

**FORM CT-18***(See rule 75)***APPLICATION FOR GRANT OF PERMISSION TO IMPORT NEW DRUG FOR SALE OR FOR DISTRIBUTION**

I/We,.....(*name and address of the applicant*)  
of M/s .....hereby apply for grant of permission to import new drug for sale.

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) Manufacturer's address including telephone number, mobile number, fax number and e-mail id:  (iii) Address for correspondence:	
4. Details of new drug to be imported (Active pharmaceutical Ingredient or Finished Formulation) [As per Annexure].	
5. Details of the manufacturer and manufacturing site [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 X of the New Drugs and Clinical Trials Rules, 2019.	

Place:

Digital Signature

Date:

(Name and designation)

**Annexure:**

Details of new drug:

Name of the new drug:	
Dosage form:	
Composition of the formulation:	
Therapeutic class of the new drug:	
Indications for which proposed to be used:	

Manufacturer of the raw material (active pharmaceutical ingredient):	
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Details of manufacturer and manufacturing site of new drug:

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).