



**National Pharmaceutical Control Bureau  
MINISTRY OF HEALTH MALAYSIA**

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Our Ref.: No. (01) in BPFK/007/03/A Chapter 1

Date: 5 June 2012

Euro Chemo-Pharma Sdn. Bhd.  
5, Jalan Astaka U8/82, Seksyen U8  
Bukit Jelutong  
40150 Shah Alam  
**SELANGOR**

**BIOEQUIVALENCE EVALUATION CENTER: LOTUS LABS PVT. LTD, NO 7, JASMA  
BHAVAN ROAD, MILLERS TANK BED AREA, BANGALORE, INDIA**

Referring the case as shown above.

2. Center for Investigational New Product, National Pharmaceutical Control Bureau (BPFK) has evaluated the examination report from US FDA towards the examination conducted on 3-6 May 2010 in Bioequivalence Evaluation Center above.

3. BPFK receives Bioequivalence evaluation performed in the facility from May 2010 to May 2013.

Thank you.

**“TO SERVE THE COUNTRY”**

Yours faithfully,

**(TAN ANN LING)**  
Director of Regulatory,  
National Pharmaceutical Control Bureau,  
Ministry of Health Malaysia

Copies sent to:

1. Ms. Siti Aida Abdullah  
Deputy Director of New Product Registration Center
2. Dr. Kamaruzaman Saleh  
Deputy Director of Center for Investigational New Product
3. Ms. Mazuwin Zainal Abidin  
Head of Generic Product Section, New Product Registration Center