

F.No. 4-14/2015/BAL-09/Performics
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated: **26 APR 2018**

To,

M/s. Perfomics Analytical Labs LLP,
Plot no. 20, Road no. 12, Tech Park IP,
Nacharam, Hyderabad, Telangana State.

Sub: - Renewal of approval of Bioanalytical facility of M/s. Perfomics Analytical Labs LLP,
Plot no. 20, Road no. 12, Tech Park IP, Nacharam, Hyderabad, Telangana State – Reg.

Sir,

Please refer to your application no. nil dated 10.07.2017 received by this Directorate vide diary no. 34208/2017 dated 27.07.2017 on the subject matter.

Approval is hereby granted to M/s. Perfomics Analytical Labs LLP, Plot no. 20, Road no. 12, Tech Park IP, Nacharam, Hyderabad, Telangana State for carrying out test and analysis of bioanalytical samples received from approved BA/BE study centre for the protocol approved by this Directorate.

Subject to the following conditions:

1. This certificate shall remain valid for the period of three years from the date of issue. However, there will be periodical assessment of performance of the said study centre for continued acceptance of protocol and reports in this regard.
2. Firm shall accept the bioanalytical samples for carrying out test and analysis from the approved BA/BE Centre and for the protocol approved by this Directorate and concerned Ethics Committee.
3. Any change in analytical staff, person-in-charge or any change in constitution of the institution shall be forthwith reported to the approving authority.
4. The firm shall allow an Inspector appointed under the Act to enter, with or without prior notice, any premises where testing and analysis is carried on and to inspect the premises.
5. The approval is for carrying out test and analysis of bioanalytical samples and not meant for conducting BA/BE or any clinical study on subjects.
6. The data generated from this bioanalytical center prior to the date of approval shall not be accepted for submission to the Indian Drug Regulatory Authority.

You are hereby requested to rectify the deficiencies observed during the inspection and forward your compliance report to DDC (I), CDSCO, Hyderabad under intimation to this office.

Your's faithfully,


(Dr.K.Bangarurajan)

Joint Drugs Controller (India)

Copy to:- Deputy Drug Controller (India), CDSCO, Zonal Office Hyderabad, CDSCO Bhavan, Beside T.B. Centre, S.R. Nagar, Hyderabad (A.P.) – 500038.