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 |  |  |
| D5 Label (Mock-up) for Diluent |  |  |
| **Section E** | 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) |  |  |
| 3) Non-clinical GLP compliance list (applicant to fill) |  |  |
| 4) The Checklist A or B (refer **Appendix 4** in the Drug Registration Guidance Document)  |  |  |
| 5) Justification of extrapolation of Indications are required *(For biosimilar products)\** |  |  |
| 6) Annex A & B from the FRP guidelines are to be filled and provided *(For FRP pathway products)\** |  |  |
| **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 SummariesTable of ContentsIntroductionPharmacology Written SummaryPharmacology Tabulated SummaryPharmacokinetics Written SummaryPharmacokinetics Tabulated SummaryToxicology Written SummaryToxicology 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  |  |  |
| Periodic Benefit-Risk Evaluation Report (PBRER) (Latest/Current) |  |  |
| Risk Management Plan Malaysia-Specific Annex (MSA) (if any) with name and address of local Person – In charge  |  |  |
| **Other Documents** | Specialist Folders: 8 sets – indexed, listing with summary/ abstracts of each paper) |  |  |

\*if applicable

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

**General pointers:**

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 DVD/ Pendrive to include the full Clinical Study Reports (CSRs) for all trials, in bookmarked format.
4. Please ensure each section and subsection/ titles (in the hard copy and Pendrive) are bookmarked, tagged, and titled clearly.
5. Please refer the following regarding the applicable forms or appendix for the submission:
6. <https://www.npra.gov.my/index.php/en/guideline-bio/1710-appendix-4-guidelines-on-registration-of-biologics.html>
7. <https://www.npra.gov.my/index.php/en/component/content/article/159-english/application-form-biologics/1527063-application-forms-biologics.html?Itemid=1391>
8. <https://www.npra.gov.my/index.php/en/guideline-bio.html>

**Hardcopy in soft plastic file to be submitted at the PPPK counter during manual submission appointment**

1. Cover letter for submission.
2. Form NPRA/423/01 Senarai Semak Untuk Penyerahan Manual Permohonan Pendaftaran Produk Baru Seksyen Biologik
3. A list of all clinical studies conducted/ongoing/planned in Malaysia
4. Eight (8) sets of specialist folders (include clinical overview, published papers, Clinical Study Report Summary [if published papers are not available] & Package Insert**. For biosimilar products**, justification of extrapolation of Indications are required.

**DVD/Pendrive 1**

1.   Part I

2.   Part II

3.   Part III

 4.   Part IV - To submit the latest Periodic Benefit-Risk Evaluation Report (PBRER) & Risk Management Plan (RMP) Malaysia-Specific Annex (MSA)

5.   Appendix 1 Format for Clinical Studies in Malaysia (if applicable)

6.   Appendix 2 Format for Synopsis of Individual Studies

7.   Complete checklist A or B (if applicable) of Appendix 4

8.   Quest3+ Print Registration Form

**DVD/Pendrive 2**
Full Clinical study reports (CSRs) for all trials in bookmarked format.

(Versi Julai 2024)