DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

CHECKLIST ON DOCUMENTS SUBMITTED
PART II - SECTION 1: QUALITY REQUIREMENTS FOR DRUG SUBSTANCE

PRODUCT:	**REFERENCE NO:**

No.	**Documents Required**		**APPLICANT** APPLICATION TYPE					**DRU**	**DRU REMARKS**
			NCE	**Biotech**	**MaV**	**MiV**	**G**		
SECTION A – Drug Substance									
	Table of Contents		☐	☐	☐	☐	☐	☐	
SECTION B – Quality Overall Summary									
S1.	**General Information**								
	1.1	Nomenclature	☐	☐	*☐		☐	☐	
	1.2	Structure	☐	☐			☐	☐	
	1.3	General Properties	☐	☐	*☐		☐	☐	
S2.	**Manufacture**								
	2.1	Manufacturer(s) Name and Address	☐	☐			☐	☐	
	2.2	Description of Manufacturing Process and Process Controls	☐	☐				☐	
	2.3	Quality Control of Starting Materials	☐	☐				☐	
	2.4	Controls of Critical Steps and Intermediates	☐	☐				☐	
	2.5	Process Validation and/or Evaluation	☐	☐				☐	
	2.6	Manufacturing Process Development	☐	☐				☐	

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			APPLICATION TYPE						
			NCE	Biotech	MaV	MiV	G		
S3.	**Characterisation**								
	3.1	Elucidation of Structure and Other Characteristics	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.			☐	☐	☐	☐	
	3.2	Impurities	☐	☐				☐	
		• Compendial requirements or equivalent information from the manufacturer.					☐	☐	
S4.	**Control of Drug Substance**								
	4.1	Specification	☐	☐				☐	
		• Compendial specifications or equivalent information from the manufacturer.			☐	☐	☐	☐	
	4.2	Analytical Procedures	☐	☐				☐	
		• Compendial methods or equivalent information from the manufacturer.			☐	☐	☐	☐	
	4.3	Validation of Analytical Procedures	☐	☐				☐	
		• Required for non-compendial method only.			☐	☐	☐	☐	
	4.4	Batch Analyses	☐	☐				☐	
		• Analytical Reports of <u>three recent batches</u> is required.	☐	☐				☐	
	4.5	Justification of Specification	☐	☐				☐	
S5.	**Reference Standards or Materials**		☐	☐				☐	
		• Compendial requirements or equivalent information from manufacturer.			*☐	*☐	☐	☐	

No.	Documents Required	APPLICANT					DRU	DRU REMARKS
		APPLICATION TYPE						
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S6.	**Container Closure System**	☐	☐				☐	
S7.	**Stability**							
	Stability Report	☐	☐				☐	
	• Manufacturer stability data or equivalent information.			*☐	*☐	☐	☐	
S8.	**Other Data, if any**	☐	☐	☐	☐	☐	☐	

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