



APL INSTITUTIONAL REVIEW BOARD (APL-IRB)

APL-IRB-219/04

Date: November 02nd, 2004

Chairman

Justice Y.V. Narayana (Retd.)

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Bhushan

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Dr. G. Kusuma, MD DCH

Dr. P.S.N. Murthi, FRCS (Retd.)

Mr. Vinod Kumar (Retd.)

Dr. P. R. K. Reddy

Dr. Aruna MD

To

The Principal Investigator
Clinical Pharmacology Department
APL Research Centre
Survey No.313, Bachupally Village
Quthubullapur Mandal
R.R. District – 500 072.

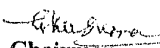
**Sub: Decision of APL-IRB for expedited approval on BA research
with Study No. Amx-06/04**

**Ref: Your Letter No. CPD/336/04 dated November 02nd, 2004 and
other relevant documents.**

Dear Sir,

With reference to your above mentioned letter and after reviewing the enclosed final Protocol and Informed Consent documents, IRB is pleased to grant expedited 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 Amoxicillin 500 mg capsules (Test) of Aurobindo Pharma Ltd., India and Amoxil (Reference) capsules of GlaxoSmithkline, UK, in 24 healthy, adult, male, human subjects under fasting conditions." as per ICH-GCP / GLP guidelines.

Sincerely yours,


Chairman

APL-IRB

