

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 20th August, 2015

**G.S.R. 648(E).**—The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, shall be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

**Draft rules.**

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2015.  
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 36, in the second proviso, after clause (iii), the following clause shall be inserted, namely:-  
“(iv) the permit is granted for a period of six months or in special circumstances for such period beyond six months as may be specified.”
3. In the said rules, in rule 96, in sub-rule (1),-
  - (A) in clause (i),-
    - (a) the brackets and letter “(A)” shall be omitted;
    - (b) sub-clause (c) shall be omitted;
  - (B) in the proviso to clause (iii), the words “and to a preparation included in the National Formulary of India” shall be omitted;
  - (C) after clause (xii), the following clause shall be inserted, namely:-  
“(xiii) the conditions of storage with specific temperature range in thick and bold letters.”
4. In the said rules, in Schedule A,-
  - (a) in Form 12-B,-
    - (i) in paragraph 3, after the words “six months”, the words “or for such period beyond six months as may be specified”, shall be inserted;
    - (ii) after paragraph 3, the following paragraph shall be inserted, namely:-  
“4. The permit shall be valid from \_\_\_\_ to \_\_\_\_.”;
  - (b) in Forms 25, 25-A, 25-F, 28, 28-A, 28-B, 28-D and 28-DA, under the conditions of licence, after condition 4, the following provisos shall be inserted, namely:-  
“Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:  
Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.”;
  - (c) in Form 25-B, under the conditions of licence, after condition 5, the following provisos shall be inserted, namely:-



“Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:

Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.”;

- (d) in Form 25-C, under the conditions of licence, after condition 3, the following provisos shall be inserted, namely:-

“Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:

Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.”;

5. In the said rules, in Schedule K, after serial number 35 and the entries relating thereto, the following serial number and entries shall be inserted, namely:-

Class of Drugs	Extent and Conditions of Exemption
36. Sterile solutions intended for parenteral administration with 100 ml. in one container for single use manufactured for export by the hundred per cent export oriented units.	The provisions of Chapter IV of the Act and rules thereunder which require them to obtain a licence in Form 28D or 28DA from the Central Licence Approving Authority subject to the condition that such drugs have been manufactured for export purpose under a licence granted by the State Licensing Authority.”.

[F.No. X.11014/2/2015-DFQC]

K. L. SHARMA, Jt. Secy.

Note.—The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number G.S.R.611(E) dated the 31st July, 2015.