NPRA/423/01

**PUSAT PENDAFTARAN PRODUK**

**BAHAGIAN REGULATORI FARMASI NEGARA**

*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**  (√) | **NPRA**  (√) |
| **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 |  |  |
| D4 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) |  |  |
| **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**  **(Please complete GLP Compliance Form)** |  |  |
| **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 |  |  |
| 1. Summary of Clinical Pharmacology Studies |  |  |
| 1. Summary of Clinical Efficacy |  |  |
| 1. 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 (8 sets – indexed, listing with summary/ abstracts of each paper) |  |  |
| Periodic Safety Update Report (PSUR) (Latest/Current) |  |  |
| Risk Management Plan (if any) with name and address of local Person – In charge |  |  |
| **Other Documents** |  |  |  |

\*if applicable

**Please ensure the following are adhered to:**

**Product dossiers**:

1. Dossiers are arranged according to the ACTD format
2. Please adhere to the requirements in the ICH Stability Guidelines

3. Part I-IV of the dossier to be submitted in the CD including the full Clinical Study Reports (CSRs) for all trials, in bookmarked format

**Additional items to be provided:**

1. The Checklist A or B (refer **Appendix 4** in the Drug Registration Guidance Document)
2. Synopses of Individual Studies (in softcopies)
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 (in hardcopy x 2 copies)
5. Soft copies of all submitted documents in a CD-ROM
6. 1 CD ROM containing full Clinical study reports (CSRs) for all trials in **bookmarked** format
7. Eight (8) sets of specialist folders (include clinical overview, published papers, Clinical Study Report Summary

[if only published papers are not available], Package Insert & Justification of extrapolation of Indications {for biosimilar products only)

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

Thank you.

(Versi Jun 2022)