

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostics Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

File No. 29/Misc/3/2012-DC (09)

Date: **27 DEC 2012**

To,
All Zonal/Sub-Zonal/Port Officers of CDSCO

SUB: Clarification regarding NOC for import of diagnostic kits/ reagents - Reg.

Sir,

It is to clarify that as per current practices:

1. Kit intended for use in determining the presence of host cell protein contamination, etc., in products manufactured by expression in the CHO cell line and other technology. For Research and manufacturing use only and is not intended for diagnostic use in humans or animals.
2. In – Vitro diagnostic kits / reagents used in determining the presence of histamine, drugs substances , Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water & Soil etc.
3. Empty Specimens collection tubes without needle used for the collection of Blood, Urine, Stool, Sputum, Semen,,etc for purpose of specimens collection.

are not being regulated under provision of Drugs & Cosmetic Act and Rules (through Form 10 or Form 11 etc.) during import. Therefore, such cases may be examined and released at the level of ADC (I)/ In charge / port officer without referring for NOC.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (India)