

1. (1) इन नियमों का संक्षिप्त नाम औषधि और प्रसाधन सामग्री (तीसरा संशोधन) नियम, 2019 है।  
(2) ये राजपत्र में उनके प्रकाशन की तारीख को प्रवृत्त होंगे।
2. औषधि एवं प्रसाधन सामग्री नियम, 1945 की अनुसूची ट में क्रम संख्या 37 और उससे सम्बंधित प्रविष्टियों के पश्चात्, निम्नलिखित क्रम संख्यांक और प्रविष्टियां अन्तःस्थापित की जाएंगी, अर्थात:-

औषधि - वर्ग	छूट की सीमा और शर्तें
“38. केवल निर्यात के लिए विनिर्मित किए जाने के लिए, एकल उपयोग हेतु आशयित औषधियों के तैयार खुराक के रूप में एक आधान में 100 मि. लि. की मात्रा में आंत्रबाह्य प्रयोग के लिए अजीवाणु घोल।	अधिनियम के अध्याय 4 के और उसके अधीन बनाए गए नियमों के उपबंध, जिनके अधीन केंद्रीय अनुज्ञप्ति अनुमोदन प्राधिकारी से, प्ररूप 28घ या 28घक में, इस शर्त के अधीन कि ऐसी औषधियों को राज्य अनुज्ञापन प्राधिकारी द्वारा अनुदत्त अनुज्ञप्ति के अधीन केवल निर्यात के प्रयोजन के लिए विनिर्मित किया गया है, अभिप्रास करना अपेक्षित है।” ।

[फा.सं. एक्स.11014/10/2018-डीआर]

डॉ. मनदीप के भण्डारी, संयुक्त सचिव

**टिप्पण:** मूल नियम अधिसूचना संख्या एफ.28-10/45-एच (1), तारीख 21 दिसंबर, 1945 द्वारा भारत के राजपत्र में प्रकाशित किए गए थे और अधिसूचना संख्या सा.का.नि. 20(अ), तारीख 10 जनवरी, 2019 द्वारा अंतिम बार संशोधित किया गया था।

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 25th January, 2019

**G.S.R. 47(E).**—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 719(E), dated the 30<sup>th</sup> July, 2018 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 4<sup>th</sup> August, 2018;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2019.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, after serial number 37 and the entries relating thereto, the following serial number and entries shall be inserted, namely:—

Class of Drugs	Extent and Conditions of Exemption
“38. Sterile solutions intended for parenteral administration with 100 ml in one container of the finished dosage form for single use manufactured for export only.	The provisions of Chapter IV of the Act and rules made 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 only under a licence granted by the State Licensing Authority.”.

[F.No. X.11014/10/2018-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette *vide* notification number F.28-10/45-H (1), dated 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 20(E), dated 10<sup>th</sup> January, 2019.