F. No. T-11011/8/2020-Drug Policy Section (AYUSH)
Government of India
Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Dated: 22nd September, 2020

To

All State Licensing Authorities: – 18245

Subject: Clarification about the licensing / approval of various dosage forms of Ayurvedic, Siddha and Unani (ASU) formulations/products – reg.

During the lockdown period in the wake of COVID 19 outbreak, Ministry has received representations from some State Licensing Authorities and Ayurveda, Siddha and Unani (ASU) drug manufacturers regarding manufacturing of ASU products in various dosage forms and their licensing or approval under the relevant provisions of Drugs & Cosmetics Rules, 1945.

2. The issues raised by the stakeholders have been examined in the light of legal definitions of ASU drug/medicine prescribed in Section 3(a) and (h)(i) of the Drugs & Cosmetics Act, 1940 and the guidelines provided under Rule 158-B of the Drugs & Cosmetics Rules, 1945 for grant of license or approval for manufacturing of various categories and sub-categories of ASU products. Accordingly, it is observed and hereby clarified that any ASU drug/medicine intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals can be manufactured in any dosage form/drug delivery system except for parenteral route administration, provided following conditions are fulfilled-

i) That the formulation itself or the ingredients of the formulation are mentioned in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule to the Drugs & Cosmetics Act, 1940;

ii) That the product applied for obtaining license/approval from the Licensing Authority qualifies the definition of ASU drug/medicine prescribed in Section 3(a) or Section 3(h)(i) of the Drugs & Cosmetics Act, 1940;

iii) That the standards of the formulation/ingredients are in accordance with the ASU pharmacopoeias & Formularies or in-house standards of the licensed manufacturer;

iv) That the excipients used in the manufacturing of concerned ASU drug/medicine are in accordance with the provisions of Rule 169 of Drugs & Cosmetics Rules, 1945 for permitted excipients;

Ministry of AYUSH
ISSUED ON
30 SEP 2020
Ayush Bhawan, B-Block
G.P.O. Complex, INA, New Delhi-23

v) That the evidence of shelf-life or date of expiry claim of the ASU product is in accordance with the provisions of Rule 161-B of the Drugs & Cosmetics Rules, 1945;

vi) That proof of safety and effectiveness of the applied product has been submitted in accordance with the provisions of Rule 158-B of the Drugs & Cosmetics Rules, 1945 for various categories & sub-categories of ASU drugs/medicines;

vii) That the labelling, packing and limit of alcohol in the applied ASU product are in accordance with the provisions of Rule 161 of the Drugs & Cosmetics Rules, 1945 and;

viii) That adequate manufacturing area and infrastructural facilities are available for the manufacturing of applied formulation/product in accordance with GMP requirements specified in Schedule T under Rule 157 of the Drugs & Cosmetics Rules, 1945.

3. The State Licensing Authority and the Expert Committee may accordingly examine, process and dispose of the application of the licensed drug manufacturer seeking approval of any ASU formulation/product.

(Dr. S.R. Chinta)
Deputy Adviser and
Assistant Drug Controller