APPENDIX 3: ANCILLARY DRUG DOSSIER REQUIREMENT FOR MEDICAL DEVICE-DRUG COMBINATION PRODUCT

Part I: General Information	
No.	**Section A: Combination Product Particulars**
1.	Combination Product Name
2.	Name & Strength of Active Substance and Excipient
3.	Dosage Form
4.	Product Description
5.	Pharmacodynamics
6.	Pharmacokinetics
7.	Indication
8.	Recommended Dose
9.	Route of Administration/Mode of Delivery
10.	Contraindication
11.	Warning and Precautions
12.	Interaction with Other Medicaments (If Applicable)
13.	Pregnancy and Lactation (If Applicable)
14.	Side Effects (If Applicable)
15.	Symptoms and Treatment of Overdose (If Applicable)
16.	Storage Condition (If Applicable)
17.	Shelf Life (If Applicable)
18.	Declaration of human/ animal origin (If Applicable)
No.	**Section B: Drug Product Formula**
1.	Batch Manufacturing Formula
No.	**Section C: Mock-up Label**
1.	General Labelling Requirement “Controlled Medicine/ Ubat Terkawal” (for Scheduled poison only unless exempted)
2.	Specific labelling requirement as stated in DRGD (if applicable)

PART II: QUALITY OF DRUG COMPONENT	
1.	Information on Development Studies
2.	Manufacturing Process and Process Controls
3.	Control of Excipients (if applicable)
	a. Specifications of Excipient
	b. Justification of Specifications (if applicable)
4.	Control of Drug Substances
	a) Nomenclature, Structure of Drug Substance, General Properties
	b) Manufacturer Name and Address
	c) Description of Manufacturing Process and Process Controls (only for biologic component)
	d) Controls of Materials (only for biologic component)
	e) Controls of Critical Steps and Intermediates (only for biologic component)
	f) Process Validation and/or Evaluation (only for biologic component)
	g) Manufacturing Process Development (only for biologic component)
	h) Elucidation of Structure and Characteristics(only for biologic component)
	i) Impurities (only for biologic component)
	j) Specifications
	k) Batch Analysis (only for biologic component)
	l) Certificate of Analysis for TWO batches
	m) Justification of Specifications (only for biologic component)
	n) Reference Standards or Materials (only for biologic component)
	o) Container Closure System (only for biologic component)
	p) Stability (only for biologic component)
PART III: NON CLINICAL DOCUMENT (Applicable only to New Chemical Entity and Biologic Component)	
	Section A: Table of Contents
No.	**Section B: Nonclinical Overview**
1.	Overview of the Nonclinical Testing Strategy
2.	Pharmacology
3.	Pharmacokinetics

4.	Toxicology
5.	Other Non-Clinical Study
6.	Integrated Overview & Conclusions
7.	List of Literature Citations
No.	**Section C: Nonclinical Written and Tabulated Summaries**
No.	**Section D: Nonclinical Study Reports**
No.	**Section E: List of Key Literature References**
PART IV: CLINICAL DOCUMENT (Applicable only to category New Chemical Entity and Biologic Component)	
No.	**Section A: Table of Contents**
No.	**Section B: Clinical Overview**
1.	Product Development Rationale
2.	Overview of Biopharmaceutics
3.	Overview of Clinical Pharmacology
4.	Overview of Efficacy
5.	Overview of Safety
6.	Benefits & Risks Conclusions
No.	**Section C: Clinical Summary**
1.	Summary of Biopharmaceuticals Studies and Associated Analytical Methods
2.	Summary of Clinical Pharmacology Studies
3.	Summary of Clinical Efficacy
4.	Summary of Clinical Safety
5.	Synopses of Individual Studies
No.	**Section D: Tabular Listing of all Clinical Studies**
No.	**Section E: Clinical Study Reports**