**Check List for Grant of License to Import Small Quantities of Drugs for Clinical Trials, Examination, Test or Analysis.**

|  |  |
| --- | --- |
| DY # & DATE ►(FOR OFFICIAL USE ONLY) |  |
| NATURE OF CONSIGNMENT (PLEASE TICK THE RELEVANT BOX) |
| RAW MATERIAL □  | FINISHED /SEMI FINISHED DRUGS □  | PACKING MATERIAL □ |
| NAME & ADDRESS OF IMPORTER (IN BLOCK LETTERS) ▼ | NAME & ADDRESS OF EXPORTERS (IN BLOCK LETTERS) ▼ |
| NAME OF RAW MATERIAL / FINISHED DRUG/ PACKING MATERIAL IMPORTED (IN BLOCK LETTERS) |  |

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| --- | --- | --- | --- | --- |
| **S.NO.** | **Documents** | **Original** | **Photocopy** | **Remarks** |
|  | Form-4 (Application for license to import drugs) (Rule 6(3)) | □ | □ |  |
|  | Fee challan R.S./- 7500 as per S.R.O. 526(I)/2021, dated 30-04-2021 | □ |  |  |
|  | Form-3 (Rule 5(1)) | □ | □ |  |
|  | Copy of License (DML) & its Renewal / In case of clinical trials copy of form V (License to act as Contract Research Organization or Clinical Trial Site or Laboratory) and Form VI (Approval to conduct the clinical trial, BA or BE study),as per S.R.O. 697 (I)/2018. | □ | □ |  |
|  | Form-7 (Rule 14(d)(i)) | □ | □ |  |
|  | Certificate of Analysis (Rule 14(d)(ii)) | □ | □ |  |
|  | Latest Testing Reference USP/BP/EU/JP etc of raw material |  |  |  |
|  | Valid API manufacturing license (for APIs) and GMP Certificate of the exporting firms by respective Drug Regulatory Authority (Letter No. F.1-10/2016-Add:Dir(R.I)/M-264 dated 30th March,2017 | □ | □ |  |
|  | API requirement data, Complete testing protocols/Stability studies protocols. | □ | □ |  |
|  | Any other document (s) Particularly Required (Please Specify in remarks columns) | □ | □ |  |
|  | Name of ware house Pharmacist | □ | □ |  |

|  |  |
| --- | --- |
| Submitted byName…………... ……….……………....Signature………………………………………………………….Rank…………….......……………Contact ....................................................... | Received byName………………………………………………………………...Signature……………………………………………………………Designation…………………………………………………………………………………………………………………………………. |

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| Remarks of AD (I&E)………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….……………………………………………………………………………………………………………………………...................Signature of AD (I&E) |
| DECISION | Issue □  |  Re-process □ | Reject □ |

|  |  |
| --- | --- |
| Documents received duly signed and stampedName……………………………………Signature……………………. | Objection notedName……………………………………Signature…………………… |

Every page/document must be signed and stamped by the firm. Yes No

In case of photocopies of documents from supplier; undertaking that the firm shall submit the original documents in specified period of time.

Yes No