List of Approved Biosimilars (DCA 365 – 8th October 2021)

No.	Active Substance	Product Name	Registration No.	Product Registration Holder	Manufacturer	Reference Product
1.	Adalimumab	AMGEVITA 40 mg/0.8 ml solution for injection in pre-filled syringe	MAL19056101AZ	AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD	AMGEN MANUFACTURING, LTD, UNITED STATES	Humira (Abbvie)
2.	Adalimumab	AMGEVITA 20 mg/0.4 ml solution for injection in pre-filled syringe	MAL19056100AZ	AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD	AMGEN MANUFACTURING, LTD, UNITED STATES	Humira (Abbvie)
3.	Adalimumab	AMGEVITA 40 mg/0.8 ml solution for injection in pre-filled autoinjector	MAL19056105AZ	AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD	AMGEN MANUFACTURING, LTD, UNITED STATES	Humira (Abbvie)
4.	Adalimumab	IDACIO solution for injection in pre-filled pen 40mg/0.8ml	MAL21106014ACRZ	FRESENIUS KABI MALAYSIA SDN BHD	FRESENIUS KABI AUSTRIA GMBH, HAFNERSTRABE 36, 8055 GRAZ, AUSTRIA	Humira (Abbvie)
5.	Adalimumab	IDACIO solution for injection in pre-filled syringe 40mg/0.8ml	MAL21106015ACRZ	FRESENIUS KABI MALAYSIA SDN BHD	FRESENIUS KABI AUSTRIA GMBH, HAFNERSTRABE 36, 8055 GRAZ, AUSTRIA	Humira (Abbvie)
6.	Adalimumab	IDACIO solution for Injection for paediatric use 40mg/0.8ml	MAL21106016ACRZ	FRESENIUS KABI MALAYSIA SDN BHD	FRESENIUS KABI AUSTRIA GMBH, HAFNERSTRABE 36, 8055 GRAZ, AUSTRIA	Humira (Abbvie)
7.	Bevacizumab	MVASI Concentrate for Solution for Infusion 25 mg/ml	MAL19086005ACZ	AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD	AMGEN MANUFACTURING, LTD, UNITED STATES	Avastin (Roche)

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8.	Bevacizumab	KRABEVA Bevacizumab (r-DNA Origin) Concentrate for Solution for Intravenous Infusion 25mg/mL	MAL20126007AZ	BIOCON SDN. BHD.	BIOCON BIOLOGICS INDIA LIMITED, INDIA	Avastin (Roche)
9.	Enoxaparin sodium	INHIXA 2000iu/0.2ML (PREFILLED SYRINGE FOR INJECTION)	MAL21026024ACZ	MEDISPEC (M) SDN. BHD.	SHENZHEN TECHDOW PHARMACEUTICAL CO. LTD., CHINA	Clexane (Sanofi)
10.	Enoxaparin sodium	INHIXA 4000iu/0.4ML (PREFILLED SYRINGE FOR INJECTION)	MAL21026025ACZ	MEDISPEC (M) SDN. BHD.	SHENZHEN TECHDOW PHARMACEUTICAL CO. LTD., CHINA	Clexane (Sanofi)
11.	Enoxaparin sodium	INHIXA 6000iu/0.6ML (PREFILLED SYRINGE FOR INJECTION)	MAL21026026ACZ	MEDISPEC (M) SDN. BHD.	SHENZHEN TECHDOW PHARMACEUTICAL CO. LTD., CHINA	Clexane (Sanofi)
12.	Enoxaparin sodium	Enoxaparin Sandoz 2,000 IU (20 mg)/0.2 mL Solution for Injection in Pre-filled Syringe	MAL21026027ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
13.	Enoxaparin sodium	Enoxaparin Sandoz 4,000 IU (40 mg)/0.4 mL Solution for Injection in Pre-filled Syringe	MAL21026028ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
14.	Enoxaparin sodium	Enoxaparin Sandoz 6,000 IU (60 mg)/0.6 mL Solution for Injection in Pre-filled Syringe	MAL21026029ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
15.	Enoxaparin sodium	CRUSIA 2000 IU (20 mg)/0.2 ml Solution for Injection in Pre-filled Syringe	MAL21026030ACZ	UNIMED SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)

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16.	Enoxaparin sodium	CRUSIA 4000 IU (40 mg)/0.4 ml Solution for Injection in Pre-filled Syringe	MAL21026031ACZ	UNIMED SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
17.	Enoxaparin sodium	CRUSIA 6000 IU (60 mg)/0.6 ml Solution for Injection in Pre-filled Syringe	MAL21026032ACZ	UNIMED SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
18.	Enoxaparin sodium	CRUSIA 8000 IU (80 mg)/0.8 ml Solution for Injection in Pre-filled Syringe	MAL21026033ACZ	UNIMED SDN. BHD.	ROVI CONTRACT MANUFACTURING S.L., SPAIN	Clexane (Sanofi)
19.	Erythropoietin (Epoetin Alfa)	Binocrit 2,000 IU/1 ml solution for injection in a pre-filled syringe	MAL20112122ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Eprex (Johnson & Johnson)
20.	Erythropoietin (Epoetin Alfa)	Binocrit 4,000 IU/0.4 ml solution for injection in a pre-filled syringe	MAL20112123ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Eprex (Johnson & Johnson)
21.	Erythropoietin (Epoetin Alfa)	Binocrit 10 000 IU/1 ml solution for injection in a pre-filled syringe	MAL20112124ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Eprex (Johnson & Johnson)
22.	Erythropoietin (Epoetin Alfa)	Binocrit 40, 000 IU/1 ml solution for injection in a pre-filled syringe	MAL20112125ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Eprex (Johnson & Johnson)
23.	Erythropoietin (Epoetin zeta)	EPO STADA 2000IU/0.6ml Solution for Injection in a Pre-filled Syringe	MAL15105038ACZ	INNO BIO VENTURES SDN. BHD.	STADA ARZNEIMITTEL AG, GERMANY	Eprex (Johnson & Johnson)
24.	Erythropoietin (Epoetin zeta)	EPO STADA 4000IU/0.4ml Solution for Injection in a Pre-filled Syringe	MAL15105040ACZ	INNO BIO VENTURES SDN. BHD.	STADA ARZNEIMITTEL AG, GERMANY	Eprex (Johnson & Johnson)

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25.	Erythropoietin (Epoetin zeta)	EPO STADA 10000IU/1.0ml Solution for Injection In a Pre-filled Syringe	MAL15105039ACZ	INNO BIO VENTURES SDN. BHD.	STADA ARZNEIMITTEL AG, GERMANY	Eprex (Johnson & Johnson)
26.	Erythropoietin (Epoetin Alfa)	Erysaa Prefilled Syringe 2000IU/0.5mL	MAL19016091ACRZ	DUOPHARMA (M) SDN. BHD.	PANGEN BIOTECH INC, SOUTH KOREA	Eprex (Johnson & Johnson)
27.	Erythropoietin (Epoetin Alfa)	Erysaa Prefilled Syringe 4000IU/0.4mL	MAL19016090ACRZ	DUOPHARMA (M) SDN. BHD.	PANGEN BIOTECH INC, SOUTH KOREA	Eprex (Johnson & Johnson)
28.	Erythropoietin (Epoetin Alfa)	Erysaa Prefilled Syringe 2000IU/0.5mL	MAL20016134ASZ	DUOPHARMA (M) SDN. BHD.	DUOPHARMA (M) SDN. BHD.	Eprex (Johnson & Johnson)
29.	Filgrastim	Zarzio 30 MU/0.5 ml solution for injection or infusion	MAL12035084ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	IDT BIOLOGIKA GMBH, GERMANY	Neupogen (Amgen)
30.	Filgrastim	Zarzio 48 MU/0.5 ml solution for injection or infusion in pre-filled syringe	MAL12035085ACZ	NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.	IDT BIOLOGIKA GMBH, GERMANY	Neupogen (Amgen)
31.	Filgrastim	Nivestim 120 mcg/0.2 ml solution for injection/infusion	MAL13085064ARZ	HOSPIRA MALAYSIA SDN. BHD.	HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA	Neupogen (Amgen)
32.	Filgrastim	Nivestim 480mcg/0.5ml solution for injection/infusion	MAL13085065ARZ	HOSPIRA MALAYSIA SDN. BHD.	HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA	Neupogen (Amgen)

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33.	Filgrastim	Nivestim 300mcg/0.5ml solution for Injection/Infusion	MAL13085067ARZ	HOSPIRA MALAYSIA SDN. BHD.	HOSPIRA ZAGREB D.O.O HOSPIRA ZAGREB D.O.O, CROATIA	Neupogen (Amgen)
34.	Filgrastim	Accofil (filgrastim) 30 MU/0.5ml Solution for injection/ infusion in prefilled syringe	MAL21036006AZ	ACCORD HEALTHCARE SDN.BHD.	INTAS PHARMACETICALS LTD., BIOTECHNOLOGY DIVISION, INDIA	Neupogen (Amgen)
35.	Filgrastim	Accofil (filgrastim) 48 MU/0.5ml Solution for injection/ infusion in prefilled syringe	MAL21036007AZ	ACCORD HEALTHCARE SDN.BHD.	INTAS PHARMACETICALS LTD., BIOTECHNOLOGY DIVISION, INDIA	Neupogen (Amgen)
36.	Human Insulin	INSUGEN-R (Regular) Insulin Injection, Soluble 100IU/mL	MAL14015110AZ	BIOCON SDN. BHD.	BIOCON LIMITED, INDIA	Actrapid (Novo Nordisk)
37.	Human Insulin	INSUGEN-N (NPH) Insulin Injection, Isophane 100IU/mL	MAL14015109AZ	BIOCON SDN. BHD.	BIOCON LIMITED, INDIA	Insulatard (Novo Nordisk)
38.	Human Insulin	INSUGEN-30/70 (Biphasic) Insulin Injection, Biphasic Isophane 100IU/mL	MAL14015111AZ	BIOCON SDN. BHD.	BIOCON LIMITED, INDIA	Mixtard (Novo Nordisk)
39.	Human Insulin	INSUGEN-R (Regular) Insulin Injection, Soluble 100IU/mL	MAL16045058ASZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	Actrapid (Novo Nordisk)
40.	Human Insulin	INSUGEN-N (NPH) Insulin Injection, Isophane 100IU/mL	MAL16065009ASZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	Insulatard (Novo Nordisk)

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41.	Human Insulin	INSUGEN-30/70 (Biphasic) Insulin Injection, Biphasic Isophane 100IU/mL	MAL16065010ASZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	Mixtard (Novo Nordisk)
42.	Infliximab	Remsima Powder for Concentrate for Solution for Infusion	MAL15015118ACRZ	CELLTRION HEALTHCARE MALAYSIA SDN. BHD.	CELLTRION,INC., SOUTH KOREA	Remicade (Johnson & Johnson)
43.	Insulin Aspart	RapiLog Insulin Aspart Injection (rDNA origin) 100 U/Ml	MAL21016004AZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	NovoRapid (Novo Nordisk)
44.	Insulin Aspart	RapiLog One Insulin Aspart Injection (rDNA Origin) 100U/mL, Pre-filled Pen	MAL21016003AZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	NovoRapid (Novo Nordisk)
45.	Insulin Glargine	BASALOG Insulin Glargine Injection (rDNA Origin) 100 IU/mL	MAL16065057AZ	BIOCON SDN. BHD.	BIOCON, INDIA	Lantus (Sanofi)
46.	Insulin Glargine	BASALOG ONE Insulin Glargine Injection (rDNA Origin) 100 IU/mL Prefilled Pen	MAL17107078AZ	BIOCON SDN. BHD.	BIOCON, INDIA	Lantus (Sanofi)
47.	Insulin Glargine	BASALOG Insulin Glargine Injection (rDNA Origin) 100 IU/mL	MAL18026007ASZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	Lantus (Sanofi)
48.	Insulin Glargine	BASALOG ONE Insulin Glargine Injection (rDNA origin) 100IU/mL, Prefilled Pen	MAL18046014ASZ	BIOCON SDN. BHD.	BIOCON SDN BHD, JOHOR, MALAYSIA	Lantus (Sanofi)

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49.	Insulin Glargine	Glaritus 100 IU/mL Solution for injection	MAL20126005AZ	SM PHARMACEUTICALS SDN. BHD.	WOCKHARDT LIMITED (BIOTECH PARK), INDIA	Lantus (Sanofi)
50.	Insulin Glargine	Glaritus 100IU/mL Solution for injection in Pre-filled Pen	MAL20126006AZ	SM PHARMACEUTICALS SDN. BHD.	WOCKHARDT LIMITED (BIOTECH PARK), INDIA	Lantus (Sanofi)
51.	Pegfilgrastim	Pelgraz 6 mg solution for injection in a pre-filled syringe	MAL20076003AZ	ACCORD HEALTHCARE SDN. BHD.	INTAS PHARMACEUTICALS LIMITED BIOPHARMA DIVISION, INDIA	Neulastim (Amgen)
52.	Pegfilgrastim	Filpegla 6mg/0.6ml Solution for Injection in Pre-filled Syringe	MAL20116004AZ	CIPLA MALAYSIA SDN. BHD.	USV PRIVATE LIMITED, INDIA	Neulastim (Amgen)
53.	Pegfilgrastim	Fulphila 6 mg/ 0.6 mL Solution for Injection	MAL21016005AZ	MYLAN HEALTHCARE SDN. BHD.	BIOCON LIMITED (INDIA)	Neulastim (Amgen)
54.	Rituximab	TruximaTM (rituximab) 10mg/ml Concentrate for Solution for Infusion	MAL18086131AZ	CELLTRION HEALTHCARE MALAYSIA SDN. BHD.	CELLTRION, INC., SOUTH KOREA	Mabthera (Roche)
55.	Somatropin	SciTropin A 5mg/1.5ml (15 IU) Cartridge Solution for Injection	MAL20102067AZ	UNITED ITALIAN TRADING (M) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Genotropin (Pfizer)
56.	Somatropin	SciTropin A 10mg/1.5ml (30 IU) Cartridge Solution for Injection	MAL20102068AZ	UNITED ITALIAN TRADING (M) SDN. BHD.	SANDOZ GMBH, AUSTRIA	Genotropin (Pfizer)

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57.	Trastuzumab	Hertraz 440mg Powder for Concentrate	MAL18106049AZ	DUOPHARMA (M) SDN. BHD.	BIOCON LIMITED, INDIA	Herceptin (Roche)
58.	Trastuzumab	ZUHERA Trastuzumab for Injection (rDNA Origin) 150mg/vial	MAL18126013AZ	BIOCON SDN. BHD.	BIOCON LIMITED, INDIA	Herceptin (Roche)
59.	Trastuzumab	ZUHERA Trastuzumab for Injection (rDNA Origin) 440 mg/vial	MAL18126014AZ	BIOCON SDN. BHD.	BIOCON LIMITED, INDIA	Herceptin (Roche)
60.	Trastuzumab	Herzuma (trastuzumab) 150 mg Powder for Concentrate for Solution for Infusion	MAL19056037AZ	CELLTRION HEALTHCARE MALAYSIA SDN. BHD.	CELLTRION, INC., SOUTH KOREA	Herceptin (Roche)
61.	Trastuzumab	Herzuma (trastuzumab) 440 mg Powder for Concentrate for Solution for Infusion	MAL19056038AZ	CELLTRION HEALTHCARE MALAYSIA SDN. BHD.	CELLTRION, INC., SOUTH KOREA	Herceptin (Roche)