**Application for preliminary approval of a new local manufacturing site**

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| **Applicant details** |

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| --- | --- | --- | --- |
| Registered Company Name: | | | |
|  | | | |
| Head Office address (if applicable): | | | |
|  | | | |
| Company contact person : |  | | |
| Designation of the contact person |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| Type of business : |  | | |
| If partnership | **Please provide all partnership details** | | |

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| **Location details** | | | | | | | | | | | | | | | | | |
| Site address: |  | | | | | | | | | | | | | | | | |
| District: |  | | | | | | | | | | | | | | | | |
| GPS Positioning: | Latitude |  |  |  |  |  |  |  | Longitude |  |  |  |  |  |  |  |  |
| Current status | Land only | | | | | | | | New building completed | | | | | | | | |
| Existing building | | | | | | | | Equipment installed | | | | | | | | |
| New building under  construction | | | | | | | | Other (Please specify) | | | | | | | | |

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| **Site activities-** | | | | | | | | | | | |
| Product types to be manufactured | | Activities to be carried out at the site | | | | | | | | | |
| Medicine | ☐ | Manufacture | | | | | | | | ☐ | |
| Medical Devices | ☐ | Assembly and Packaging | | | | | | | | ☐ | |
| Borderline products | ☐ | Batch release | | | | | | | | ☐ | |
| Cosmetics | ☐ | Re-packing | | | | | | | | ☐ | |
| Other  (Please specify) | ☐ | Other  (Please specify) | | | | | | | | ☐ | |
|  | | |  |  | | |  | |  | |
| |  | | --- | | **Product categories to be manufactured at the site** | | 1. Please specify  2.  3. | | | | | | | | | | | |
|  | | |  | |  |  | |  | | |
| **Operations with Special Requirements** | | | | | | | | | | | | |

1. **Involves manufacture of sterile products** Yes ☐ No ☐
2. **Involves manufacture of biological products** Yes☐ No ☐

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| **Products with Special requirements (if any)** | |  |
| **1.** | Beta lactam Antibiotics (please specify – e.g. penicillin) | ☐ |
| **2.** | Other highly sensitizing antibiotics | ☐ |
| **3.** | Cytotoxic | ☐ |
| **4.** | Sex hormones | ☐ |
| **5.** | Live Cells | ☐ |
| **6.** | Pathogenic Organisms (Biosafety Level 3 or 4) | ☐ |
| **7.** | Radiopharmaceuticals | ☐ |
| **9.** | Other <Please specify> | ☐ |

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| **Supporting Documentation** |  |
| Certificate of incorporation issued by Registrar of Companies (or similar) including addendums | ☐ |
| Site plan that indicate activities involved in adjacent lands | ☐ |
| Proposed building plan | ☐ |
| Environmental certificate issued by the Central Environmental Authority (or similar) | ☐ |
| Request letter for an inspection of the site | ☐ |
| Organization chart (if available) | ☐ |
| Signed Technical Agreements (where applicable) | ☐ |

**Declaration by the applicant:**

I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

I declare that I have read the relevant legislation and guidelines and, I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the NMRA act and regulations made there under.

If my application is granted, I shall abide by the Act and Regulations and any other standards set by the Authority.

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Signature of the applicant Date

Name:

Contact No: