Duly filled specimen pro forma for submission of application in Form MD-12 for obtaining Manufacturing Test license

1. The name of the applicant (firm) shall be mentioned as registered under applicable law like company act, proprietorship etc.

3.(i) The address shall be mentioned as registered under applicable law like company act, proprietorship etc.

3. (iii)The applicant shall mentioned the name and address of the site where the actual test batches will be developed/manufactured

4. (1)Only the common name or generic name of device shall be mentioned.

4.(3) Should mention the model number/name or catalogue number as mentioned in DMF & IFU/ UM/ PI and labels of the device(s), if available.

4.(4) The grouping category (Single, System, Group, Family, etc) shall be as per guidelines published on the CDSCO website

(Click here: Link1 ; Link2)

4.(5) Proposed risk class of the devices shall be as per classification list published on the CDSCO website or as per the claim of the manufacturer (Click here)

4.(7) Only applicable for sterile product otherwise the applicant shall mention 'Not Applicable'.

FORM MD-12

[See sub-rule (1) of rule 31]

Application for License to Manufacture Medical Device for Purpose of Clinical Investigation, Test, Evaluation, Examination, Demonstration or Training

1. Name of Applicant:
2. Nature and constitution of manufacturer:
3. (i) Corporate/registered office address:

(ii) Testing or evaluation site address:

(iii) Address for correspondence:

4. Details of medical device(s) to be manufactured

S. No	Details of Device(s)
1.	1. Generic Name: 2. Brand Name (if registered under the Trade Marks Act, 1999): 3. Model No. (If any): 4. Medical Device Grouping: 5. Proposed Class of Medical Device: 6. Proposed Intended Use: 7. Whether Sterile or Non-sterile: 8. Proposed Quantity:

5. Please refer details in Payment receipt attached.

6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: Signature

Date: (Name & Designation)

2. The applicant may select the option as provided in the portal e. g., proprietorship, LLP, Pvt. Ltd. etc.

3.(ii)
- In case of testing/ evaluation/ examination, the applicant shall mention the name and address of the testing centre(s) where the proposed test is to be carried out.
- In case of demonstration/ training, the applicant shall mention the name and address of the site(s) where the demonstration/ training is to be performed.
- In case of Clinical investigation, the applicant shall mention the name and address of each site(s) where the clinical study is to be carried out.

4.(2) The specific brand name of the device shall be mentioned (If any).

4.(6) The proposed intended use of the device as mentioned in manufacturer's draft IFU/ UM/ PI (If applicable).

4.(8) The proposed quantity (in metric units) shall be properly justified in the line of test protocol submitted

5. Payment shall be made as per the Second schedule of Medical Devices Rules, 2017

It should be digitally signed using digital signature certificate as per IT Act.

Shall be in DD/MM/YYYY

Place where the address of the applicant (firm) is located

Abbreviations: *DMF: Device Master File* *IFU/ UM/ PI: Instructions for use/ User Manual/ Package Insert* *CLA: Central Licensing Authority*