(*Borang BPFK/400/03*)

PUSAT PENDAFTARAN PRODUK
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

Senarai Semak Untuk Penyerahan Manual Permohonan Pendaftaran Produk Baru Seksyen Biologik

Satu salinan sahaja diperlukan. Salinan pendua akan dikembalikan kepada pemohon

Nama Produk : _____

Nama & Alamat Pemohon : _____

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BIL	PERKARA	PEMOHON (√)	BPFK (√)
PART I	**ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION**		
Administrative Information	Company Registration Certificate		
	World Wide Registration Status		
Section A	Product Particulars (A1 – A17)		
Section B	Product Formula		
Section C	Particulars of Packing		
Section D	D1 Label (mockup) for immediate container		
	D2 Label (mockup) for outer carton		
	D3 Proposed Package Insert		
	Proposed Patient Information Leaflet in BM (Risalah Maklumat Ubat Pesakit) and English		
Section E	**Supplementary Documentation**		
	Letter of Authorization		
	Letter of Acceptance*		
	Patent Statement*		
	Certificate of Pharmaceutical Product		
	Certificate of Good Manufacturing Practice		
	Summary of Product Characteristics (Product Data Sheet)		
	Protocol of Analysis (2 sets) Analytical Validation (2 sets) ***1 set to be submitted for Centre for Quality Control evaluation*		
Other Supporting Documents	1) Information on local clinical trials conducted (if any) refer **Appendix 1**		
	2) Information on application for KPK's approval on named-patient basis (if any)		
Part II	**QUALITY DOCUMENT**		
Section A	Table of Contents		
Section B	Quality Overall Summary		

Section C	Body of Data (P & S)		
Part S	Drug Substance (S1 – S7)		
	Certificate of Analysis for Drug Substance (2 batches)		
Part P	Drug Product (P1 – P9)		
	Stability Data		
	Certificate of Analysis for Drug Product (2 batches)		
	Certificate for Fitness of Plasma (For *Blood Products*)*		
	Summary Lot Protocol (For *Vaccines/ Blood Products*)*		
	Batch Release Certificate (For *Vaccines & Blood Products*)*		
	TSE Risk Free Declaration*		
PART III	**NONCLINICAL DOCUMENT**		
Section A	Table of Contents		
Section B	Non-clinical Overview		
Section C	Non-clinical Written and Tabulated Summaries Table of Contents Introduction Pharmacology Written Summary Pharmacology Tabulated Summary Pharmacokinetics Written Summary Pharmacokinetics Tabulated Summary Toxicology Written Summary Toxicology Tabulated Summary, **with GLP status**		
Section D	Non-clinical Study Reports		
Section E	List of Key Literature References		
PART IV	**CLINICAL DOCUMENT**		
Section A	Table of Contents		
Section B	Clinical Overview		
Section C	Clinical Summary		
	1. Summary of Biopharmaceutics and Associated Analytical Methods		
	2. Summary of Clinical Pharmacology Studies		
	3. Summary of Clinical Efficacy		
	4. Summary of Clinical Safety		
Section D	Tabular Listing of All Clinical Studies, **with GCP status**		
Section E	List of Key Literature Reference		
Section F	Published Clinical Papers (7 sets – indexed, listing with summary/ abstracts of each paper)		
	Periodic Safety Update Report (PSUR) (Latest/Current)		
	Risk Management Plan (if any)		
Other Documents			

*if applicable

Please ensure the following:

Product dossiers:

1. Dossiers are arranged according to the ACTD format
2. Please adhere to the requirements in the ICH/ASEAN Stability Guidelines
3. Each section and subsection/titles are divided and labeled according to the title using an index divider with full title (e.g: P2.4: Manufacturing Process Development)
4. Ensure that documents do not overflow in the ring rile. If needed, kindly use a ring folder of 70mm.

Additional items to be provided:

1. The Checklist A or B (refer *Appendix 3* in the Drug Registration Guidance Document)
2. Synopses of Individual Studies as per format provided (in softcopies) **Appendix 2**
3. A list of all non-clinical and clinical studies and GLP/GCP adherence status (in hardcopy)
4. A list of all clinical studies conducted/ongoing/planned in Malaysia as per format attached in **Appendix 1** (in hardcopy x 2 copies)
5. Softcopies of all submitted documents in a CD-ROM
6. Two (2) CD-ROMs containing full Clinical Study Reports (CSRs) for all trials, in bookmarked format
7. Seven (7) sets of specialist folders (include clinical overview, published paper OR Clinical Study Report Summary, Package Insert)
8. A cover letter for the analytical methods and validation file to be sent to lab (PKK)

These are required to expedite the manual submission and also the evaluation process later on.

Thank you.

Appendix 1

Format for Clinical Studies Conducted/Ongoing/Planned in Malaysia:

Protocol no.	Title of trial	Trial site(s)	Name of investigator(s)	Trial status (completed/ ongoing/ planned)	No. of subjects

Appendix 2

Format for Synopsis of Individual Studies:

Reference	
Objective	
Study Design	
Study Period	
Participants	
Methods	
Primary Endpoints	
Results	
Conclusion	