

**टिप्पणः** मूल नियम अधिसूचना संख्या एफ.28-10/45-एच (1), तारीख 21 दिसंबर, 1945 द्वारा भारत के राजपत्र में प्रकाशित किए गए थे और अंतिम संशोधन अधिसूचना संख्या सा.का.नि. 1186 (अ), तारीख 7 दिसंबर, 2018 द्वारा किया गया था।

**MINISTRY OF HEALTH AND FAMILY WELFARE**  
**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 12<sup>th</sup> December, 2018

**G.S.R. 1193(E).**—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sections 12 and 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. 1000(E), dated the 5<sup>th</sup> October, 2018 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of fifteen 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 10<sup>th</sup> October, 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 by section 12 and section 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 (Tenth Amendment) Rules, 2018.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 24,-  
(a) in sub-rule (1),-  
(i) for the words “one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees”, the words “ten thousand rupees for a single drug and an additional fee at the rate of one thousand rupees” shall be substituted;  
(ii) in the proviso, for the words “one hundred rupees”, the words “one thousand rupees” shall be substituted;  
(b) in sub-rule (3), for the words “two hundred and fifty rupees shall be paid”, the words “one thousand five hundred rupees shall be paid for making amendment in the licence or” shall be substituted.
3. In the said rules, in rule 24A,-  
(a) in sub-rule (3),-  
(i) in clause (i), for the words and letters “one thousand and five hundred US dollars”, the words and letters “ten thousand US dollars” shall be substituted;  
(ii) in clause (ii) and proviso thereto, for the words and letters “one thousand US dollars” wherever they occur, the words and letters “five thousand US dollars” shall be substituted;  
(b) in sub-rule (5), for the words and letters “five thousand US dollars”, the words and letters “twenty five thousand US dollars” shall be substituted;  
(c) in sub-rule (7), for the words and letters “three hundred US dollars or its equivalent in Indian rupees shall be paid”, the words and letters “one thousand eight hundred US dollars

or its equivalent in Indian rupees shall be paid for making amendment in the registration certificate or” shall be substituted.

4. In the said rules, in rule 34, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “five thousand rupees for a single drug and an additional fee of two thousand rupees” shall be substituted.
5. In the said rules, in rule 34A, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “six hundred rupees for a single drug and an additional fee of three hundred rupees” shall be substituted.
6. In the said rules, in rule 122A, in sub-rule (1), in clause (b),-
  - (i) for the words “fifty thousand rupees”, the words “two lakh fifty thousand rupees” shall be substituted;
  - (ii) in the first proviso and in the second proviso, for the words “fifteen thousand rupees”, at both the places where they occur, the words “one lakh rupees” shall be substituted.
7. In the said rules, in rule 122D, in sub-rule (1), for the words “fifteen thousand rupees”, the words “fifteen thousand in case of application for manufacture of the fixed dose combinations and one lakh rupees in case of import application of the fixed dose combinations” shall be substituted..
8. In the said rules, in rule 129A,-
  - (a) in sub-rule (1), for the words and letters, “two hundred and fifty US dollars or its equivalent to Indian rupees for each brand of cosmetic”, the words and letters “two thousand US dollars or its equivalent to Indian rupees for each brand of cosmetic and a fee of fifty US dollars for each variant” shall be substituted;
  - (b) in sub-rule (5), for the words and letters “one hundred US dollars”, the words and letters “five hundred US dollars” shall be substituted.

[F. No. X.11014/32/2018-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H(1), dated the 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 1186(E), dated the 7<sup>th</sup> December, 2018.