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File No. 7-5/2016/Misc./041
Directorate General of Health Services
Central Drugs Standard Control Organization
(O/o Drugs Controller General India)

Directorate of Food and Drugs Administration
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09/10/17

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FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 04 OCT 2017

To

All the State/UT Drugs Controller

Subject: Criteria for verification of compliance reports of the manufacturing firms in continuation to the Risk Based Inspections conducted in their jurisdiction.

Sir,

Risk based inspection is a continuous programme to ensure Quality, Safety and Efficacy of the drugs available throughout the country. This directorate has planned joint Inspections of 249 units out of which 185 inspections were successfully completed and 64 could not be completed due to various reasons in various states to assess the level of Good Manufacturing Practices (GMP) as per Schedule M and Good Laboratory Practices (GLP) as per Schedule L1 of Drugs and cosmetics Rules .

In this regard this office has already forwarded joint inspection reports of all 185 manufacturing units to the concerned State Licensing Authorities to take necessary action.

Review Committee examined these inspection reports and recommended:

1) Manufacturing units rated less than 25% of SCHEDULE-M compliance or more than 10% of critical non-compliance may be issued Stop Production Order with Show Cause Notice by the Concerned State Licensing Authority
2) Manufacturing Units rated between ≥25% to <50% of SCHEDULE-M compliance or less than 10% of critical non-compliance may be issued Show Cause Notice and initiate immediate necessary actions.
3) Manufacturing Units rated between ≥50% to <75% of SCHEDULE-M compliance and no critical non-compliance may be advised by the respective State Licensing Authority to rectify the non-conformity of Schedule M within six months.
4) Manufacturing Units rated ≥75% and above of SCHEDULE-M compliance and no critical non-compliance of SCHEDULE-M may be advised by the respective State Licensing Authority to approach Zero Defects Concept.

Therefore manufacturing units whose "**Schedule M compliance is ≥75%**" and "**critical non-compliance is ≤10%**" are required to be verified by State Licensing Authority alone for better compliance at their end.

Also manufacturing units whose "**Schedule M compliance is less than 75 %**" or "**critical non-compliance is more than 10%** " are required to be verified by deputing the same inspection team comprising of one ADC (I), one DI from CDSCO and one officer from State, preferably the same officer who has participated earlier in Risk Based Inspection and the schedule for joint inspection will be communicated to all state/UT licensing authorities very soon.

Your kind cooperation in this matter is highly appreciated.

Yours faithfully,

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