APPENDIX 15

REQUIREMENTS FOR FULL EVALUATION AND ABRIDGED EVALUATION

IMPORTANT NOTES:

1. This appendix is for reference purpose only, where applicable. It may not follow the sequence in the online product registration application forms (in QUEST system).
2. Online application forms are available for different product categories.
3. Applicant shall follow and comply with all requirements in the online application forms as well as any supplementary documentation requested by the Authority.

1. FULL EVALUATION (based on ACTD/ ACTR)

No.	Product Category	Part I	Part II	Part III	Part IV
1.	New Drug Products (NCE)	√	√	√	√
2.	New Drug Products (Hybrid)	√	√	Refer to Appendix 3	Refer to Appendix 3
3.	Biologics	√	√	√	√
4.	Generics (Scheduled Poison)	√	√	Not Applicable	Not Applicable
5.	Generics (Non-Scheduled Poison)	√	√	Not Applicable	Not Applicable
6.	Health Supplements: Disease Risk Reduction Claims (High)	√	√	√	√
7.	Natural Products with Therapeutic Claim	√	√	√	√

Part I - Administrative data and product information
Part II - Data to support product quality (Quality Document)
Part III - Data to support product safety (Nonclinical Document)
Part IV - Data to support product safety and efficacy (Clinical Document)

1.1 General Requirements for Full Evaluation

No.	Step I: Product Validation
1.	Product name (Please provide brand name and full product name)
2.	Dosage Form
3.	Active Ingredient(s) a) Active Ingredient Name b) Strength of Active Ingredient (Quantity unit/ dose) c) Source of Active Ingredient (Animal – e.g. Bovine, Porcine, Ovine or Others/ Plant/ Others) d) Form of Active Ingredient e) Remarks (if any)
4.	Excipient(s) a) Excipient name b) Strength of Excipient (Quantity unit/ dose) c) Function of excipient (e.g. absorbent, diluents, bulking agent, coating agent, anti-caking agent etc.) d) Source of excipient e) Remarks (if any)
5.	Is there any source of ingredients derived from animal origin, including active ingredient? (Yes/ No) If yes, please declare the origin
6.	Manufacturer (Name and Address)
7.	Is there any contract manufacturer involved? (Yes/ No)
8.	Is the product a second source product? (Yes/ No) If yes, please provide: a) Letter of declaration stating that this product is a second source product b) Registration number and product name of the first source
9.	Is there any repacker/ packer involved? (Yes/No)
10	Is the product manufactured for export only? (Yes/No)
11.	Is the product under patent protection? (Yes/No) If yes, please provide: a) Patent protection b) Filling date

No.	Step I: Product Validation
	c) Grant date d) Patent statement
12.	Is this an imported product? (Yes/ No)
13.	Does this product containing any premix? (Yes/ No) a) State your premix form b) Manufacturer name c) Manufacturer address d) Certificate of Good Manufacturing Practice (GMP) e) Formulation f) Manufacturing Process g) Specification of Analysis h) Certificate of Analysis (CoA)
14.	Is this a replacement product? (Yes/ No) If yes, please provide: a) Letter of Declaration stating that this product is a replacement product b) Registration number and product name of the replaced product
15	Does this product need priority review? (Yes/ No) If yes, please provide: a) Application letter b) Priority review status c) Date of grant
16	Request for data exclusivity (DE)? (Yes/ No) Is yes, please provide: a) DCA reference country (for DE) b) Date of approval in reference country c) Duration of DE granted in reference country d) Letter of intent
17	Is this product certified halal? (Yes/ No) If yes, please provide: a) Halal certificate b) certificate number
18	Does this product contain a medical device component? (Yes/ No)

No.	Step I: Product Validation
19.	Is there any other manufacturer (repacker)? (Yes/ No) a) Manufacturer (repacker) name b) Manufacturer (repacker) address c) Certificate of Good Manufacturing Practice (GMP) d) Packaging Process
20.	Is this an imported product? (Yes/ No)

Step II:	
Part I: Administrative Data and Product Information	
No.	**Section A: Product Particulars**
1.	Active Ingredient
2.	Excipient
3.	Dosage Form
4.	Product Description
5.	Pharmacodynamics
6.	Pharmacokinetics
7.	Indication
8.	Recommended Dose
9.	Route of Administration
10.	Contraindication
11.	Warning and Precautions
12.	Interaction of Other Medicaments
13.	Pregnancy and Lactation
14.	Side Effects
15.	Symptoms and Treatment of Overdose
16.	Effects on Ability To Drive And Use Machine
17.	Preclinical Safety Data (*Not applicable for Generics*)
18.	Instructions for Use (e.g., incompatibilities - For injection only)
19.	Storage Condition
20.	Shelf Life

Step II:	
21.	Therapeutic Code/ ATC Code
	Section B: Product Formula
1.	Batch Manufacturing Formula
2.	Attachment of Batch Manufacturing Formula Documentation
	Section C: Particulars of Packing Please refer to **Appendix 23: Patient Dispensing Pack for Pharmaceutical Products**
1.	Pack Size (Fill details by weight/ volume/ quantity)
2.	Immediate Container Type (Container Type and Description) e.g. Aluminium/ Glass/ Metal/ Paper/ Plastic/ Others
3.	Barcode/ Serial No. (Optional)
4.	Recommended Distributor's Price (RM) (Optional)
5.	Recommended Retail's Price (RM) (Optional)
	Section D: Label (Mock-up) For Immediate Container, Outer Carton, Proposed Package Insert, Consumer Medication Information Leaflet (RiMUP) Please refer to: **Appendix 19: General Labelling Requirements** **Appendix 20: Specific Labelling Requirements**
1.	Proposed Label Mock-up for Immediate Container
2.	Proposed Label Mock-up for Outer Carton
3.	Proposed Package Insert
4.	Consumer Medication Information Leaflet (RiMUP)
5.	Label Mock-up for Diluent
	Section E: Supplementary Documentation
1.	Product Owner
2.	Letter of Authorization from Product Owner
3.	Letter of Appointment of Contract Manufacturer from Product Owner (if applicable)
4.	Letter of Acceptance from Contract Manufacturer (if applicable)

Step II:	
5.	Letter of Appointment of the Repacker from the Product Owner
6.	Letter of Acceptance from the Repacker
7.	Certificate of Pharmaceutical Product (CPP)
8.	CPP Issuing Body
9.	Is this product licensed to be placed on the market for use in the exporting country? (Yes/ No) (If no, please state the reason)
10.	Is the product on the market in the exporting country? (Yes/ No) (If no, please state the reason)
11.	Date of Issue of CPP
12.	Date of Expiry of CPP
13.	Certificate of Free Sale (CFS)
14.	CFS Issuing Body
15.	Date of Issue of CFS
16.	Date of Expiry of CFS
17.	Certificate of Good Manufacturing Practice (GMP)
18.	GMP Issuing Body
19.	Date of Issue of Certificate of GMP
20.	Date of Expiry of Certificate of GMP
21.	Is there any other manufacturer(s) involved? (Yes/ No) a) Manufacturer name b) Manufacturer address c) Processing Step d) Certificate of Good Manufacturing Practice (GMP)
22.	Importer (Name and address)
23.	Store (Name and address)
24.	Summary of Product Characteristics (Product Data Sheet)
25.	Company core Data Sheet (CCDS)
26.	Analysis Protocol
27.	Validation of Analysis Protocol
28.	Other Supporting Document (if any)

Step II:	
29.	Worldwide Registration Status
30.	Post-Approval Commitment(s)
31.	TSE Risk-Free Commitment
PART II: QUALITY OF PRODUCT	
	Section P: Drug Product (Finished Product)
	Section A: Quality Overall Summary
	Section B: Table of Contents
	Section C: Body of Data
1.	Description and Composition
2.	Pharmaceutical Development a) Information on Development Studies b) Components of the Drug Product c) Finished Products d) Manufacturing Process Development e) Container Closure System f) Microbiological Attributes g) Compatibility
3.	Manufacturer a) Batch Formula b) Manufacturing Process and Process Controls Manufacturing Process Flowchart c) Control of Critical Steps & Intermediates d) Process Validation and/or Evaluation
4.	Control of Excipients a) Specifications b) Analytical Protocol c) Validation of Analytical Protocol d) Justification of Specifications e) Excipient of Human or Animal Origin f) Novel Excipients
5.	Control of Finished Products a) Specifications b) Analytical Protocol c) Validation of Analytical Protocol d) Batch Analyses Certificate of Analysis (CoA) – 2 batches

Step II:	
	e) Characterization of impurities f) Justification of Specifications g) Viral Inactivation/Removal Studies (applicable to biologics) h) Plasma Master File (PMF) (applicable to biologics) i) Certificate of Fitness for Purpose/ Compliance Certificate/ Plasma Quality/ Certificate (applicable to biologics) j) Batch Release Certificates (2 batches) (applicable to biologics) k) Summary Lot Protocol (2 batches) (applicable to biologics)
6.	Reference Standards or Materials
7.	Container Closure System
8.	Stability
9.	Product Interchangeability/ Equivalent Evidence (Bioavailability/ Bioequivalence, BA/BE) Please refer to **Appendix 16: Bioequivalence (BE) Requirements**
No.	**Section S: Drug Substance** *Refer to **Appendix 11: Regulatory Control of Active Pharmaceuticals Ingredients (APIs)**
1.	General Information a) Nomenclature b) Structure and Attachment for Structure of Drug Substance c) General Properties
2.	Manufacturer a) Manufacturer Name and Address b) Description of Manufacturing Process and Process Controls c) Controls of Materials d) Controls of Critical Steps and Intermediates e) Process Validation and/or Evaluation f) Manufacturing Process Development
3.	Characterisation a) Elucidation of Structure and Characteristics b) Impurities
4.	Control of Drug Substances a) Specifications b) Analytical Procedures c) Validation of Analytical Procedures d) Batch Analysis e) Justification of Specifications
5.	Reference Standards or Materials

Step II:	
6.	Container Closure System
7.	Stability
PART III: NONCLINICAL DOCUMENT	
	Section A: Table of Contents
	Section B: Nonclinical Overview
1.	Overview of the Nonclinical Testing Strategy
2.	Pharmacology
3.	Pharmacokinetics
4.	Toxicology
5.	Integrated Overview & Conclusions
6.	List of Literature Citations
	Section C: Nonclinical Written and Tabulated Summaries
	Section D: Nonclinical Study Reports
	Section E: List of Key Literature References

PART IV: CLINICAL DOCUMENT	
	Section A: Table of Contents
	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
	Section C: Clinical Summary
1.	Summary of Biopharmaceutics 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

	Section D: Tabular Listing of all Clinical Studies
	Section E: Clinical Study Reports
	Section F: **List of Key Literature References, Published Clinical Papers, Latest Periodic Benefit-Risk Evaluation Report (PBRER) and Risk of Management Plan (RMP)**
PART IV: CLINICAL DOCUMENT	
	Section A: Table of Contents
	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
	Section C: Clinical Summary
1.	Summary of Biopharmaceutics 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
	Section D: Tabular Listing of all Clinical Studies
	Section E: Clinical Study Reports
	Section F: **List of Key Literature References, Published Clinical Papers, Latest Periodic Benefit-Risk Evaluation Report (PBRER) and Risk of Management Plan (RMP)**
PART IV: CLINICAL DOCUMENT	
	Section A: Table of Contents
	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
	Section C: Clinical Summary
1.	Summary of Biopharmaceutics 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
	Section D: Tabular Listing of all Clinical Studies
	Section E: Clinical Study Reports
	Section F: **List of Key Literature References, Published Clinical Papers, Latest Periodic Benefit-Risk Evaluation Report (PBRER) and Risk of Management Plan (RMP)**

2. ABRIDGED EVALUATION

No.	Product Category
1.	* Generics (Non-Scheduled Poison)
2.	Health Supplements: a) General or Nutritional Claims b) Functional Claims (Medium)
3.	Natural Products

* Generics (non-scheduled poison) that are evaluated under abridged evaluation include, but are not limited, to the following:

a) Antiseptics/ skin disinfectants;
b) Locally-acting lozenges/ pastilles;
c) Topical analgesic/ counter-irritants;
d) Topical nasal decongestants;
e) Emollient/ demulcent/ skin protectants;
f) Keratolytics;
g) Anti-dandruff;
h) Oral care;
i) Anti-acne;
j) Medicated plasters/ patch/ pad; and
k) Topical antibacterial.

2.1 General Requirements for Abridged Evaluation

No.	Step I: Product Validation
1.	Product Name Please provide brand name and full product name
2.	Dosage Form
3.	Active Ingredient(s) a) Active Ingredient name b) Strength of Active Ingredient (Quantity unit per dose) c) Source of Active Ingredient (Animal – e.g. Bovine, Porcine, Ovine or Others/ Plant/ Others) d) Form of Active Ingredient e) Remarks (if any)
4.	Excipient(s) a) Excipient name b) Strength of Excipient (Quantity unit per dose) c) Function of excipient (e.g. absorbent, diluents, bulking agent, coating agent, anti-caking agent etc.) d) Source of excipient e) Remarks (if any)
5.	Is there any source of ingredients derived from animal origin, including active ingredient? (Yes/ No) If yes, please declare the origin
6.	Manufacturer (Name and Address)
7.	Is there any contract manufacturer involved? (Yes/ No)
8.	Is the product a second source product? (Yes/ No) If yes, please provide: a) Letter of declaration stating that this product is a second source product b) Registration number and product name of the first source
9.	Is there any repacker/ packer involved? (Yes/No)
10.	Is the product manufactured for export only? (Yes/No)
11.	Is this an imported product? (Yes/ No)
12.	Does this product containing any premix? (Yes/ No) a) State your premix form b) Manufacturer name c) Manufacturer address d) Certificate of Good Manufacturing Practice (GMP) e) Formulation f) Manufacturing Process g) Specification of Analysis

No.	Step I: Product Validation
	h) Certificate of Analysis (CoA)
13.	Is this a replacement product? (Yes/ No) If yes, please provide: a) Letter of Declaration stating that this product is a replacement product b) Registration number and product name of the replaced product
14.	Is this product certified halal? (Yes/ No) If yes, please provide: a) Halal certificate b) certificate number

Step II:	
No.	**Section A: Product Particulars**
1.	Active Ingredient
2.	Excipients
3.	Dosage Form
	a) Source of Capsule Shell
	b) Certificate to verify the source of the capsule shell
	c) Coloring agent used in capsule shell (Please attach CoA of the capsule shell)
4.	Product Description
5.	Indication
6.	Recommended Dose
7.	Route of Administration
8.	Contraindication
9.	Warning and Precautions
10.	Interaction of Other Medicaments
11.	Pregnancy and Lactation
12.	Side Effects
13.	Symptoms and Treatment of Overdose
14.	Effects on Ability To Drive And Use Machine
15.	Preclinical Safety Data
16.	Instructions for Use

Step II:	
17.	Storage Condition
18.	Shelf Life
19.	Therapeutic Code/ ATC Code
No.	**Section B: Product Formula**
1.	Batch Size
2.	Batch Manufacturing Formula
3.	Attachment of Batch Manufacturing Formula Documentation
No.	**Section C: Particulars of Packing** Please refer to **Appendix 23: Patient Dispensing Pack for Pharmaceutical Products**
1.	Pack Size (Fill details by weight/ volume/ quantity) Measurement Type
2.	Immediate Container Type (Container Type and Description) e.g. Aluminum/ Glass/ Metal/ Paper/ Plastic/ Others
3.	Barcode/ Serial No. (Optional)
4.	Recommended Distributor's Price (RM) (Optional)
5.	Recommended Retail's Price (RM) (Optional)
6.	Other Related Attachment (if any)
No.	**Section D: Label (Mock-up) For Immediate Container, Outer Carton, Proposed Package Insert, Consumer Medication Information Leaflet (RiMUP)** Please refer to: **Appendix 19: General Labelling Requirements** **Appendix 20: Specific Labelling Requirements**
1.	Proposed Label Mock-up for Immediate Container
2.	Proposed Label Mock-up for Outer Carton
3.	Proposed Package Insert
4.	Proposed Patient Information Leaflet (PIL) / Consumer Medication Information Leaflet (RiMUP)
No.	**Section E: Particulars of Product Owner, Manufacturer, Importer and Other Manufacturer(s) Involved and Store address**
1.	Product Owner

Step II:	
2.	Letter of Authorization from Product Owner
3.	Letter of Appointment of Contract Manufacturer from Product Owner (if applicable)
4.	Letter of Acceptance from Contract Manufacturer (if applicable)
5.	Letter of Appointment of the Repacker from the Product Owner
6.	Letter of Acceptance from the Repacker
7.	Certificate of Pharmaceutical Product (CPP)
8.	CPP Issuing Body
9.	Is this product licensed to be placed on the market for use in the exporting country? (Yes/ No) (If no, please state the reason)
10.	Is the product on the market in the exporting country? (Yes/ No) (If no, please state the reason)
11.	Date of Issue of CPP
12.	Date of Expiry of CPP
13.	Certificate of Free Sale (CFS)
14.	CFS Issuing Body
15.	Date of Issue of CFS
16.	Date of Expiry of CFS
17.	Certificate of Good Manufacturing Practice (GMP)
18.	GMP Issuing Body
19.	Date of Issue of Certificate of GMP
20.	Date of Expiry of Certificate of GMP
21.	Is there any other manufacturer(s) involved? (Yes/ No) a) Manufacturer name b) Manufacturer address c) Processing Step d) Certificate of Good Manufacturing Practice (GMP)
22.	Importer (Name and address)
23.	Store (Name and address)
24.	***Analysis Protocol****
25.	***Validation of Analysis Protocol ***

Step II:	
26.	Other Supporting Document (if any)
27,	Post-Approval Commitment(s)
28.	TSE Risk-Free Commitment
PART II: QUALITY OF PRODUCT	
No.	**Section P: Drug Product (Finished Product)**
1.	Control of Finished Products a) Specifications b) Analytical procedures c) Validation of Analytical Procedures d) Batch Analyses - Certificates of Analysis (CoA) e) Manufacturing Process and Process Control f) Control of Critical Steps and Intermediate
2.	Stability
No.	**Section S: Drug Substance**
1.	Control of Drug Substances a) Specifications b) Certificates of Analysis (CoA)