

Annexure Sheet  
(To be filled up by the firm)

1. Application Ref No. : \_\_\_\_\_
  - Application Date : \_\_\_\_\_
2. Name of the Company : \_\_\_\_\_
  - Address of the Company : \_\_\_\_\_
3. Subject: \_\_\_\_\_
4. Challan Fees/No./Date : \_\_\_\_\_
5. Basic Division : \_\_\_\_\_  
(New Drugs, / Import Division / Biological (Vaccine, Stem Cell, Blood Products, recombinant products) / Medical Devices / Diagnostic Kits / Blood Bank / Cosmetics / Narcotic Drug / Export & Neutral Codes / Test license / LVP Division Pharmacovigilance)
6. Type of Application : \_\_\_\_\_ (Choose the type from the list given in page/2).

I Mr./ Dr. / Mrs \_\_\_\_\_  
representing M/s \_\_\_\_\_

Hereby solemnly affirm that the information furnished as above are absolutely true and is based on the facts.

*Signature & Seal*

## Type of Application

<ul style="list-style-type: none"> <li>• Investigational New Drug (IND)</li> <li>• New Drug Approval (NDA)</li> <li>• Subsequent New Drug Application (SNDA)</li> <li>• Post Marketing Surveillance Study (PMS)</li> <li>• Periodic Safety update Reports (PSUR)</li> <li>• Package insert approval</li> <li>• Clinical Trial Approval (Domestic) (CTA)</li> <li>• Global Clinical Trial (GCT)</li> <li>• Post Approval Change</li> <li>• BE Study (Domestic approval) (BED)</li> <li>• BE Study for Export (BEE)</li> <li>• Serious Adverse Events (SAE)</li> <li>• Registration Certificate (RC)</li> <li>• Import License (Form-10) (IL)</li> <li>• Import of Drugs having Dual Use</li> <li>• Request for Shelf Life Extension</li> <li>• Drug Manufacturing License (DML) (CLAA)</li> <li>• NOC for Form-29 (Trial Batch release)</li> </ul>	<ul style="list-style-type: none"> <li>• Test License (Form-11) (TL)</li> <li>• Export NOCs</li> <li>• Neutral Code</li> <li>• Narcotic Drugs</li> <li>• Correspondences relating to Blood Banks Licensing (BBL)</li> <li>• Cosmetics</li> <li>• WHO-GMP/COPP</li> <li>• Permission under Rule -37</li> <li>• Free Sale Certificate</li> <li>• Miscellaneous Correspondence</li> </ul> <p style="margin-top: 20px;">N.B. Submission made in response to query or for an amendment to permission issued should be accompanied with a copy of query or permission letter.</p>
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