

T-13011/1/2022-DCC-Part(3)  
भारत सरकार/ Government of India  
आयुष मंत्रालय/ Ministry of Ayush

NBCC Office Block-3 (2<sup>nd</sup> Floor),  
East Kidwai Nagar, New Delhi-110023.  
Dated : 20<sup>th</sup> November, 2023

To,

All State/ UT Ayush Drug Licensing Authorities.

**Subject: Clarification regarding use of prefix/ suffix and details of additives in respect of Ayurvedic, Siddha and Unani (ASU) drugs -reg.**

As you are aware that the provisions related to use of prefix or suffix with the name of Ayurvedic, Siddha and Unani (ASU) drugs and permitted excipients for ASU drugs are prescribed under Rules 157(1B) and Rule 169 of The Drugs and Cosmetics Rules, 1945 respectively.

2. It has been brought to the notice of Ministry of Ayush that in recent past, ASU drugs manufacturers have received notices from the Ayush drug regulators declaring their products not of standard quality (NSQ) /misbranded for the following reasons –

- *Name of the manufacturer company is on the label of ASU drug defined under section 3(a) of the Drugs and Cosmetics Act, 1940.*
- *Details of excipients are not declared on the label of Patent or Proprietary ASU drug defined under section 3(h) of the Drugs and Cosmetics Act, 1940.*

3. In this regard, it is to clarify that –

(i) Mark/brand name or company name mentioned on the top or bottom of the label/ product name of ASU classical drug approved under Section 3 (a), is not violation of Rule 157 (1B) of Drugs and Cosmetics Rules, 1945. However, mark/brand name or company name mentioned before or after the name of classical ASU medicine as prefix or suffix is violation of Rule 157 (1B) of Drugs and Cosmetics Rules, 1945.

(ii) As per the provisions prescribed under Rule 169 of Drugs and Cosmetics Rules, only the name of preservatives and colouring agents are required to be mentioned on the label and details of additives used in various processes and in formulating dosage forms are required to be given only in the application for licenses (i.e. not on the label).

4. This issues with the approval of Competent Authority.

Yours faithfully,



(Arjun Kumar)

Under Secretary to the Government of India

**Copy to:**

1. All Ayurveda, Siddha and Unani (ASU) drugs manufacturers/ Associations.