

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
1.	<b>Pseudoephedrine hydrochloride 60mg + triprolidine hydrochloride 2.5mg</b>	Actifed Tablet (MAL19860267A)	The Wellcome Foundation Ltd, UK
		Actifed Tablet (MAL19989031AC)	Parke Davis Pty Ltd, Australia
		Actifed Tablet (MAL19860267A)	Wellcome Ltd, Australia
		<b>Products are available in Korea, Singapore, Vietnam, Cambodia, Indonesia, Sri Lanka, India and Thailand</b> (Information obtained via an email from GSK dated 26 <sup>th</sup> Sept 2012 )	
		<b>As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014’ – 18 August 2014: Actifed Tablet from Aspen bad Oldesloe, Germany, GSK Pulogadung, Indonesia and Samil Pharm, Republic of Korea can also be used as a comparator.</b>	
		<b>As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015, 7 September 2015, the following product is being added to the existing list of comparator:-</b>	
		Fedac Tablet (MAL19900594AZ)	Drug Houses of Australia Pte Ltd, Singapore
2.	<b>Losartan 100mg + Hydrochlorothiazide 25mg</b>	Fortzaar Tablet (MAL20013017ARZ)	Merck Sharp & Dohme Ltd, UK
		<b>As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016’ – 13 January 2017: Actifed Tablet from Glaxo Wellcome GmbH &amp; Co., Bad Oldesloe, Germany can also be used as a comparator.</b>	
3.	<b>Losartan 100mg + Hydrochlorothiazide 12.5mg</b>	Hyzaar Tablet 100/12.5mg (MAL06081219ARZ)	Merck Sharp & Dohme Ltd, UK
4.	<b>Losartan 50mg + Hydrochlorothiazide 12.5mg</b>	Hyzaar Tablet (MAL19990960ARZ)	Merck Sharp & Dohme Ltd, UK
5.	<b>Amoxicillin + Clavulanic Acid</b>	Augmentin Tablet 375mg (MAL19871292AZ)	Smithkline Beecham Pharmaceuticals United Kingdom
		Augmentin Tablet 625mg (MAL19986474ARZ)	Smithkline Beecham Pharmaceuticals United Kingdom
		Augmentin Tablet 1g (MAL19972945ARZ)	Smithkline Beecham Pharmaceuticals United Kingdom

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
6.	<b>Triamterene + hydrochlorothiazide</b>	Dyazide Tablet (MAL19950581A)	SmithKline Beecham Pharm, UK
		Dyazide Tablet (MAL19871039A)	SmithKline & French (Aust), Australia
7.	<b>Levonorgestrel 0.15mg + Ethinylestradiol 0.03mg</b>	Microgynon 30 Tablet (MAL19900570AZ)	Schering AG Berlin, Germany
		Nordette 21 Tablet (MAL20013009AZ)	Pfizer Ireland Pharmaceuticals, Ireland
8.	<b>Levonorgestrel 0.15mg + Ethinyl estradiol 0.03mg + Ferrous Fumarate 75mg</b>	Microgynon 30 ED FE Tablet (MAL19900571AZ)	Schering AG Berlin, Germany
9.	<b>Cyproterone Acetate 2.0mg + Ethinyl Estradiol 0.035mg</b>	Diane 35 Tablet (MAL19900568ARZ)	Bayer Weimar GmbH und Co. KG, Germany
		Diane-35 Tablet (MAL20001806ASC)	Schering GHBH & Co Productions KG, Germany  PT Schering Indonesia
10.	<b>Amiloride Hydrochloride 5mg + Hydrochlorothiazide 50mg</b>	Moduretic 50/5 Tablet (MAL19920200AR)	Frosst Iberica S.A, Spain
		(Information obtained via email from MSD dated 5 <sup>th</sup> December 2014) Product is available in the following countries:- i. <b>Asia Pacific region: Australia, French Polynesia, Hong Kong, New Caledonia, Taiwan</b> ii. <b>US region: United States</b> iii. <b>Europe region: France, Ireland, Italy, Martinique, Spain, UK, Belgium, Cyprus, Czech Republic, Greece, Luxembourg, Portugal, Slovak Republic, Austria, Estonia, Finland, Norway, Switzerland</b> iv. <b>Latin America region: Argentina, Brazil, Brazil Supera, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Falkland Islands, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Peru, Uruguay, Venezuela</b> v. <b>Others: Angola, Ivory Coast, Kenya, Libya, Mali, Morocco, Nigeria, South Africa, Turkey, Ukraine</b>	
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016 – 16 Jun 2016: Moduretic Tablet from Aspen Port Elizabeth Pty Ltd, South Africa can also be used as a comparator.	

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
11.	<b>Sulphamethoxazole 400mg + Trimethoprim 80mg.</b>	Bactrim Roche Tablet (MAL19870887A)	F. Hoffman La Roche Ltd, Switzerland
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013 – 13 March 2013: Bactrim Tablet from Roche Toluca, Mexico & Roche (Phillipine) Inc, Filipina can also be used as a comparator.	
		Pharmaniaga Co-Trimoxazole Tablet (MAL19871882AZ)	Pharmaniaga Manufacturing Berhad
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014, 18 <sup>th</sup> August 2014:-  1. Co-Trimoxazole Tablet manufactured by Pharmaniaga Manufacturing Berhad is being added to the existing list of comparator.	
12.	<b>Trimethoprim 90mg + Sulphadiazine 410mg Tablet</b>	Triglobe Tablet 500mg (MAL19870919AR)	Astrazeneca Sweden
13.	<b>Paracetamol 500mg + Dihydrocodeine 10mg</b>	Codopar 118 Tablet 1986042938A + DF 118 Tablet MAL19962828ARSZ	Glaxosmithkline Pharmaceutical Sdn Bhd, Malaysia  GlaxoSmithKline South Africa
14.	<b>Phenylephrine HCL 10mg + Triprolidine HCL 2.5mg.</b>	Actidil Tablet 2.5mg MAL19890070A + Codral Relief Decongestant	The Wellcome Foundation LTD, London, United Kingdom  Johnson & Johnson Australia
15.	<b>Atenolol 100mg + Chlorthalidone 25mg</b>	Tenoretic Tablet MAL19871032AZ	Astrazeneca UK Ltd, United Kingdom
		Tenoret 50 Tablet MAL19871033AZ	Astrazeneca UK Ltd, United Kingdom
16.	<b>Irbesartan + Hydrochlorothiazide</b>	Coaprovel 150mg/12.5mg Tablet MAL20014479AZ	Sanofi Winthrop Industrie, France
		Coaprovel 300mg Tablet MAL20014478AZ	Sanofi Winthrop Industrie, France
		Coaprovel 300/25mg Tablet MAL08091408AZ	Sanofi Winthrop Industrie, France

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
17.	<b>Orphenadrine Citrate 35mg + Paracetamol 450mg</b>	Norgesic Tablet MAL19871086A  Norgesic Tablet MAL13115130ACZ	iNova Pharmaceuticals (Australia) Pty Ltd, Australia  Adcock Ingram Limited - A Medreich Group Company (India)
18.	<b>Paracetamol 500mg + Phenylephrine HCl 5mg</b>	Panadol Sinus Relief PE Caplet MAL09062126AZ	Glaxosmithkline Australia Pty Ltd, Australia
19.	<b>Uracil 224mg + Tegafur 100mg</b>	<p>As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2012 – 13 September 2012, the following requirement to be submitted in place of bioequivalence report :-</p> <p>i) Validation process report for 3 consecutive batches ii) Comparative dissolution profile for 3 consecutive batches (time points : 0, 5, 15, 30 &amp; 45 minutes )</p> <p>Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.</p>	
20.	<b>Telmisartan + Hydrochlorothiazide</b>	Micardis Plus 80/25mg Tablet, MAL09032035A  Micardis Plus 40/12.5mg Tablet, MAL20034439AZ  Micardis Plus 80/12.5mg Tablet MAL20034440AZ	Boehringer Ingelheim, West Germany  Boehringer Ingelheim, West Germany  Boehringer Ingelheim, West Germany
21.	<b>Drospirenone 3mg + Ethinyl Estradiol 30mcg</b>	Yasmin Tablet MAL20040023ARZ	Schering Gmbh, Germany
22.	<b>Paracetamol 325mg + Tramadol 37.5mg</b>	Ultracet Tablet MAL20051462AZ	Janssen Korea Ltd, Korea
23.	<b>Ethinylloestradiol 20mcg + Desogestrel 150mcg</b>	Mercilon Tablet MAL19962539AZ  Mercilon Tablets MAL19900640AZ	Organon (Ireland) Ltd., Ireland  N.V. Organon, Netherlands
24.	<b>Desogestrel 0.15mg + Ethinyl estradiol 0.03mg</b>	Marvelon Tablet MAL19872093AZ	N.V. Organon, Netherlands

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
25.	<b>Drosperinone 3mg + Ethinylestradiol 0.02mg</b>	Yaz Tablets MAL20091884ACRZ	Schering Gmbh & Co. Germany
26.	<b>Ezetimibe + Simvastatin</b>	Vytorin 10/10mg Tablet MAL20041212ARZ	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/20mg Tablet, MAL20041213ARZ	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/40mg Tablet, MAL20041214ARZ	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/80mg Tablet MAL20041215ARZ	MSD International Gmbh (Singapore), Singapore
27.	<b>Valsartan + Hydrochlorothiazide</b>	Co-Diovan 80/12.5mg Film-Coated Tablet MAL09062164ARSZ	Novartis Farma S.P.A, Italy
		Co-Diovan 320/12.5mg Film-Coated Tablet MAL09051533ARZ	Novartis Pharma Stein AG, Switzerland
		Co-Diovan 320/25mg Film-Coated Tablet MAL09051534ARZ	Novartis Pharma Stein AG, Switzerland
		Co-Diovan Tablets MAL20000246A	Novartis Pharma AG, Switzerland
		Co-Diovan 160/12.5mg Film-Coated Tablet MAL09062165ARSZ	Novartis Pharma S.P.A, Italy
		Co-Diovan 160/25mg Film Coated Tablet MAL09062166ARSZ	Novartis Pharma S.P.A, Italy
28.	<b>Ethinylestradiol (0.04mg, 0.03mg, 0.03mg)+ Levonorgestrel (0.0075mg, 0.125mg, 0.05mg)</b>	Trinordiol 21 Tablet MAL20000740A	Pfizer Ireland Pharmaceuticals Ireland

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
29.	<b>Rifampicin 300mg + Isoniazid 150mg</b>	Rimactazid 300mg Sugar Coated Tablet MAL19871621A	Novartis South Africa (Pty) Ltd, South Africa
		This product is available in Egypt, Saudi Arabia and Spain. (Information obtained via an email from Novartis dated 21 <sup>st</sup> March 2016)	
30.	<b>Metformin + Glibenclamide</b>	Glucovance 500mg/2.5mg MAL20051296AZ	Merck Sante SAS, France
		Glucovance 250mg/1.25mg MAL20051295A	Merck Sante SAS, France
		Glucovance 500/5mg MAL20051297AZ	Merck Sante SAS, France
31.	<b>Levonorgestrel + Estradiol</b>	Loette 21 Tablet MAL19992694AZ	Pfizer Ireland Pharmaceuticals, Ireland
32.	<b>Aliskiren Hemihydrate + Hydrochlorothiazide</b>	Rasilez HCT 150/12.5mg Film-Coated Tablet MAL20091951AR	Novartis Pharma S.P.A, Italy
		Rasilez HCT 300/12.5mg Film-Coated Tablet MAL20091953AR	Novartis Pharma S.P.A, Italy
		Rasilez HCT 300/25mg Film-Coated Tablet MAL20091954AR	Novartis Pharma S.P.A, Italy
		Rasilez HCT 150/25mg Film-Coated Tablet MAL20091952AR	Novartis Pharma S.P.A, Italy
33.	<b>Metformin + Glimepiride</b>	Amaryl M 1/250mg Tablet MAL20091866AZ	Handok Pharmaceuticals Co. Ltd., Korea
		Amaryl M 2/500mg Tablet MAL20091867AZ	Handok Pharmaceuticals Co. Ltd., Korea
34.	<b>Perindopril tert-butylamine + Indapamide</b>	Coversyl Plus 4mg/1.25mg Tablet MAL20013354AZ	Les Labs Servier Industrie, France
		Coversyl Plus 4mg/1.25mg Tablet MAL09011458ACSZ	Kotra Pharma (M) Sdn. Bhd., Malaysia

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
		Preterax Tablet MAL20020003AZ	Les Labs Servier Industrie, France
35.	<b>Perindopril arginine + Indapamide</b>	Coversyl Plus 10mg/2.5mg Film-coated Tablet MAL20091950AZ  Coversyl Plus 5mg/1.25mg Film-coated Tablet MAL20081839AZ	Servier (Ireland) Industrie Ltd, Ireland  Les Laboratoires Servier Industrie, France
36.	<b>Paracetamol + Codeine</b>	Panadeine Forte Tablet MAL19871079A  Panadeine Tablet MAL19950068AZ	Winthrop Labs, Australia  Sanofi India Limited, India Aventis Pharma Limited, India
37.	<b>Lamivudine 150mg + Zidovudine 300mg</b>	Combivir Tablet MAL19991350ARZ	GlaxoSmithKline Pharmaceuticals SA, Poland  Glaxo Wellcome Operations UK Ltd, United Kingdom
38.	<b>Fexofenadine Hydrochloride 60mg + Pseudoephedrine Hydrochloride 120mg</b>	Telfast-D Tablet MAL20040553ARZ	Sanofi-Aventis US LLC 10236 Marion Park Drive, 64137, Kansas City, US  Sanofi Winthrop Industrie, 56, Route de Choisy au Bac, 60205 Compiègne, France (DCA 270, November 2013)
39.	<b>Simethicone 300mg + Alverine Citrate 60mg</b>	Meteospasmyl Capsule MAL19990251ACZ	LGV Capsules 20,Rue Louis Charles Vernin,77190 Dammarie Les Lys, France
40.	<b>Estradiol Valerate 2mg + Cyproterone Acetate 1mg</b>	Climen 28 Sugar Coated Tablet MAL20040218AZ	Delpharm Lille SAS, France
41.	<b>Vildagliptin + Metformin</b>	Galvus Met 50/500mg Film-coated Tablet MAL12035005ARZ	Novartis Pharma Stein AG, Switzerland

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products			
		Trade Mark/Registration Reference No.	No./	Manufacturer	
		Galvus Met 50/850mg Film-Coated Tablet MAL20091864ARZ		Novartis Pharma Stein AG, Switzerland	
		Galvus Met 50/1000mg Film-Coated Tablet MAL20091865ARZ		Novartis Pharma Stein AG, Switzerland	
42.	<b>Bisoprolol hemifumarate + hydrochlorothiazide</b>	Lodoz 10mg Tablet MAL05051114A		Merck KgaA, Germany	
		Lodoz 5mg Tablet MAL05051113AZ		Merck KgaA, Germany	
		Lodoz 2.5mg Tablet MAL05051115ASZ		Merck KgaA, Germany	
		Lodoz MAL20040552A		Pt Merck Indonesia	
43.	<b>Dydrogesterone + estradiol</b>	Femoston Conti Tablet MAL20040952AZ		Abbott Biological B. V, Netherlands	
		Femoston 2/10 Tablet MAL06021201AZ		Abbott Biological B. V, Netherlands	
		Femoston 2/20 Tablet MAL19991348A		Solvay Pharmaceuticals B.V 1, Netherlands	
		Femoston 1/10 Tablet MAL20040819AZ		Abbott Biological B. V, Netherlands	
44.	<b>Paracetamol + Dextrometorphan + Pseudoephedrine Hydrochloride</b>	Panadol-CF Tablet MAL19930413A		Winthrop Labs, Australia	
45.	<b>Paracetamol + Pseudoephedrine</b>	Panadol C Tablet MAL19950231AZ		Sterling Drug (M) Sdn Bhd	
46.	<b>Paracetamol + Pseudoephedrine + Dextromethorphan</b>	Panadol CC Caplet MAL19950383AZ		Sterling Drug (M) Sdn Bhd	



**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
47.	<b>Perindopril + Amlodipine</b>	Coveram 10mg/10mg Tablet MAL20091913AZ	Servier (Ireland) Industries Ltd., Ireland
		Coveram 10mg/5mg Tablet MAL20091912AZ	Servier (Ireland) Industries Ltd., Ireland
		Coveram 5mg/10mg Tablet MAL20091911AZ	Servier (Ireland) Industries Ltd., Ireland
		Coveram 5mg/5mg Tablet MAL20091910AZ	Servier (Ireland) Industries Ltd., Ireland
48.	<b>Olmesartan Medoxomil + Hydrochlorothiazide</b>	Olmetec Plus 20/12.5mg Film-Coated Tablet MAL20071700ARZ	Daiichi Sankyo Europe Gmbh, Germany
		Olmetec Plus 40/12.5mg Film-Coated Tablet MAL20071701ARZ	Daiichi Sankyo Europe Gmbh, Germany
		Olmetec Plus 40/25mg Film-Coated Tablet MAL20071702ARZ	Daiichi Sankyo Europe Gmbh, Germany
49.	<b>Olmesartan Medoxomil + Amlodipine Besilate</b>	Azoren 20 mg/5 mg Film-Coated Tablets MAL12055003ARZ	Daiichi Sankyo Europe Gmbh, Germany
		Azoren 40 mg/10 mg Film-Coated Tablets MAL12055005ARZ	Daiichi Sankyo Europe Gmbh, Germany
		Azoren 40 mg/5 mg Film-Coated Tablets MAL12055004ARZ	Daiichi Sankyo Europe Gmbh, Germany
50.	<b>Levodopa + Carbidopa</b>	Sinemet 25/100 Tablet MAL19913441A	Merck Sharp & Dohme (Australia) Pty. Ltd., Australia
		Sinemet 25/250 Tablet MAL19913442A	Merck Sharp & Dohme (Australia) Pty. Ltd., Australia
		Sinemet Tablet 25/250mg MAL19871095AR	Merck Sharp & Dohme Int, United States

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
		Sinemet 25/100 Tablet MAL19871096AR	Merck Sharp & Dohme Int, United States
51.	<b>Arthemether + Lumefantraine 20/120mg</b>	Riamet Tablet MAL20032242ARZ	Beijing Novartis Pharma Ltd
52.	<b>Ethinylestradiol 0.03mg + Gestodene 0.075mg</b>	Gynera Tablet MAL09122026ACZ	Schring do Brasil Quimica e Farmaceutica Ltda., Brazil
53.	<b>Ethinylestradiol 0.02mg + Gestodene 0.075mg</b>	Meliane Sugar Coated Tablet MAL20001807AZ	Delpharm Lille S.A.S., France
54.	<b>Estradiol Hemihydrate 1mg + Norethisterone Acetate 0.5mg</b>	Activelle Tablet MAL20001814AZ	Novo Nordisk A/S, Denmark
55.	<b>Candesartan+ HCTZ</b>	Atacand Plus Tablets 16/12.5mg MAL20021128ARZ  Atacand Plus Tablet 32/12.5mg MAL10043677A	Astra Zeneca Ab, Sweden
56.	<b>Sulfadoxine + Pyrimethamine</b>	Fansidar Roche Tablet MAL19871340ARZ	F.Hoffmann-La Roche Ltd, Switzerland
57.	<b>Caffeine 100mg + Ergotamine tartrate 1mg</b>	Cafergot Tablet MAL19871105AC  Cafergot Tablet MAL13035053ACZ	Novartis Pharm UK Ltd  CENEXI SAS, France
58.	<b>Pseudoephedrine Sulphate + Loratadine</b>	Clarinase Repetab MAL19930250ACZ	Schering-PI Labo N.V Belgium.
59.	<b>Amlodipine Besylate + Atorvastatin Calcium</b>	Caduet Film-Coated Tablet 5mg/10mg MAL20061542ARZ  Caduet Film-Coated Tablet 5mg/20mg MAL20061543ARZ	Pfizer Manufacturing Deutschland GmbH., Germany  Pfizer Manufacturing Deutschland GmbH., Germany

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products		
		Trade Mark/Registration Reference No.	No./	Manufacturer
		Caduet Film-Coated Tablet 5mg/40mg MAL20061544ARZ		Pfizer Manufacturing Deutschland GmbH., Germany
		Caduet Film-Coated Tablet 5mg/80mg MAL20061545AZ		Pfizer Manufacturing Deutschland GmbH., Germany
		Caduet Film-Coated Tablet 10mg/10mg MAL20061546ARZ		Pfizer Manufacturing Deutschland GmbH., Germany
		Caduet Film-Coated Tablet 10mg/20mg MAL20061547ARZ		Pfizer Manufacturing Deutschland GmbH., Germany
		Caduet Film-Coated Tablet 10mg/40mg MAL20061548ARZ		Pfizer Manufacturing Deutschland GmbH., Germany
		Caduet Film-Coated Tablet 10mg/80mg MAL20061549ARZ		Pfizer Manufacturing Deutschland GmbH., Germany
60.	<b>Amlodipine Besylate + Valsartan</b>	Exforge 5mg/80mg Film-Coated Tablet MAL20081727ARZ		Novartis Farmaceutica S.A., Spain
		Exforge 5mg/160mg Film-Coated Tablet MAL20081728ARZ		Novartis Farmaceutica S.A., Spain
		Exforge 5mg/320mg Film-Coated Tablet MAL11040002ARZ		Novartis Pharma Stein AG, Switzerland
		Exforge 10mg/160mg Film-Coated Tablet MAL20081729ARZ		Novartis Farmaceutica S.A., Spain
		Exforge 10mg/320mg Film-Coated Tablet MAL11040003ARZ		Novartis Pharma Stein AG, Switzerland

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
61.	<b>Levodopa + Carbidopa Monohydrate + Entacapone</b>	Stalevo 75/18.75/200mg Film-coated Tablet MAL11030095ACRZ	Orion Corp, Finland
		Stalevo 125/31.25/200mg Film-coated Tablet MAL11030094ACRZ	Orion Corp, Finland
		Stalevo 200/50/200mg Film-coated Tablet MAL09102942ACRZ	Orion Corp, Finland
		Stalevo 150/37.5/200mg Film-coated Tablets MAL20051355ACRZ	Orion Corp, Finland
		Stalevo 50/12.5/200mg Film-coated Tablets MAL20051345ACRZ	Orion Corp, Finland
		Stalevo 100/25/200mg Film-coated Tablets MAL20051339ACRZ	Orion Corp, Finland
62.	<b>Telmisartan + Amlodipine Besilate</b>	Twynsta Tablet 40/5mg MAL20112135ACZ	Cipla Limited, India
		Twynsta Tablet 40/10mg MAL20112136ACZ	Cipla Limited, India
		Twynsta Tablet 80/5mg MAL20112137ACZ	Cipla Limited, India
		Twynsta Tablet 80/10mg MAL20112138ACZ	Cipla Limited, India
63.	<b>Rifampicin + Ethambutol HCl + Pyrazinamide + Isoniazide</b>	Akurit-4 Tablet MAL20051429AZ	Lupin Limited, India
64.	<b>Chlorpheniramine Maleate + Phenylephrine HCl + Paracetamol</b>	Panadol Allergy Sinus PE Caplet MAL11080002AZ	GlaxoSmithKline Australia Pty. Ltd., Australia

**LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
65.	<b>Dutasteride + Tamsulosin HCl</b>	Duodart 0.5mg/0.4mg Capsules MAL20112150ACRZ	Catalent Germany Schorndorf GmbH, Germany
66.	<b>Ledipasvir + Sofosbuvir</b>	HARVONI (Ledipasvir 90mg/Sofosbuvir 400mg) Film-coated Tablets MAL16035013AZ	Gilead Sciences Ireland UC, Ireland
67.	<b>Drospirenone 2mg + Estradiol Hemihydrate 1mg</b>	Angeliq Tablet MAL20061594ARZ	Bayer Weimar GmbH und Co . KG, Germany
68.	<b>Amlodipine Camsylate + Losartan Potassium</b>	Cozaar XQ 5/100mg Tablet MAL12025078ACRZ  Cozaar XQ 5/50 mg Tablet MAL12025077ACRZ	Hanmi Pharm. Co., Ltd. (Paltan Site), South Korea
69.	<b>Artesunate + Mefloquine HCl</b>	Artesunate and Mefloquine Hydrochloride Tablets 100/220mg MAL12035082AZ  Artesunate and Mefloquine Hydrochloride Tablets 25/55 mg MAL12035081AZ	Cipla Ltd, India
70.	<b>Tegafur + Gimeracil + Oteracil Potassium</b>	TS-ONE Capsule 20 MAL12075066ARZ  TS-ONE Capsule 25 MAL12075067ARZ	Taiho Pharmaceutical Co. Ltd., Japan
71.	<b>Estradiol Valerate + Norgestrel</b>	Progyluton Tablets MAL20021014AZ	Bayer Weimar GmbH und Co. KG, Germany

**Note:**

If you need further clarification, kindly email to [somiyaton@npra.gov.my](mailto:somiyaton@npra.gov.my),  
[muikiat@npra.gov.my](mailto:muikiat@npra.gov.my), [ngpeiling@npra.gov.my](mailto:ngpeiling@npra.gov.my) & [amalina@npra.gov.my](mailto:amalina@npra.gov.my)

Updated on 28/03/2017