Safeguarding public health



RESTRICTED – COMMERCIAL Dr.Bapuji APL Research Centre 313, Bachupally Quthubullapur (M) RR District Hyderabad -500 090 Andhra Padesh India

Date: 12th January 2012

Inspection Reference Number: INSP GCP 19276/426199-0001

GOOD CLINICAL PRACTICE (GCP) INSPECTION

E-mail: jason.wakelin-smith@mhra.gsi.gov.uk

Aurobindo Pharma Ltd APL Research Centre 19th – 21st October 2011

Dear Dr.Bapuji

Thank you for your letter dated 9th December 2011 responding to the observations contained within the post inspection report.

The inspection team have considered your response and have accepted the actions, which you have taken, or planned, to correct the reported deficiencies and prevent future recurrence.

I would be grateful if you could acknowledge receipt of this letter.

Yours sincerely,

Jason Wakelin-Smith Inspector MHRA

Medicines and Healthcare products Regulatory Agency Central Region Office Medicines Inspectorate 2 Falcon Way Welwyn Garden City Hertfordshire AL7 1TW T 01707 299130 F 01707 376649 www.mhra.gov.uk