

## **FORM 9**

**(See rule 24)**

### **Form of undertaking to accompany an application for an import licence**

Whereas ..... of..... Intends to apply for a licence under the Drugs and Cosmetics Rules, 1945, for the import into India, of the drugs specified below manufactured by us, we.....of.....hereby give this undertaking that for the duration of the said licence—

- (1) The said applicant shall be our agent for the import of drugs into India;
- (2) We shall comply with the conditions imposed on a licence by 1[rules 74 and 78] of the Drugs and Cosmetics Rules, 1945;
- (3) We declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;
- (4) We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.
- (5) Every drug manufactured by us for import under licence into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945;
- (6) We shall comply with such further requirements, if any, as may be specified by Rules, by the Central Government under the Act and of which the licensing authority has given to the licensee not less than four months' notice.

**Names of Medical Device (s) and class of Medical Device (s)**

(As mentioned in Form 41)

**Particulars of premises where manufacture is carried on**

(As mentioned in Form 41)

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of the Indian Agent / Manufacturer  
(Name & Designation)  
Seal / Stamp