No. 7-5/2016/Misc./041
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road,
New Delhi-110002.

23rd August, 2016

NOTICE

In order to ensure safety, efficacy and quality of drugs available in the country, CDSCO has prepared a detailed checklist for all manufacturing facilities to comply with the requirements of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) as specified under Schedule-M and Schedule L-1 of Drugs and Cosmetics Rules respectively. The checklist includes an elaborate tool kit for verification of GMP/GLP along with benchmarks based on the concept of rating manufacturing sites on the basis of an estimated risk that they may pose to patients and users of medicines. The checklist also includes WHO GMP and PIC/S standards.

2. The tool has been devised with a view to ensure that each Pharma manufacturing unit also carries out self-assessment of the level of compliance (GMP/GLP). It has been decided that the self-assessment be mandatorily carried out by unit and details of such assessment may be shared with State Licensing Authority and CDSCO.

3. In view of the above, it is requested that all drug manufacturing units may carry out assessment of their units and assign themselves Quality rating on the basis of benchmarks provided by CDSCO and submit the report to the concerned Licensing Authority and Office of DCG (I) by November 15, 2016

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

To

1. All Drugs manufacturers
2. All Pharma Associations

Copy to:

(i) All State Drug Controllers
(ii) PPS to JS (R), MoHFW