



Agence française de sécurité sanitaire
des produits de santé

Inspection and companies department

Saint-Denis, 18 October 2006

Clinical trials inspection unit

Person in charge of the dossier: O. Le Blaye
Tel: +33 1 55 87 40 19

Copie certifiée conforme

TRANSLATION

INSPECTION REPORT

Response from the inspector to the observations of Mr. Sankar

Title of the trial inspected:

"Open label, balanced, randomized, two-treatment, two-sequence, two-period, single-dose, cross-over bioequivalence study of [REDACTED] produced by [REDACTED], [REDACTED] and [REDACTED] tablets containing [REDACTED] of [REDACTED] produced by [REDACTED] for [REDACTED] France, in healthy, adult, male, human subjects under fasting condition"
[REDACTED]

3-4 February 2006

GVK Biosciences Pvt. Ltd.
Swarna Jayanthi commercial complex
Ameerpet
Hyderabad-50038
India



Mr Sankar's observations of 07 October 2006 in reply to the inspection report dated 08 September 2006, call for the following response:

- D1 (insufficient documentation regarding the individual packaging of investigational medicinal products): deviation maintained for the trial inspected; note is taken of the corrective measures taken after the inspection.
- R1 (lack of documentation of the controls performed by the QA representative): remark maintained for the trial inspected; note is taken of the corrective measures taken after the end of the trial, before the inspection.
- E2 (lack of documentation of the anticoagulant used): deviation maintained for the trial inspected; note is taken of the corrective measures taken after the inspection.

The observations made during the inspection are not liable to jeopardise the acceptability of the trial data.

[signed]

Olivier LE BLAYE
Afssaps Inspector

