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Government of Goa,  
Dte. of Food & Drugs Admn.,  
Old I.P.H.B. Bldg,  
Altinho, Panaji Goa.  
Dated:- /11/2010.

**FOR INFORMATION AND COMPLIANCE OF ALL CONCERNED**

To,

**All the Allopathic Drug Manufacturers and  
Approved Testing Laboratory**

**Sub:- Implementation and compliance to schedule L-I on Good Laboratory Practices**

As you are aware that the Government of India has amended the Drugs & Cosmetic Rules, 1945 to incorporate Schedule L-I on Good Laboratory Practices and requirement of Premises and Equipment which were published under Notification No. GSR 780 (E) dated 10/11/2008 and period of two years was granted for the Pharma Industries to meet necessary arrangement to comply with requirement of Schedule L-I before the same are made mandatory. Accordingly the said notification mentioned under the said Rules has come into force on **1<sup>st</sup> November 2010**.

All the laboratories under the pharmaceutical units as well as approved testing units are required to comply with the provision of Schedule L-I in respect of Good Laboratory Practices, in respect of testing, calibration, validation and other technical activities carried out in the laboratories. It also further provides for maintenance, calibration and validation of equipments at regular intervals and the laboratories are required to prescribed SOP's and implement them and maintained records for the same. Internal quality system audits are also required in practice to verify that the operation conducted in the laboratories complied with requirements of quality systems.

In the light of the above, all pharmaceuticals units are hereby directed to ensure the compliance of the **Schedule L-I on Good Laboratory Practices** which are also in operation with effect from **1<sup>st</sup> November 2010** and they shall submit a detail compliance report in this regard to this Directorate **on or before 30/11/2010 positively**, so that the said compliance are thereafter verified by the enforcement staff through their special inspection drive for the purpose.

**(Salim A Veljee)**  
Director, Food & Drugs Admn.

