भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर २३, राज नगर
गाज़ियाबाद २०१००२ (उ.प्र.), भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar
Ghaziabad 201 002 (U.P.), INDIA

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

**Date:** 16th April 2021

**To,**
**All Stakeholders of Indian Pharmacopoeia**

## NOTICE

**Subject: Approach to Alternative Rapid Microbiological Methods-regarding.**

The Indian Pharmacopoeia Commission (IPC) has proposed a new General Chapter on 'Approach to Alternative Rapid Microbiological Methods' and the draft has been posted on the IPC website (www.ipc.gov.in) on 9th April 2021 for inviting comments, if any, from all the stakeholders (copy enclosed). The draft has been prepared after intense and in-depth consultation with relevant subject experts and approved by IPC's Expert Working Group-Microbiology. The best practices followed in other countries and the procedures and approaches provided under similar chapters in other Pharmacopoeias (like USP, BP etc.) have also been taken into consideration while preparing this draft.

As we are aware that current pandemic due to COVID-19 has urgently warranted for making available quality medicines to the patients at the earliest. This includes, but not limited to, Remdesivir Injection which has been approved by the CDSCO for restricted emergency use for the treatment of patients with severe COVID-19 infection. Recently the healthcare system has faced challenges in maintaining continuous supply of COVID-19 related drugs, particularly Remdesivir Injection, and it emerged that application of rapid alternative methods to the official Indian Pharmacopoeia (IP) methods may help in tackling this challenge.

In view of the above, as an interim measure it is proposed that the stakeholders may follow the draft General Chapter on 'Approach to Alternative Rapid Microbiological Methods' available on IPC's website. The proposed draft Rapid Microbiological Methods would enable faster laboratory testing of the drug(s) thereby making them accessible to the patients at the earliest without compromising the quality of the product. This approach would be in line with the provisions of the 'Alternative Methods' already given in the General Notices of the IP (Volume I, Page 12) wherein it is mentioned that automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance.

Accordingly, the manufacturers may submit validated data of the alternative Rapid Microbiological Methods and obtain the necessary approvals from appropriate Drug Regulatory Authorities under the provisions of the Drugs and Cosmetics Act 1940 and Rules 1945 there under.

**(Dr. Rajeev Singh Raghuvanshi)**

**Encl.** As above.

**Copy to:**

1. Dr. Mandeep K. Bhandari, Joint Secretary (Regulations), Ministry of Health & Family Welfare, Govt. of India, Nirman Bhawan, New delhi 110011.
2. Dr. V.G. Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi 110 002.
3. All State Drug Controllers