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Good Laboratory Practice: A compulsory requirement for nonclinical laboratory testing

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Abstract-

Good Laboratory Practice (GLP) is a mandatory requirement to be followed by all manufacturing units in India who are engaged in production of drugs & pharmaceuticals and also for approved drug testing laboratories. GLP was made compulsory under schedule L1 of Drugs & Cosmetics Act 1940 and Rules 1945 by GSR 780(E) on 10th November, 2008 and effective from 1st November, 2010. Internationally, concept of GLP was first introduced in Newzeland (1972) (1), thereafter Denmark (1972). USFDA made GLP a mandatory requirement from 1978 onwards. EU countries started following GLP from 1987.

OECD principles of GLP were first accepted in 1981, revised in 1996, reviewed on 26th November 1997. At present there are 38 countries under OECD (**Organization for Economic Co-operation and Development**) where they follow common guidelines of GLP and also there are few OECD nonmember countries that also follow OECD, principle of GLP. GLP is followed to generate accurate, precise and reliable data. Advantages of following GLP are many, such as improvement of product quality, enhances credibility of testing data by saving cost and time of repetitive testing of same product. It promotes acceptance of test data internationally.

Key words: - GLP, OECD, NABL, USFDA, WHO, Schedule L1.

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