

¹[FORM 10

(See rules 23 and 27)

*Licence to import drugs (excluding those specified in Schedule X) to the Drugs and
Cosmetic Rules, 1945*

Licence Number.....

Date... ..

1. (Name and full address of the importer) is hereby licensed to import into India during the period for which the licence is in force, the drugs specified below, manufactured by M/s (name and full address) and any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from tounless it is sooner suspended or cancelled under the said rules.

3. Names of drugs to be imported.

Place :

Date :

Licensing Authority
Seal/Stamp

Conditions of Licence.

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and the date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

1. Subs. by G.S.R. 604(E), dt. 24.8.2001.