

Amendment No: 01 approved on 2013-10-02 to SLS 1316 : 2007

Insert following at the end of Clause 14 :

“15 INTERNAL AUDITING

15.1 Organization should make arrangements to conduct internal audits at planned intervals to verify the Good Manufacturing Practice (GMP) system with respect to applicable standards/ GMP internal system/ legal requirements.

15.2 Records relevant to internal auditing should be maintained. Any nonconformity raised during the audit should be rectified without any delay with correction(s), causes, corrective action(s) and verification of effectiveness of action(s) taken.

16 BRAND LIABILITY

16.1 If the organization uses the brand name of another company in Sri Lanka or foreign, the liability documents should be maintained by the relevant organization.

17 GMP MEETINGS

17.1 GMP meetings shall be conducted at regular intervals with responsible relevant personnel to review/discuss good practices and continual improvement related matters including emergency preparedness. Records shall be maintained with review output.”