**APPENDIX A**

**PART A COMPANY AND PRODUCT DETAILS**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **COMPANY DETAILS** | | | | | | | |
| **Company Name** |  | | | | | | |
| **Company Address** |  | | | | | | |
| **Company Entity** | * Government: 󠆼󠆼 Ministry of Health 󠆼󠆼 Non Ministry of Health   (Please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | * Private | | |
| **Part I (Type and Purpose of Application):** | | | | | | | |
| Type of Inspection: | * New Source | | * Additional source/s | | | * Others; (Please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Type of product registration | * Stage I Screening | | * Stage II Screening | | | * Full dossier | |
| Required to be licensed by CKAPS | ☐ Yes | | * No | | |  | |
| Layout approved by NPRA | * Yes; Ref No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   Date of approval: \_\_\_\_\_\_\_\_\_\_ | | * No | | |  | |
| **Part II (Type of source/s):** | | | | | | | |
| \*please indicate different product/s name and active ingredients by semi colon (;) respectively | Product type and source | | Product/s name\*: | | | Product/s active ingredients\*; | |
| 󠆼 | Human and/or animal source |  | | |  | |
| 󠆼 | Animal / plant source (non-transgenic) |  | | |  | |
| 󠆼 | Biotechnology fermentation / cell culture |  | | |  | |
| 󠆼 | Virus or bacteria / fermentation / cell culture |  | | |  | |
| 󠆼 | Animal sources (transgenic) |  | | |  | |
| 󠆼 | Others; (Please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | | |  | |
| **Part III [Activities conducted (if applicable)]:** | | | | | | | |
|  |  | Collection |  | Processing; such as manipulation, fermentation, centrifuge | |  | Others; (Please specify):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Fill and Finish |  | Quality Control testing | |

**Part B Cell & Gene Therapy Products (CGTPs) Manufacturers**

a) Facility background

|  |  |
| --- | --- |
| i. Mandatory | ii. Optional |
| 󠆼 Site Master File | 󠆼 CKAPS License |
| 󠆼 NPRA’s Product Classification Letter | 󠆼 Ethics Clearance e.g. MOH, MREC, University Ethics etc) |
| 󠆼 NPRA’s Letter for Facility Layout Approval | 󠆼 NPRA’s Clinical Trial Import License/ Clinical Trial Exemption  󠆼 Product Listing by NPRA |

b) Product scope

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Product Name | Targeted product of interest | a Source | b Processing activities | Packaging Type | Indication | Treatment Centre  - Name  - Address | c Product Development Stages |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Description & examples:

|  |  |  |
| --- | --- | --- |
| a Product type and source   * Human and/or animal sources * Animal or plant source; non-transgenic * Biotechnology fermentation / cell culture * Virus or bacteria / fermentation / cell culture * Animal sources; transgenic * Others (Please specify):\_\_\_\_\_\_\_\_\_\_ | b Processing activities   * Collection * Processing * Process description: \_\_\_\_\_\_\_\_\_ * Fill & Finish | c Product Development Stages   * Pre-clinical * Phase I / II /III / IV * Registered |