PROTECTION PLUS INSTITUTIONAL REVIEW BOARD (P+- IRB)

PROTECTION PLUS IRB/TLS/CPD/226/08
Date: 13th June 2008

To

The Principal Investigator
Clinical Pharmacology Department.
2nd Floor, Trident Life Sciences Limited
Survey No.: 66 (Part) & 67 (Part)
Miyapur Village, Serilingampally mandal
Hyderabad-500 050, India.

Sub: Decision of PROTECTION PLUS IRB for approval on BE Research Study with Protocol No. 117/08, Version: 00, Dated: 21st May 2008.

Ref: Your Letter No.: TLS/CPD/PROTECTION PLUS IRB/203/08, Dated: 09th June 2008 and other relevant documents.

Dear Sir,

Dr. Loka Vanaja Reddy	Prof. V. V. Hara Gopal
Dr. Shahina Sugra Siddiqua	Mr. Karuturi Vijay Chowdary
Dr. R.V. Reddy	Dr. L. Revathi
Mr. T.R. Datt	Dr. C. Sukumar

With reference to your above mentioned letter and after reviewing of the enclosed Protocol No. 117/08, Version 00: 21st May 2008 and Informed Consent documents (English & Telugu) Version: 00, Dated: 21st May 2008 by the above mentioned members, the IRB is pleased to grant approval for conducting the study titled "**An open label, randomized, two treatment, two sequence, two period, cross-over, single-dose, comparative oral bioavailability study of Escitalopram oxalate 20 mg tablets (Test) of Aurobindo Pharma Ltd., India and Cipralex 20 mg tablets (Reference) of H. Lundbeck A/S, Denmark in 28 healthy, adult, male, human subjects under fasting conditions.**" as per ICH-GCP / GLP guidelines.

Sincerely yours,

PROTECTION PLUS INSTITUTIONAL REVIEW BOARD ★ Date: 13/06/08

Dr. Loka Vanaja Reddy
Chairman

HIG - 210, Phase I & II, 2nd Floor, Maharashtra Bank Circle, KPHB Colony Kukatpally, Hyderabad - 500 072.
Phone : +91 - 40 - 40117197, Fax : +91 - 40 - 40117198, E-mail : protectionplusirb06@gmail.com