DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

CHECKLIST ON DOCUMENTS SUBMITTED
PART II - SECTION 2: QUALITY REQUIREMENTS FOR DRUG PRODUCT

PRODUCT:	**REFERENCE NO:**

No.	**Documents Required**		**APPLICANT**					**DRU**	**DRU REMARKS**
			APPLICATION TYPE						
			NCE	**Biotech**	**MaV**	**MiV**	**G**		
SECTION A – Drug Product									
	Table of Contents		☐	☐	☐	☐	☐	☐	
SECTION B – Quality Overall Summary									
P1.	**General Information**								
	1.1	Description (Physical Characteristics)	☐	☐	*☐	*☐	☐	☐	
	1.2	Composition (Complete Formula)	☐	☐	*☐	*☐	☐	☐	
P2.	**Pharmaceutical Development**								
	2.1	Information on Development Studies	☐	☐				☐	
	2.2	Components of Drug Product	☐	☐				☐	
		• Literature data.			*☐	*☐	☐	☐	
	2.3	Finished Product							
		• Formulation Development	☐	☐			☐	☐	
		• Overages	☐	☐			☐	☐	
		• Physicochemical & Biological Properties	☐	☐			☐	☐	
	2.4	Manufacturing Process Development	☐	☐				☐	
	2.5	Container Closure System	☐	☐			☐	☐	
	2.6	Microbiological Attributes	☐	☐	*☐		☐	☐	

No.	Documents Required		APPLICANT					DRU	DRU REMARKS
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			NCE	Biotech	MaV	MiV	G		
	2.7	Compatibility	☐	☐				☐	
		• Literature data.			*☐	*☐	☐	☐	
P3.	**Manufacture**								
	3.1	Batch Formula	☐	☐	*☐		☐	☐	
	3.2	Manufacturing Process and Process Control	☐	☐	*☐	*☐	☐	☐	
	3.3	Controls of Critical Steps and Intermediates	☐	☐			☐	☐	
	3.4	Process Validation and/or Evaluation	☐	☐			☐	☐	
P4.	**Control of Excipients**								
	4.1	Specifications	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
	4.2	Analytical Procedures	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
	4.3	Excipients of Human and Animal Origin	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
	4.4	Novel Excipients	☐	☐				☐	
P5.	**Control of Finished Products**								
	5.1	Specifications	☐	☐	*☐	*☐	☐	☐	
		• Certificate of Analysis of <u>two recent batches</u> of finished product.	☐	☐	*☐	*☐	☐	☐	
	5.2	Analytical Procedures	☐	☐	*☐	*☐	☐	☐	

No.	Documents Required		APPLICANT					DRU	DRU REMARKS
			APPLICATION TYPE						
			NCE	Biotech	MaV	MiV	G		
	5.3	Validation of Analytical Procedures	☐	☐	*☐	*☐	☐	☐	
	5.4	Batch Analyses	☐	☐				☐	
		• A tabulated summary of batch analyses should be provided.			☐	☐	☐	☐	
	5.5	Characterisation of Impurities	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
	5.6	Justification of Specification	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
P6.	**Reference Standards or Materials**		☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			*☐	*☐	☐	☐	
P7.	**Container Closure System**		☐	☐	*☐	*☐	☐	☐	
P8.	**Stability**								
		Stability Report	☐	☐	*☐		☐	☐	
P9.	**Product Interchangeability**				*☐		☐	☐	

Note: Please refer to the **Guide to Application for Registration of Medicinal Products** for the specific requirements of each Application Type

Key:

*****	**:**	If required	**MaV**	**:**	Major Variation
NCE	**:**	New Chemical Entity	**MiV**	**:**	Minor Variation
Biotech	**:**	Biotechnological Products	**G**	**:**	Generics