



# INSTITUTIONAL REVIEW BOARD (Savior- IRB)

Savior-IRB-409/06

Date: October 25<sup>th</sup>, 2006

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(Retd.)

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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 Savior-IRB for approval on BE research with  
Study No. Gap-03/06**

**Ref: Your Letter No. CPD/1067/06 dated October 24<sup>th</sup>, 2006 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 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 Gabapentin 400 mg capsules (Test), manufactured by Aurobindo Pharma Ltd., India and Neurontin 400 mg capsules (Reference), marketing authorization holder Parke Davis, UK, in 36 healthy, adult, male, human subjects under fasting conditions.**" as per ICH-GCP/GLP guidelines.

Sincerely yours,

*Y.V. Narayana*



Chairman  
Savior-IRB