

F.No.4-14/97-DC (MTR)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated

To,

✓ M/s Micro Therapeutic Research Labs Pvt Ltd.,
Selaiyur, East Tambaram,
Chennai-59

23 MAY 2011

Sub:-Approval of Bioavailability/Bioequivalence Study Centre of M/s Micro
Therapeutic Research Labs Pvt Ltd., East Tambaram, Selaiyur, Chennai-59

Sir,

Please refer to your letter no. Nil dated 22nd April, 2011 on the above
subject

As per documentation submitted by you, this Directorate, will accept the
protocol and bioavailability / bioequivalence study reports of New drugs from your
laboratory subject to following conditions:-

1. Specific Protocol for conducting BE/BA studies with new drug formulations should
be cleared by Institutional Ethics Committee and then got approved from this
office on case to case basis.
2. After one year there will be assessment of performance of the said study center
for continued acceptance of reports.

Yours faithfully,


(Dr. K. Bangarurajan)
Deputy Drugs Controller (India)

Copy to;

The Dy. Drugs Controller (I),
CDSCO (South Zone),
2nd Floor, Shastri Bhawan Annexe,
26, Haddows Road, Chennai-6