

उक्त नियम में, अनुसूची क में, प्ररूप 50 के पश्चात्, निम्नलिखित प्ररूप अंतःस्थापित किया जाएगा, अर्थात्:-

**प्ररूप 51**

[नियम 71(9), 71क(5), 71ख(v), 76(11) और 76क(v) देखिए]

किसी ब्रांड नाम या व्यावसायिक नाम के अधीन किसी ओषधि के विपणन के लिए अनुज्ञापन प्राधिकारी को वचनबंध का प्ररूप

- (1) मैं ..... का ..... ब्रांड नाम या व्यावसायिक नाम ..... के अधीन निचे विनिर्दिष्ट ओषधि विपणन करने का आशय रखता हूँ
- (i) ओषधि का नाम
- (ii) खुराक प्ररूप
- (iii) संरचना
- (2) मैं, व्यापार चिन्ह रजिस्ट्री, केंद्रीय ओषधि मानक नियंत्रण संगठन द्वारा रखे गए ब्रांड नाम या व्यावसायिक नाम के लिए केंद्रीय आंकड़ा संचय, भारत में विनिर्मित ओषधि के व्यौरों पर मादित्य और संदर्भ पुस्तकों और इंटरनेट में जाँच पड़ताल के आधार पर अपने सर्वोत्तम ज्ञान पर, यह वचनबंध करता हूँ की इस प्रकार का या समान ब्रांड नाम या व्यावसायिक नाम देश में किसी ओषधि के संबंध में पहले से विद्यमान नहीं है और प्रस्तावित ब्रांड नाम या व्यावसायिक नाम से विपणन में कोई भ्रम या धोखा नहीं होगा।

स्थान .....

तारीख .....

(विनिर्माता या विनिर्माता की ओर से  
हस्ताक्षर, नाम पदनाम मुहर/मुद्रा)।"

[फा. सं. एक्स. 11018/48/2018-डीआरएम]

डॉ. मनदीप के. भण्डारी, संयुक्त सचिव

टिप्पण : मूल नियम अधिसूचना संख्या फा. 28-10/45-एच (1), तारीख 21 दिसम्बर, 1945 द्वारा भारत के राजपत्र में प्रकाशित किए गए थे और अधिसूचना संख्या सा.का.नि. 653(अ), तारीख 13 सितंबर, 2019 द्वारा अंतिम बार संशोधित किए गए थे।

**MINISTRY OF HEALTH AND FAMILY WELFARE**

(Department of Health and Family Welfare)

**NOTIFICATION**

New Delhi, the 6th November, 2019

**G.S.R. 828(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. 152(E), dated the 26<sup>th</sup> February, 2019, 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 said Official Gazette were made available to the public on the 27<sup>th</sup> February, 2019;

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 (Thirteenth 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 (hereinafter referred to as said rules), in rule 71, after sub-rule (8), the following sub-rule shall be inserted, namely:—

“(9) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.”.
3. In the said rules, in rule 71A, after sub-rule (4), before the proviso, the following sub-rule shall be inserted, namely:—

“(5) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.”.
4. In the said rules, in rule 71B, after clause (iv), before the proviso, the following clause shall be inserted, namely:—

“(v) in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.”.
5. In the said rules, in rule 76, after sub-rule (10), the following sub-rule shall be inserted, namely:—

“(11) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.”.
6. In the said rules, in rule 76A, after clause (iv), before the proviso, the following clause shall be inserted, namely:—

“(v) in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of

drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market:".

7. In the said rules, in Schedule A, after Form 50, the following Form shall be inserted, namely:—

**"FORM 51**

[See rules 71(9), 71A(5), 71B(v), 76(11) and 76A(v)]

*Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name*

- (1) I ..... of..... intend to market the drug specified below under a brand name or trade name - .....

(i) Name of the drug :

(ii) Dosage form :

(iii) Composition :

- (2) I hereby give this undertaking that to the best of my knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

Place.....

Date .....

[Signature, Name, Designation Seal/Stamp of manufacturer or on behalf of the manufacturer]."

[F. No. X.11018/48/2018-DRS]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 653(E), dated the 13th September, 2019.