

Documents to be uploaded with the application form for obtaining License to manufacture drugs for purposes of examination, test or analysis

1. Forwarding letter
2. Form 30
3. Undertaking
4. List of items in triplicate with product detail
5. List of Directors with address on letter head
6. List of directors print out from MCA website
7. List of SOP's
8. List of machineries
9. List of instruments with calibration record
10. Bio-waste management agreement
11. Fire NOC
12. Cleaning and sanitation record mentioning schedule and inspected by
13. Pollution Consent
14. List of technical staff along with copies of Offer letter, joining letter and educational certificate of Technical staff.
15. Water test report of RO water as well as HPLC water

Note: Copies of documents should be self attested

Product details

The following details of products is to be mentioned

1. Name of the Drug
2. Class of the drug
3. Indications of the drug
4. Dosage and strength of the formulation
5. Route of administration
6. Composition of the product
7. SOP of analytical procedure
8. Manufacturing process with flow chart
9. List of staff with qualification & Experience
10. Details of the raw material used to manufacturer
11. Details of the test to be performed on formulation
12. Address of the facilities where formulation is to be manufactured

Undertaking

Format for the undertaking is as under:

We, M/s. (Name of Firm with address) hereby undertake that the product mentioned below manufactured by us under Form – 29 license will not be utilized for any Clinical Trial or any other commercial purpose.