P	NV	W	NV	NV	NV	NV	XE	NV
1.8.3.2	Annotated - Educational/RMP Materials	P	P	P	P	P	P	P	P	P	NV	NV	P	NV	W	NV	NV	NV	NV	XE	NV
1.8.3.3	Finalised Artwork - Educational/RMP Materials	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	P	NV	NV	NV	NV	XE	NV
1.9	Foreign Regulatory Information																				
1.9.1	Registration Status in Other Countries	W	E	W	E	W	W	W	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.9.2	Proof of Approval																				
1.9.2.1	Proof of Approval from Reference Countries	P	E	P	E	P	E	P	P	W	P	E	P	P	NV	NV	NV	NV	NV	XE	NV
1.9.2.2	Proof of Approval from Other Countries	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.9.3	Data Set Similarities and Differences	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.9.4	Foreign Evaluation/Assessment Reports	P	E	P	E	P	E	P	P	P	P	P	P	P	NV	NV	NV	NV	NV	XE	NV
1.9.5	Appendix 18A Dossier Clarification Supplement	P	NV	P	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.9.6	Declaration on Rejection, Withdrawal and Deferral	E	E	E	E	E	E	W	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	NV	XE	NV
1.A	Additional Data																				
1.A.1	[DESCRIPTION]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	NV	P	P
5.3.6	Reports of Postmarketing Experience																				
node-extension	[DESCRIPTION]	P	P	P	P	P	P	P	P	P	NV	NV	P	NV	NV	E	NV	NV	NV	XE	NV

E	Error	The document is required in the sequence being submitted. If no document is present, it will lead to a validation error and the sequence being rejected.
W	Warning	The document is expected in the sequence. If no document is present, it will lead to a warning and could possibly lead to the sequence being rejected.
P	Possible	The document is required in certain circumstances for the particular sequence type, but not all. A list of the sections where content has been provided will be created by the validator for review purposes in content screening. The absence of a required document could lead to the sequence being rejected.
XE	Excluded: Error	The document is not allowed for the particular Submission Type and will result in an Error if included.
XW	Excluded: Warning	The document is not expected for the particular Submission Type and will result in a Warning if included.
NV	Not Validated	The presence or absence of the document is not checked in the electronic validation of the particular Sequence Type.
	Not Yet Defined	Not yet planned within the scope of the eCTD.