Versi 2 (2022)

**PUSAT PENILAIAN PRODUK & KOSMETIK**

**BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)**

*Senarai Semak Untuk Penyerahan Manual Permohonan Pendaftaran*

*Produk Baru, Seksyen Ubat Baru*

Nama Produk : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Nama & Alamat : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pemohon \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **BIL** | **PERKARA** | **PEMOHON****(/)** | **NPRA****(/)** |
| 1 | One (1) CD-ROM/pendrive containing: |
| (i) All submitted Part I-IV documents as per Quest 3+ system. |  |  |
| (ii) List of all non-clinical and clinical studies and GLP/GCP adherence status. |  |  |
| (iii) List of all clinical studies conducted/ongoing/planned in Malaysia as per format provided – refer **Appendix 1**. If no locally conducted trials, to provide a declaration stating that there are no local trials.  |  |  |
| (iv) Full Clinical Study Reports (CSRs) for all trials, in bookmarked format. |  |  |
| (v) Full Non-Clinical Study Reports (CSRs) for all trials, in bookmarked format. |  |  |
| (vi) Named-patient use information for this product in Malaysia (to include the name of the requesting doctor(s), the hospital/institution, the number of patients and the quantity approved for use).  |  |  |
| 2 | Nine (9) hardcopies of indexed folders containing proposed package insert and pivotal published clinical papers (or in-house report synopses, if published paper unavailable). Please ensure that the corresponding in-house protocol number is specified in the index for each published paper provided. |  |  |

**Appendix 1**

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

Product Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Active Pharmaceutical Ingredient (API) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dosage form/strength/size/volume : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product Registration Holder : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **API Number** | **Protocol Number of Clinical Trial Conducted in Malaysia** | **Title of Clinical Trial Conducted in Malaysia** | **Trial Site(s)** | **Name Of Investigator(s)** | **Trial Status****(Completed/ Ongoing/ Planned)** | **No. of Subjects** |
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