T-20020/9/2020-DCC

I/69442/2023

**Government of India**
**Ministry of Ayush**
**Drug Policy Section**

**NBCC Office Block-III(2nd Floor),**
**East Kidwai Nagar, South Ex-I,**
**New Delhi-110023**

**Advisory**

Whereas, Rule 169 of Drugs & Cosmetics Act 1940 and Rules made there under provides the details of conditions to use Permitted Excipients along with their standards i.e. additives, preservatives, antioxidants, flavouring agents, chelating agents etc. permitted in the Indian Pharmacopoeia (IP), Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 in Ayurveda, Siddha and Unani drugs., wherein it is mentioned that:

I. Preservatives and Coloring agents shall be mentioned on the label for the information of the consumer as required under rule 161 of the Drugs and Cosmetics Rules, 1945.
II. Additives used in various processes and in formulating dosage forms shall be mentioned clearly with quantities used, in the application for licenses and the record for the same shall be maintained by the manufacturers.

2. Whereas, it has come to the notice of Ministry of Ayush thatsome of Govt. Authorities in few states/UTs are insisting upon mentioning of quantity of Preservatives and Coloring agents on the label.

3. However in the Rule, it is made clear that the Rule 169 just provide for mentioning of name of the Preservatives and Coloring agents on the label. The quantity of the Preservatives and Coloring agents need not be mentioned over the label. However manufacturers have to submit the details of Preservatives and Coloring agents along with the quantity to the Licensing Authority at the time of License.

4. Accordingly, all State Licensing Authorities/ Government Analysts are directed to revise their actions and take further necessary steps.

5. This issues with the approval of Competent Authority.

27/11/23

**(Arjun Kumar),**
Under Secretary to the Government of India

**To,**

**All State/UT's Licensing Authority,**
**All Govt. Analyst.**