IRB Approval Letter

JAMIA HAMDARD INSTITUTIONAL REVIEW BOARD
MEETING HELD AT 1600 HOURS ON JULY 28, 2010 (012/10)

APPROVAL OF NEW PROJECTS

IRB Members Present
Prof. S.D. Seth (Chairperson)
Dr. Farhan Jalees Ahmad (Convenor/Member Secretary)
Dr. Prem Kapoor
Mrs. Mariamma Kurian
Mr. M.H. Zahidi
Dr. (Mrs.) Manju Chhugani
Prof. S.H. Ansari
Dr. Naresh Kumar
Dr. Surender Singh

IRB Members Absent
None

The members present represented a quorum, being at least 50% plus one of all the members, and having at least one medically qualified person and at least one lay person present.

Protocol Title: An open label, balanced, randomized, three-treatment, three-period, three-sequence, crossover comparative bioavailability study of single oral-dose of two batches of olopatadine hydrochloride 10 mg extended release tablet of Ranbaxy Laboratories Limited with two oral doses of ALLELOCK® 5 mg tablets (each dose containing olopatadine hydrochloride 5 mg administered 12 hourly; total dose 10 mg), of Kyowa Hakko Kogyo Co. Ltd., in healthy, adult, human male subjects under fed condition

Project Number: 374_OLOPA_10
ICF Version Number: 1

Date of Protocol: Version 01; July 16, 2010
Date of ICF: July 16, 2010

Summary of Significant Issues Discussed and Controverted:
The Protocol, Informed Consent Form (ICF) both English and Hindi versions, volunteer’s compensation and accompanying product information were reviewed by the IRB. Of the members present, 9 voted for APPROVAL, 0 voted against and 0 abstained.

THE PROTOCOL INCLUDING ICFs ARE APPROVED.

Prof. S.D. Seth, IRB Chairperson

[Signature]

Date: 28/07/2010

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