F.No.4-14/2013-DC (Misc.)
Dte. General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi – 110002.
Dated the 09 JAN 2014

OFFICE MEMORANDUM

Subject:- Requirement of obtaining approval from the office of Drugs Controller General (India) (DCGI) prior to initiation of activity of Bio Analytical Laboratory for the purpose of analysis of samples obtained from Bio Availability and Bio Equivalence studies- regarding.

Bioavailability (BA) study is conducted to assess the rate and extent to which the active drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of drug at the site of action.

Bioequivalence(BE) study is conducted to establish the absence of a significant difference in the rate and extent of absorption of an active drug from a pharmaceutical formulation in comparison to the reference formulation having the same active drug when administered in the same molar dose under similar conditions.

Such BA/BE studies are conducted in various study centres across the country. Report of BA/BE studies are accepted only from those centres, which are approved by CDSCO to conduct such studies.

Such study centres are required to have Clinical as well as Bioanalytical facilities to conduct BA/BE studies. However, there are some centres which may not have both the facilities of their own. In such cases, these centres avail the facility of others to conduct BA/BE studies.

It is brought to the notice of all concerned that no such facility either Clinical or Bioanalytical, should involve in conduct of BA/BE studies unless otherwise approved by CDSCO.

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