

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUN 2020

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	115-18	Kajian BE	1) Levozal Film Coated Tablet 5mg 2) Xyzal (Levocetirizine Dihydrochloride) 5mg Film Coated Tablet	RA Chem Pharma Limited Clinical Research & Biosciences Division Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India.	Lulus
2.	Amlodipine10Fasted-Hovid	Kajian BE	1) Istin 10mg Tablet 2) Hovasc 10mg Tablet	Clinical Research Ward (CRW) Clinical Trial Unit Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor	Lulus
3.	AV104-101	Kajian BA	1) AV104 Transmucosal Film – 18mg/film 2) Selincro 18mg Film-coated Tablets	Borneo Kinetics Sdn. Bhd., Heart Centre, Kota Samarahan	Lulus
4.	IK1591-(01) Metformin XR	Kajian BE	1) Glupac SR prolonged-release Tablet 1000mg 2) Glucophage® SR prolonged-release Tablet 1000mg	Info Kinetics Sdn Bhd 5 th Floor Gleneagles Penang No. 1, Jalan Pangkor 10050 George Town Pulau Pinang	Lulus

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
5.	GXE4KGBio-001	Fasa III	1) Efepoetin alfa 1mg/1 mL, solution (pre-filled syringe) 2) Efepoetin alfa 0.6mg/0.6 mL, solution (pre-filled syringe) 3) Methoxy polyethylene glycol-epoetin beta, 50mcg/0.3ml, solution (pre-filled syringe) 4) Methoxy polyethylene glycol-epoetin beta, 100mcg/0.3ml, solution (pre-filled syringe)	1) Hospital Kuala Lumpur 2) Hospital Raja Permaisuri Bainun 3) Hospital Serdang 4) Hospital Seri Manjung 5) Hospital Sibul 6) University Malaya Medical Centre	Lulus