BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
NATIONAL PHARMACEUTICAL CONTROL BUREAU
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46200 Petaling Jaya
Selangor Darul Ehsan
MALAYSIA

Tel. : +603-7883 5400
Faks (*Fax*) : +603-7956 2924
Laman Web (*Web*) : www.bpfk.gov.my

Our Ref. : NPRA/007/06/J9/2(11)
Date : 2nd August 2016

Dr. Feng-Nien Ko
CEO
Protech Pharmaservices Corporation,
Bioanalytical Laboratory
11th floor, No. 3, Park Street,
Nangang District,
Taipei 115, Taiwan.

Dear Sir,

NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) BIOEQUIVALENCE CENTRE COMPLIANCE PROGRAMME

The matter above and inspection conducted at your premise(s), Protech Pharmaservices Corporation, Taiwan during 14th – 18th March 2016 is referred.

Clinical Site	Protech Pharmaservices Corporation, Clinical Pharmacology Unit, Mackay Memorial Hospital Tamshui Branch, No. 45, Minsheng Rd., Tamsui District, New Taipei City 25160, Taiwan
Bio-analytical Site	Protech Pharmaservices Corporation, Bioanalytical Laboratory 11th floor, No. 3, Park Street, Nangang District, Taipei 115, Taiwan.

2. The corrective actions and preventives actions (CAPAs) were provided and found to be satisfactory. Thus, the inspection has been concluded as closed in BE/IEC Compliance Meeting.

3. Herewith, we enclosed the *Certificate of NPRA Bioequivalence Centre Compliance Programme* for your perusal. The certificate is valid for three years.

4. Please be advised that if you are interested in retaining the BE Centre under the NPRA BE Centre Compliance Programme, you shall submit an application through any Malaysian registered company requesting for surveillance inspection at least 15 months before the expiry of the attached certificate. The validity of next certificate will be extended from the date of the BE/IEC Compliance Meeting or the certificate expiry date, whichever later.

Thank you.

Sincerely,

(DR KAMARUZAMAN SALEH)
Deputy Director
Centre for Investigational New Product
On behalf of Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

AGENSI REGULATORI FARMASI NEGARA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

KEMENTERIAN KESIHATAN MALAYSIA

MINISTRY OF HEALTH MALAYSIA

PROGRAM KOMPLIANS PUSAT KAJIAN BIOEKUIVALENS

BIOEQUIVALENCE CENTRE COMPLIANCE PROGRAMME

NO. SIJIL *CERTIFICATE NO.*	:	**KGCP/BE 201603**
Pusat Kajian Bioekuivalens *Bioequivalence Centre*	:	**Protech Pharmaservices Corporation, Taiwan**
Tapak Klinikal *Clinical Site*	:	**Protech Pharmaservices Corporation, Clinical Pharmacology Unit** Mackay Memorial Hospital Tamshui Branch, No. 45, Minsheng Rd., Tamsui District, New Taipei City 25160, Taiwan
Tapak Bioanalitikal *Bio-analytical Site*	:	**Protech Pharmaservices Corporation, Bioanalytical Laboratory** 11th floor, No. 3, Park Street, Nangang District, Taipei 115, Taiwan.
Tarikh Pemeriksaan *Date of Inspection*	:	14th – 18th March 2016
Tempoh Sah Sijil *Certificate Validity*		28th January 2017 – 27th January 2020

Pusat kajian bioekuivalens tersebut di atas telah disenaraikan di dalam Program Komplians Pusat Kajian Bioekuivalens, Agensi Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia. Sijil ini sah bagi tiga (3) tahun.

The above mentioned bioequivalence centre is listed in the Bioequivalence Centre Compliance Programme, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia. This certificate is valid for three (3) years.

Date: 2nd August 2016

Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia