

**F. No. Imp/Misc/20/2020-DC  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Import and Registration Division)**

FDA Bhawan,  
Kotla Road New Delhi 110002  
Dated:


04 DEC 2020

**CIRCULAR**

**Subject-Clarification regarding Reference Standards - Reg.**

In continuation to letter X-19014/10/04-D dated 17.11.2004 issued by this office, in one of the case for clarification regarding reference standards, wherein, after consultation with the Director, Central Drugs Testing Laboratory, Mumbai, it was communicated in the matter that Reference Standards are substances of known purity which are intended to be used exclusively for a specified analytical calibrating or referencing and not to be used as drugs, which may be clearly stated on label and/or accompanying certificate or literature.

Accordingly, for import of reference / working / impurity standards / general chemicals/ reagents, which are not intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, may not attract the provisions applicable for drugs.

  
**(Dr. V. G. Somani)**  
**Drugs Controller General (India)**

**To**

All Zonal/Subzonal/Port Offices of CDSCO

**Copy for information to:**

All stakeholders through CDSCO website