

FORM CT-24*(See rule 86)***APPLICATION FOR LICENCE TO IMPORT OF UNAPPROVED NEW DRUG FOR TREATMENT OF PATIENTS OF LIFE THREATENING DISEASE IN A GOVERNMENT HOSPITAL OR GOVERNMENT MEDICAL INSTITUTION**

I/We,

(name and full postal address of the applicant) of M/s hereby apply for grant of licence to import unapproved new drug but under clinical trial for treatment of patients of life threatening disease in a government hospital or medical institution.

The details of the application are as under:

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|--|--|
| 1. Name of Medical officer: | |
| 2. Nature and constitution of applicant: (Government Hospital or Medical Institution) | |
| 3.(i) Address including telephone number, mobile number, fax number and e-mail id of the Government Hospital or Medical Institution: (ii) Address for correspondence: | |
| 4. Details of unapproved new drug pharmaceutical formulation to be imported [As per Annexure]. | |
| 5. Details of the manufacturer and manufacturing site [As per Annexure]. | |
| 6. Details of the patient and disease [As per Annexure]. | |
| 7. Fee paid on _____ Rs___receipt or challan or transaction ID. | |
| 8. A legal undertaking stating that the unapproved new drug to be imported shall be used for the treatment of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith. | |

Place:

Date:

Digital Signature

(Name and designation)

Annexure:

Details of unapproved new drug to be imported:

| | |
|--|--|
| Name of the new drug: | |
| Dosage form: | |
| Quantity: | |
| Indications for which proposed to be used: | |

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). |
| | |

Details of patient:

| | |
|----------------------|--|
| Name of the patient: | |
| Disease name: | |

Certificate

Certified that the unapproved new drug specified above for import is urgently required for the treatment of patients suffering from and that the said drug is not available in India.

Place.....

Signature

Date.....

Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]