

## INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Government of India  
Sector 23, Raj Nagar, Ghaziabad 201 002

F. No. T.11013/02/2018-AR&D

Date: 26<sup>th</sup> February 2021

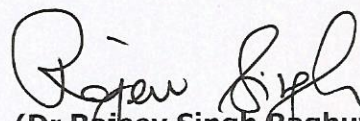
### NOTICE

#### **Subject: Clarification on Alternative Methods in the Indian Pharmacopoeia-regarding**

Indian Pharmacopoeia Commission (IPC) has been receiving many enquiries on the subject of *use of alternative methods instead of official methods included in the Indian Pharmacopoeia (IP)*. General Notices of IP (Volume I, Page 12) have the provision to use alternative methods and the same is reproduced below:

**Alternative Methods.** The tests and assays described are the official methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacturer of substance or product.

2. For removal of doubts, it is clarified that the authority competent to authorise manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval.
3. All concerned are requested to bring the above clarification to the notice of all authorities under their control.

  
(Dr Rajeev Singh Raghuvanshi)  
Secretary-cum-Scientific Director

To,

1. The Drugs Controller General (India)
2. CDSCO Zonal Offices
3. All State Drug Controllers
4. Members of the Scientific Body of IPC
5. Members of Sub-Committees of the Scientific Body of IPC
6. Directors of Drugs Testing Laboratories
7. Government Analysts
8. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations