F. No. T-13020/8/2021-DCC (AYUSH)
Government of India
Ministry of AYUSH

Dated: May, 2021

To

All State Licensing Authorities of ASU drugs.

Subject: Clarification about the licensing/approval of AYUSH-64 formulation-reg.

This Ministry had issued a memorandum of even number dated 27.4.2021 and further dated 29.4.2021 wherein all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees there under were informed to allow the licensed manufacturers for AYUSH-64 under their jurisdiction to include new indication of AYUSH 64 for repurposing as an intervention for the management of asymptomatic, mild to moderate COVID-19 in addition to existing indication(s) and to expedite the process of the licensing/approval of such applications for the manufacturing of AYUSH 64 medicine, provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, are fulfilled.

2. The issues raised by the stakeholders in this regard have been examined and following clarifications/guidelines is being provided to ease and expedite the licensing process of AYUSH 64:

i) That the already licensed manufacturers for AYUSH-64 under their jurisdiction be allowed to include new indication of AYUSH 64 for repurposing as an intervention for the management of asymptomatic, mild to moderate cases of COVID-19 in addition to existing indication(s). The standard label template to be strictly followed without any additional misleading information and name of Ministry of AYUSH is hereby attached in this regard. (Annexure)

ii) That any licensee other than those mentioned at point (i) above intending to manufacture AYUSH 64 have to get the technology transferred for AYUSH 64 from NRDC, Govt of India.

iii) That after obtaining rights and fulfillment of formalities from NRDC, licensee may apply to respective State Licensing Authority for approval under Rule 158-B.

iv) As an emergency measure the No objection certificate obtained from NRDC on submission of an undertaking by the manufacturer may be considered by the State Licensing Authorities.

v) That the State Licensing Authority may ensure that the standards of the formulation/ingredients are in accordance with the AYUSH 64 profile provided by CCRAS.

vi) That the requirement of consultation with expert committee is not required in this special case.

vii) That the Licensee has to comply other requirements as per relevant provisions of Drugs and Cosmetics Act 1940 and Rules 1945.

viii) That the excipients used in the manufacturing of concerned product is in accordance with the provisions of Rule 169 of Drugs & Cosmetics Rules, 1945 for permitted excipients.

ix.) That the licensee holding a valid license of AYUSH 64 in one particular State may be extended to any other State/UT of India where the manufacturer has a GMP certified unit approved for that category.

x.) That State Licensing Authorities are directed to consider all the data and protocols related with the products approval provided by CCRAS through NRDC to the firm and accordingly examine, process and dispose of the application of the licensed drug manufacturer seeking approval of AYUSH 64 within 7 days of application.

xi.) State registered on e-aushadhi.gov.in portal may see to utilize the portal for submission and processing of application of licensed drug manufacturer seeking approval of AYUSH 64.

3. Any further clarification in this regard may be directly addressed to dcc-ayush@nic.in, Ministry of AYUSH. The nodal officers from Drug Policy Section in this regard are Dr. Rachna Paliwal, Ph: 9830118994 and Dr. Vijay Gupta, Ph: 9811894563.

Enclosed: As above.

Digitally signed by DR. CHINTA SRINIVAS RAO
Date:Thu May 13 14:30:53 IST 2021
Reason: Approved

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

Annexure

Label Template of AYUSH 64 Tablets

AYUSH 64

Composition: Each 500mg of tablets contains Saptaparna (*Alstonia schlorais*, St. bk., Aq. Ext.) 100mg, Katuki (*Picorhizza kurroa*, Rt., Aq. Ext.) 100mg, Chirayata (*Swertia chirata*, Pl., Aq. Ext.) 100mg, Kuberaksha (Caesalpinia crista, Sd., Powder) 200mg.

Excipients: to be specified by manufacturer with quantity, if any

Preservatives: to be specified by manufacturer with quantity, if any

Colour: to be specified by manufacturer with quantity, if any

Ayurvedic Medicine

Mfd. Lic. No.: to be specified by manufacturer

Quantity: to be specified by manufacturer

Storage:

To be kept in cool and dry place, in original packaging

Indications:

Malaria, management of asymptomatic and Mild to moderate COVID -19 patients

Dose: (For Adults)

For Malaria: 4 tablets of 500mg thrice a day, after meals for 5-7 days or as directed by the Physician

For Asymptomatic COVID -19 patients: 2 tablets of 500mg twice a day, one hour after meals with warm water for 20 days or as directed by the prescribing Physician

For Mild to moderate COVID -19 patients: 2 tablets of 500mg thrice a day, one hour after meals with warm water for 20 days or as directed by the prescribing Physician

Advisory: To be taken under medical supervision

Batch No: to be specified by manufacturer

Mfd date: to be specified by manufacturer

Expiry date: to be specified by manufacturer

M.R.P.: to be specified by manufacturer

Name and address of the Manufacturer

Name and address of the Marketed by: if any