

T-18020/1/2020-DCC-Part(1)
Government of India
Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and
Homoeopathy (AYUSH)

Date: 27th April, 2021

MEMORANDUM

Due to the COVID 19 outbreak, the need for public use of ASU based immunity boosting products and medicines has been significantly emphasized and their demand has increased manifold. AYUSH 64, an Ayurvedic medicine was developed in compliance to all regulatory requirements and quality and pharmacopoeial standards by the Central Council for Research in Ayurvedic Sciences (CCRAS), an apex body for research in Ayurveda under the Ministry of AYUSH. Based on its ingredients having notable antiviral, immune-modulator and antipyretic properties and as recommended by the Interdisciplinary Committee for Inclusion of Ayurveda and Yoga in the management of mild COVID-19, the AYUSH 64 already was included in the National Clinical Management Protocol Based on Ayurveda and Yoga Interventions for the management of Asymptomatic and mild to moderate cases of COVID-19. (Copy enclosed).

2. It was further subjected to multi centric clinical trial for studying its efficacy in COVID 19 patients under joint initiative of CSIR-Ministry of AYUSH. The trial was completed and it was found that Add-on arm had showed a significant reduction in time to recovery (primary efficacy) as compared to the standard of care arm. Also, the safety and tolerability profile was good.

3. As regards the quality of life, Significant improvement in physical health in the Add-On Arm on hospital discharge and Borderline statistical improvement ($p < 0.07$) has been observed in psychological health on study completion.

4. The Monitoring Committee of CSIR-Min. of AYUSH Joint Initiative on Clinical Trials of four AYUSH Interventions for COVID-19 has also recommended that AYUSH-64 be positioned as an intervention for the management of asymptomatic, mild to moderate COVID-19 through repurposing.

5. In this regard, since the regulatory and quality control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/medicines under Drugs and Cosmetics Act, 1940 and Rules there under are enforced by the Licensing Authorities/Drug Controllers appointed by the State/UT Government, all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees there under are hereby 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).

6. The companies who are interested in technology transfer of AYUSH-64 may contact CCRAS (dg-ccras@nic.in, iprccras@gmail.com) /National Research Development Corporation (vkjain@nrdc.in). Technical support to the ASU drugs manufacturers regarding manufacturing of AYUSH-64 will be provided by Central Council for Research in Ayurvedic Sciences (CCRAS) as per the need. State Licensing Authorities are requested 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.

This issues with the approval of Secretary, Ministry of Ayush.

(Dr S.R.Chinta)
Deputy Adviser
Drug Policy Section

To,

All State/UT Licensing Authorities and Drug Controllers of AYUSH

Copy for information to:

- i. **Director (AYUSH) of all States/UTs.**
- ii. **ASU Drugs Manufacturers Associations**
- iii. **DG, CCRAS**