

Flowchart for opening/starting an ASU manufacturing firm

Apply through an application to the Director for intention to open a manufacturing ASU firm, along with signed three copies of layout plan (layout to be designed as per Schedule T, designated category of medicine), copy of trade license and possessional documents of land, copies of valid documents for nature of business like partnership deeds, .A.o.A, M.o.A for private limited firm, etc

Designated inspector appointed by the Director will visit the site and will put forward his views in a checklist and will recommend for approval.

After site approval from the Directorate the manufacturing firm may apply in form 24-D along with application, Additional information form, and with enclosed documents like pay the requisite fees in GRIPS, submit the technical staff lists along with affidavit, N.O.C from Pollution control, Fire license, electrical bill of requisite volt, list of books, list of machineries, ASU product lists, along with stability study, test report etc and other relevant documents.

Designated Inspector appointed by the Director will visit the mfg firm and will put forward his views in an inspection book in form 35 and inspection report and will recommend for approval if found satisfactory.

Certificate to manufacture ASU Drug will be provided in form 25-D from this Directorate and GMP certificate in 26 E-I. Classical drugs intend to be manufactured will be endorsed by the Director and proprietary medicine list will be forwarded to Govt. ASU expert committee for approval.

Flowchart for starting an ASU manufacturing firm under loan license

Those entrepreneurs who do not have the facility of their own manufacturing firm may apply for loan license where they can take the facility of another manufacturing firm who had their own manufacturing facility.

Apply through an application to the Director for intention to open a manufacturing ASU firm in loan license, Application in 24E , Additional information form, along with signed three copies of layout plan of stock point, copy of trade license and possessional documents of stock point land, copies of valid documents for nature of business like partnership deeds, A.o.A, M.o.A for private limited firm, etc, Agreement copy between Parent firm and loan firm, consent from parent firm, photo copy of layout of parent firm & additional information form, receipt of fess paid through GRIPS, submit the technical staff lists, NOC from Pollution control, Fire license of parent firm, electrical bill of requisite volt, ASU product list, along with stability study, test report, list of books, list of machineries etc of parent firm.etc and other relevant documents.

Designated Inspector appointed by the Director will visit the mfg firm of the parent firm as well as loan firm stock point and will put forward his views in an inspection book in form 35 and inspection report and will recommend for approval if found satisfactory.

Certificate to manufacture ASU Drug in loan license will be provided in form 25-E from this Directorate and GMP certificate in 26 E-I. Classical drugs intend to be manufactured will be endorsed by the Director and proprietary medicine list will be forwarded to Govt. ASU expert committee for approval.