**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 Exemption󠆼 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
 |