

**SENARAI PRODUK – PRODUK YANG TELAH DILULUSKAN OLEH PIHAK BERKUASA KAWALAN DADAH (PBKD) DALAM MESYUARAT PBKD KALI KE – 313
TARIKH MESYUARAT : 4 JULAI 2017**

Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
1	201506302014A/ MAL17075016AZ	ACCORD BORTEZOMIB 3.5 (Bortezomib powder for solution for injection 3.5 mg/vial)	ACCORD HEALTHCARE SDN.BHD.	INTAS PHARMACEUTICALS LIMITED (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
2	201403132022A/ MAL17075018AZ	APO- IRBESARTAN/HCTZ 150/12.5 mg TABLET	PHARMAFORTE (MALAYSIA) SDN. BHD.	Apotex Research Private Ltd (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
3	201403132023A/ MAL17075019AZ	APO- IRBESARTAN/HCTZ 300/12.5 mg TABLET	PHARMAFORTE (MALAYSIA) SDN. BHD.	Apotex Research Private Ltd (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
4	201403132024A/ MAL17075020AZ	APO- IRBESARTAN/HCTZ 300/25 mg TABLET	PHARMAFORTE (MALAYSIA) SDN. BHD.	Apotex Research Private Ltd (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
5	201404110001A/ MAL17075008AZ	Bidol (Tramadol Hydrochloride 37.5mg and Paracetamol 325 mg tablets)	HEALOL PHARMACEUTICALS SDN. BHD.	MICRO LABS LIMITED (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
6	201603302021A/ MAL17075023ACR Z	BRIDION 100MG/ML SOLUTION FOR INJECTION	MERCK SHARP & DOHME (MALAYSIA) SDN BHD	Patheon Manufacturing Services LLC (UNITED STATES)	04/07/2017 – 04/07/2022	New Registration Approval
7	201507280001A/ MAL17075028ACZ	Combi-Prost Eye Drops	Aspen Medical Products Malaysia Sdn Bhd	RAFARM S.A. (GREECE)	04/07/2017 – 04/07/2022	New Registration Approval

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
8	201511042012X/ MAL17075024XZ	CONLAX-10 (Bisacodyl Suppositories BP 10mg)	HEALOL PHARMACEUTICALS SDN. BHD.	Bliss GVS Pharma Ltd (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
9	201310072013A/ MAL17075014AZ	ELASTA 60mg FILM- COATED TABLETS	MMS PHARMA (MALAYSIA) SDN. BHD.	Pharmathen S.A. (GREECE)	04/07/2017 – 04/07/2022	New Registration Approval
10	201509082012A/ MAL17075006AZ	EPIROL Epirubicin Hydrochloride Powder for Solution for Injection 10mg	UNIMED SDN BHD	INTAS PHARMACEUTICALS LIMITED (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
11	201509082013A/ MAL17075022AZ	EPIROL Epirubicin Hydrochloride Powder for Solution for Injection 50mg	UNIMED SDN BHD	INTAS PHARMACEUTICALS LIMITED (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
12	201605232052X/ MAL17075026XC	Essentiale MAX 600mg Capsule	SANOFI-AVENTIS (MALAYSIA) SDN. BHD.	A. NATTERMANN & CIE. GMBH (GERMANY)	04/07/2017 – 04/07/2022	New Registration Approval
13	201503162012A/ MAL17075002AZ	Factive film-coated tablet 320 mg	PAHANG PHARMACY SDN. BHD.	LG CHEM LTD (KOREA,SOUTH)	04/07/2017 – 04/07/2022	New Registration Approval
14	201207192019A/ MAL17075012AZ	IRBIS 150 (Irbesartan Tablets 150 mg)	UNIMED SDN BHD	Hetero Labs Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
15	201207192018A/ MAL17075011AZ	IRBIS 300 (Irbesartan Tablets 300mg)	UNIMED SDN BHD	Hetero Labs Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
						Approval
16	201207192017A/ MAL17075010AZ	LOSAGEN 100(Losartan Potassium Tablets 100 mg)	UNIMED SDN BHD	Hetero Labs Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
17	201206132015A/ MAL17075005AZ	LOSAGEN 25 (Losartan Potassium Tablets 25mg)	UNIMED SDN BHD	Hetero Labs Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
18	201207192016A/ MAL17075009AZ	LOSAGEN 50(Losartan Potassium Tablets 50mg)	UNIMED SDN BHD	Hetero Labs Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
19	201403132014A/ MAL17075013AZ	MENELAT 30 MG TABLETS	LABORATORIES TORRENT (MALAYSIA) SDN. BHD.	TORRENT PHARMACEUTICALS LTD (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
20	201406202014A/ MAL17075015AZ	MENELAT 45 MG TABLETS	LABORATORIES TORRENT (MALAYSIA) SDN. BHD.	TORRENT PHARMACEUTICALS LTD (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
21	201512172017X/ MAL17075027XCS	Methycobal Injection 500mcg/ml	EISAI (MALAYSIA) SDN BHD (18039- D)	Nipro Pharma Corporation Ise Plant (JAPAN)	04/07/2017 – 04/07/2022	New Registration Approval
22	201502052018A/ MAL17075004ARZ	Nesina Met 12.5mg/1000mg Film-	Takeda Malaysia Sdn Bhd	TAKEDA PHARMACEUTICAL COMPANY LIMITED	04/07/2017 – 04/07/2022	New Registration Approval

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
		Coated Tablet		(JAPAN)		
23	201502052017A/ MAL17075003ARZ	Nesina Met 12.5mg/500mg Film- Coated Tablet	Takeda Malaysia Sdn Bhd	TAKEDA PHARMACEUTICAL COMPANY LIMITED (JAPAN)	04/07/2017 – 04/07/2022	New Registration Approval
24	201508102013A/ MAL17075007ACZ	Ondansetron-AFT Solution for Injection 2mg/ml	AFT PHARMACEUTICALS (SE ASIA) SDN BHD	Qilu Pharmaceutical Co.,Ltd (CHINA)	04/07/2017 – 04/07/2022	New Registration Approval
25	201605242027X/ MAL17075025X	PEGALATE ORAL SACHET	UNIMED SDN BHD	Strides Shasun Limited (INDIA)	04/07/2017 – 04/07/2022	New Registration Approval
26	201603022014A/ MAL17075001AZ	Spiolto Respimat Inhalation Solution 2.5mcg/2.5mcg per actuation	BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.	Boehringer Ingelheim Pharma GmbH & Co.KG (GERMANY)	04/07/2017 – 04/07/2022	New Registration Approval
27	201602042013A/ MAL17075021AZ	VISCLEAR EYE DROP 0.5MG/ML	Y.S.P. INDUSTRIES (M) SDN BHD	Y.S.P. INDUSTRIES (M) SDN BHD (MALAYSIA)	04/07/2017 – 04/07/2022	New Registration Approval
28	201507212015A/ MAL17075029ACZ	Xalaprost 0.005%w/v Eye Drops	Aspen Medical Products Malaysia Sdn Bhd	RAFARM S.A. (GREECE)	04/07/2017 – 04/07/2022	New Registration Approval
29	201602042012A/ MAL17075017AZ	YSP Salbutamol Injection 0.5mg/ml	Y.S.P. INDUSTRIES (M) SDN BHD	Y.S.P. INDUSTRIES (M) SDN BHD (MALAYSIA)	04/07/2017 – 04/07/2022	New Registration Approval

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30	201605232051T/ MAL17065027TC	ChapaCare Capsule	Naturemedics Laboratories Sdn Bhd	SARI TANI DESA SDN. BHD. (MALAYSIA)	20/06/2017 – 20/06/2022	New Registration Approval
31	201605162029T/ MAL17065026TC	VitaHealth Horseradish & Aged Black Garlic Plus Tablet	SWISS BIO PHARMA SDN. BHD.	ARNET PHARMACEUTICAL CORPORATION (UNITED STATES)	07/06/2017 – 07/06/2022	New Registration Approval
32	201605172029T/ MAL17065025T	Yi Shi Yuan Pi Fu Zhi Yang Wan	Yi Si Yuan Trading Sdn. Bhd.	Yi Shi Yuan Pte Ltd (SINGAPORE)	07/06/2017 – 07/06/2022	New Registration Approval
33	201008160001X/ MAL12035008X	GLUCOSAMINE CAPSULES 375mg	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD (MALAYSIA)	04/07/2017 – 04/07/2022	Re- Registration (Renewal)
34	201011030005T / MAL11035023T	Immu Activ-Plus	Bioalpha International Sdn. Bhd.	Bioalpha International Sdn. Bhd. (MALAYSIA)	04/07/2017 – 04/07/2022	Re- Registration (Renewal)
35	201010060005T/ MAL11035008T	Sweet-duce Capsule	Bioalpha International Sdn. Bhd.	Bioalpha International Sdn. Bhd. (MALAYSIA)	04/07/2017 – 04/07/2022	Re- Registration (Renewal)
36	201009170001T/ MAL11035006T	Apotec Total Women Capsule	Bioalpha International Sdn. Bhd.	Bioalpha International Sdn. Bhd. (MALAYSIA)	04/07/2017 – 04/07/2022	Re- Registration (Renewal)

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37	201107180001T/ MAL12015031T	B-Sky Fruit	Bioalpha International Sdn. Bhd.	Bioalpha International Sdn. Bhd. (MALAYSIA)	04/07/2017 – 04/07/2022	Re- Registration (Renewal)
38	201605302062A/ MAL17075033ARZ	Cyramza 100mg/10ml concentrate for solution for infusion	ELI LILLY (MALAYSIA) SDN. BHD.	ELI LILLY AND COMPANY (UNITED STATES)	04/07/2017 – 04/07/2022	New Registration Approval
39	201605302065A/ MAL17075034ARZ	Cyramza 500mg/50ml concentrate for solution for infusion	ELI LILLY (MALAYSIA) SDN. BHD.	ELI LILLY AND COMPANY (UNITED STATES)	04/07/2017 – 04/07/2022	New Registration Approval