

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0039-22	Kajian BE	Ezetimibe and Atorvastatin Tablets 10 mg/40 mg	Clinical site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India Bioanalytical site: Lambda Therapeutic Research Ltd., Lambda House, Plot No. 38, Survey No 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS
2.	ARL/21/247	Kajian BE	Sotalol Tablets 160 mg	Clinical site: Accutest Research Lab (I) Pvt. Ltd. 4th Floor, The Grand Monarch Near Seema Hall, Anand Nagar Road, Satellite, Ahmedabad-380015, India.	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Bioanalytical site: Accutest Research Laboratories (I) Pvt. Ltd., A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai – 400709, Maharashtra, India.	
3.	001-22	Kajian BE	Escitalopram Tablet 10mg	Clinical & Bioanalytical site: RA Chem Pharma Limited, Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
4.	MECID No, UMMC: 202086-8956; NMRR, MOH: 60482; JEPeM, USM: USM/JEPeM/21070522	Fasa II	INJECSOL Vitamin C (Ascorbic Acid Injection 1g/5mL)	a) University of Malaya Medical Centre b) Hospital Universiti Sains Malaysia c) Hospital Kuala Lumpur (HKL)	LULUS
5.	VICSEP	Fasa II	a) INJECSOL Vitamin C (Ascorbic Acid Injection 1g/5mL) b) INFUSOL® D5 (Dextrose 5% w/v Intravenous Infusion BP)	a) Hospital Raja Permaisuri Bainun b) Hospital Sultanah Bahiyah c) Hospital Raja Perempuan Zainab II	LULUS
6.	VT3996-301	Fasa 1b/II	a) Viracta VRx-3996 (nanatinostat) tablets, 10 mg	a) Hospital Umum Sarawak	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			b) Valganciclovir 450 mg tablets (Valganciclovir Tablets, USP)	b) University Malaya Medical Centre c) Institut Kanser Negara	
7.	1443-0002	Fasa Ib	a) BI 765063 50mg/mL solution for infusion b) BI 754091 20mg/mL solution for infusion c) BI 836880 10mg/mL solution for infusion	a) University Malaya Medical Centre b) Hospital Umum Sarawak c) Institut Kanser Negara d) Hospital Sultan Ismail	LULUS
8.	CPI 0610-04	Fasa III	a) CPI-0610 25 mg film-coated tablet b) CPI-0610 100 mg film-coated tablet c) Placebo for CPI-0610 25 mg film-coated tablet d) Placebo for CPI-0610 100 mg film-coated tablet	a) Hospital Queen Elizabeth b) Hospital Pulau Pinang c) Sunway Medical Centre d) Hospital Sultanah Aminah e) Hospital Sultanah Bahiyah f) University Malaya Medical Centre g) Hospital Ampang	LULUS
9.	INS1009-202	Fasa IIb	a) Treprostinil Palmitil Inhalation Powder 80µg capsules b) Treprostinil Palmitil Inhalation Powder 160µg capsules c) Treprostinil Palmitil Inhalation Powder 320µg capsules d) Treprostinil Palmitil Inhalation Powder placebo capsules	a) Hospital Tengku Ampuan Afzan b) Hospital Serdang c) UiTM Medical Specialist Centre d) Hospital Sultanah Bahiyah	LULUS