

FORM CT-16*(See rule 67)***APPLICATION FOR GRANT OF LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG
FOR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR
EXAMINATION, TEST AND ANALYSIS**

I/We,.....(*name and address of the applicant*)
of M/shereby apply for grant of licence to import new drug or investigational new
drug for clinical trial bioavailability or bioequivalence study or for examination, test and analysis.

The details of the application are as under:

| | |
|--|--|
| 1. Name of applicant: | |
| 2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified) | |
| 3.(i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Applicant's address including telephone number, mobile number, fax number and e- mail id: (iii) Address for correspondence: | |
| 4. Details of new drugs to be imported [As per Annexure]. | |
| 5. Particulars of overseas Manufacturer, Manufacturing sites [As per Annexure]. | |
| 6. Fee paid on _____ Rs _____ receipt or challan or transaction ID. | |
| 7. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and Chapter IX of the New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be imported from M/s shall be used exclusively for the purpose of clinical trial and no part of it shall be diverted to the domestic market. | |

Place:

Digital Signature

Date:

(Name and designation)

Annexure:

Details of new drug or investigational new drug:

| | |
|--|--|
| Names of the new drug or investigational new drug: | |
|--|--|

| | |
|--------------------|--|
| Therapeutic class: | |
| Dosage form: | |
| Composition: | |
| Indications: | |

Details of manufacturer and manufacturing site:

| | |
|--|--|
| Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer) | |
| Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site) | |