

## WHO Public Inspection Report (WHOPIR) of a Contract Research Organization

The report is the property of the organization responsible for performing the inspection.

### Part 1: General information

Name of organization	GVK Biosciences Pvt. Ltd
Physical address	Clinical R & D Division 7 <sup>th</sup> Floor, Swarna Jayanath Commercial Complex, Ameerpet Hyderabad – 500 038, India.
Postal address	Same as above
Telephone number	+91-40-6662 8888; 6663 5555
Fax number	+91-40-6662-2655
Summary of activities	Performance of preclinical and clinical studies, including bioequivalence trials (clinical and bio-analytical parts)
<b>WHO reference number</b> Study	<b>HA 406</b> # 115-06 Open label, balanced, randomized, two-treatment, two- sequence, two-period, single-dose, crossover oral bioequivalence study of fixed dose combination of Lamivudine/ Stavudine 150/40 mg tablets of Matrix Laboratories Limited, India and Epivir <sup>®</sup> (containing Lamivudine) 150 mg tablets of GlaxoSmithKline, USA and Zerit <sup>®</sup> (containing Stavudine) 40 mg capsule of Bristol – Myers Squibb Company, USA, in normal, healthy, adult, human subjects under fasting condition.
Investigational Products	Period 01: 22 January 2007 to 24 January 2007 Period 02 : 29 January 2007 to 31 January 2007  Epivir <sup>®</sup> (containing Lamivudine) 150 mg tablets Manufactured by : GlaxoSmithKline, USA Batch number : R215584  Zerit <sup>®</sup> (containing Stavudine) 40 mg capsules Manufactured by : Bristol - Myers Squibb Company, USA Batch number : 5L03092B
Reference Products	Lamivudine/Stavudine 150/40 mg tablets Manufactured by : Matrix Laboratories Limited, F-4 & F-12, Malegaon, MIDC, Sinnar- 422 113, Nashik District, Maharashtra

Sponsor	State, India. Batch number : LSTB536002 Manufacturing date : October 2006 Matrix Laboratories Limited
Date of inspection	18 January 2008
Project	Prequalification Programme : Priority Essential Medicines

## **Part 2: Summary**

### **Introduction**

GVK Biosciences Private Limited started its activity as Contract Research Organization in November 2003 and is conducting different types of bioavailability and bioequivalence studies.

The premises situated on the seventh floor of the building located in Hyderabad consisting of:

- four independent access controlled clinics, each with 34, 30 40 and 40 beds including 8 stations phlebotomy rooms, clinical examination rooms, emergency equipments and handling

The purpose of the inspection was to evaluate whether the bioequivalence studies performed for the fixed dose combination of :

**HA 406** : Lamivudine/Stavudine 150/40 mg Tablet manufactured by Matrix Laboratories Limited, India

was conducted in compliance with the submitted and assessed protocol, Good Clinical Practices (GCP) and other relevant WHO or international Good Practices and standards where applicable.

The CRO was inspected 3 and 4 February 2006 and accepted in October 2006 by the French Drug Regulatory Authority (AFSSAPS), as well as by the US FDA in May and September 2007. The site was previously inspected by WHO in September 2007.

Documentation reviewed included:

### **Clinical**

- Independent ethics committee review procedures
- Screening, and study consent forms
- Source data and results
- Master lists for subjects
- Documentation and SOPs relating to study drugs accountability and dispensing records, and study drug labels
- Randomization schedule
- Study drug administration
- Blood sample collection
- Lists of staff present during the study
- Master list of signatures of volunteers
- QA audit reports

### **Bio-analytical**

Various documents were reviewed. This included method validation for Stavudine : stock solution preparation, weighing, working standards and COA, source data, chromatograms (short term, long term, freeze thaw), validation and qualification. The concentrations indicated on chromatograms were checked against the reported tabulated data and dossier report.

Documentation reviewed included for several subjects:

- Repeat analysis record
- Chromatograms for subjects for different periods
- Results of calibration curves, and quality controls were reviewed for all runs of the study

At the time of the inspection the study was still under assessment and not yet accepted.

### **Part 3: Conclusion**

Based on the people met and the documents reviewed, and considering the findings of the inspection, reflected in the observations listed in the inspection report, the studies, clinical parts and bioanalytical parts, inspected can be considered to have been conducted at an acceptable level of compliance with WHO Good Clinical Practices (GCP) and Good Laboratory Practices (GLP), by GVK Biosciences Pvt. Ltd. located in Hyderabad, India.