

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JULAI 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	20-VIN-0498	Kajian BE	Fexofenadine 180mg Tablet	<p>Clinical site: Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi, Ahmedabad, 380015 India</p> <p>Bioanalytical site: Veeda Clinical Research Pvt.Ltd. Rev. Sur. No.12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S.G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India</p>	LULUS
2.	BX-PL21-AMP-001	Kajian BE	Tadalafil Film Coated Tablet 20mg	<p>Clinical site: Clinical Research Ward Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	LULUS
3.	105-21	Kajian BE	Midodrine Hydrochloride Tablets USP, 5mg	<p>Clinical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Bioanalytical site: AXIS Clinicals Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.	
4.	106-21	Kajian BE	Midodrine Hydrochloride Tablets USP, 5mg	Clinical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India. Bioanalytical site: AXIS Clinicals Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500 049, India.	LULUS
5.	AV104-102	Kajian BA	a) AV104 8 mg film, pH 4.25 b) AV104 8 mg film, pH 5.50 c) AV104 8 mg film, pH 7.0	Borneo Kinetics Sdn. Bhd., Sarawak General Hospital Heart Centre	LULUS
6.	MK-3475-905	Fasa III	a) Enfortumab Vedotin 30mg/Vial Lyophilized Powder for IV Infusion b) MK-3475 (Pembrolizumab) 25mg/ml, Concentrate for Solution for Infusion, 4ml Vial	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Pulau Pinang	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
7.	MK-3475-B15	Fasa III	<ul style="list-style-type: none"> a) Enfortumab Vedotin 30mg/Vial Lyophilized Powder for IV Infusion b) MK-3475 (Pembrolizumab) 25mg/ml, Concentrate for Solution for Infusion, 4ml Vial c) Gemcitabine 1000mg vial powder for solution d) Cisplatin 1mg/mL, 50mL Concentrate for Solution for Infusion 	<ul style="list-style-type: none"> a) Sarawak General Hospital b) University Malaya Medical Centre c) Sunway Medical Centre 	LULUS
8.	MAA-304	Fasa III	4.6mg of Marzeptacog alfa (activated) [MarzAA] powder in 5mL vial	<ul style="list-style-type: none"> a) Hospital Sultanah Bahiyah b) Hospital Queen Elizabeth c) Hospital Tunku Azizah d) Hospital Ampang e) Hospital Raja Perempuan Zainab II f) Hospital Tuanku Ja'afar 	LULUS
9.	MOR202C206	Fasa II	Felzartamab powder for concentrate for solution for infusion, 325 mg/vial in ISO 20R vial	University Malaya Medical Centre	LULUS
10.	GT0918-MR-3001	Fasa III	GT0918 (Proxalutamide) 100mg Tablet	Hospital Miri	LULUS