

LIST OF COMPARATOR PRODUCTS FOR FIXED DOSE COMBINATION

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
1.	Alendronate Sodium + Vitamin D3	Fosamax Plus 70mg/5600I.U. Combination Tablet MAL08031392ACRZ	Frosst Iberica, S.A., Spain
2.	Aliskiren Hemihydrate + Hydrochlorothiazide	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
3.	Amoxycillin + Clavulanic Acid	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
4.	Amiloride Hydrochloride 5mg + Hydrochlorothiazide 50mg	Moduretic 50/5 Tablet (MAL19920200AR)	Frosst Iberica S.A, Spain
		(Information obtained via email from MSD dated 5 th December 2014) Product is available in the following countries: - i. Asia Pacific region: Australia, French Polynesia, Hong Kong, New Caledonia, Taiwan ii. US region: United States iii. Europe region: France, Ireland, Italy, Martinique, Spain, UK, Belgium, Cyprus, Czech Republic, Greece, Luxembourg, Portugal, Slovak Republic, Austria, Estonia, Finland, Norway, Switzerland iv. 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	

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		Trade Mark/Registration Reference No.	No./	Manufacturer
		v. Others: Angola, Ivory Coast, Kenya, Libya, Mali, Morocco, Nigeria, South Africa, Turkey, Ukraine		
		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.		
5.	Amlodipine Besylate + Atorvastatin Calcium	Caduet Film-Coated Tablet 5mg/10mg MAL20061542ARZ Caduet Film-Coated Tablet 5mg/20mg MAL20061543ARZ Caduet Film-Coated Tablet 5mg/40mg MAL20061544ARZ Caduet Film-Coated Tablet 5mg/80mg MAL20061545AZ Caduet Film-Coated Tablet 10mg/10mg MAL20061546ARZ Caduet Film-Coated Tablet 10mg/20mg MAL20061547ARZ Caduet Film-Coated Tablet 10mg/40mg MAL20061548ARZ Caduet Film-Coated Tablet 10mg/80mg MAL20061549ARZ		Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Manufacturing Deutschland GmbH., Germany
6.	Amlodipine Besylate + Valsartan	Exforge 5mg/80mg Film-Coated Tablet MAL20081727ARZ Exforge 5mg/160mg Film-Coated Tablet		Novartis Farmaceutica S.A., Spain Novartis Farmaceutica S.A., Spain

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration Reference No.	No./ Manufacturer
		MAL20081728ARZ Exforge 5mg/320mg Film-Coated Tablet MAL11040002ARZ Exforge 10mg/160mg Film-Coated Tablet MAL20081729ARZ Exforge 10mg/320mg Film-Coated Tablet MAL11040003ARZ	 Novartis Pharma Stein AG, Switzerland Novartis Farmaceutica S.A., Spain Novartis Pharma Stein AG, Switzerland
7.	Amlodipine Camsylate + Losartan Potassium	Cozaar XQ 5/100mg Tablet MAL12025078ACRZ Cozaar XQ 5/50 mg Tablet MAL12025077ACRZ	Hanmi Pharm. Co., Ltd. (Paltan Site), South Korea
8.	Artesunate + Mefloquine HCl	Artesunate and Mefloquine Hydrochloride Tablets 100/220mg MAL12035082AZ Artesunate and Mefloquine Hydrochloride Tablets 25/55 mg MAL12035081AZ	Cipla Ltd, India
9.	Arthemether + Lumefantraine 20/120mg	Riamet Tablet MAL20032242ARZ	Novartis Saglik, Turkey Beijing Novartis Pharma Ltd
10.	Bisoprolol hemifumarate + hydrochlorothiazide	Lodoz 10mg Tablet MAL05051114A Lodoz 5mg Tablet MAL05051113AZ Lodoz 2.5mg Tablet MAL05051115ASZ Lodoz MAL20040552A	Merck KgaA, Germany Merck KgaA, Germany Merck KgaA, Germany Pt Merck Indonesia

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11.	Atenolol 100mg + Chlorthalidone 25mg	Tenoretic Tablet MAL19871032AZ Tenoret 50 Tablet MAL19871033AZ	Astrazeneca UK Ltd, United Kingdom Astrazeneca UK Ltd, United Kingdom
12.	Caffeine 100mg + Ergotamine tartrate 1mg	Cafergot Tablet MAL19871105AC Cafergot Tablet MAL13035053ACZ	Novartis Pharm UK Ltd CENEXI SAS, France
13.	Candesartan+ HCTZ	Atacand Plus Tablets 16/12.5mg MAL20021128ARZ Atacand Plus Tablet 32/12.5mg MAL10043677A	Astra Zeneca Ab, Sweden
14.	Chlorpheniramine Maleate + Phenylephrine HCl + Paracetamol	Panadol Allergy Sinus PE Caplet MAL11080002AZ	GlaxoSmithKline Australia Pty. Ltd., Australia
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.	
15.	Clopidogrel + Acetylsalicylic Acid	Co Plavix 75/100mg Film-Coated Tablet MAL12115075AZ	Sanofi Winthrop Industrie, France
16.	Cyproterone Acetate 2.0mg + Ethinyl Estradiol 0.035mg	Diane 35 Tablet (MAL19900568ARZ) Diane-35 Tablet (MAL20001806ASC)	Bayer Weimar GmbH und Co. KG, Germany Schering GHBH & Co Productions KG, Germany PT Schering Indonesia
17.	Desogestrel 0.15mg + Ethinyl estradiol 0.03mg	Marvelon Tablet MAL19872093AZ	N.V. Organon, Netherlands

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18.	Drospirinone 3mg + Ethinylestradiol 0.02mg	Yaz Tablets MAL20091884ACRZ	Bayer Weimar GmbH und Co. KG, Germany Schering Gmbh & Co. Germany
19.	Drospirenone 3mg + Ethinyl Estradiol 30mcg	Yasmin Tablet MAL20040023ARZ	Bayer Weimar GmbH und Co. KG, Germany Schering Gmbh, Germany
20.	Drospirenone 2mg + Estradiol Hemihydrate 1mg	Angeliq Tablet MAL20061594ARZ	Bayer Weimar GmbH und Co . KG, Germany
21.	Dydrogesterone + estradiol	Femoston Conti Tablet MAL20040952AZ Femoston 2/10 Tablet MAL06021201AZ Femoston 2/20 Tablet MAL19991348A Femoston 1/10 Tablet MAL20040819AZ	Abbott Biological B. V, Netherlands Abbott Biological B. V, Netherlands Solvay Pharmaceuticals B.V 1, Netherlands Abbott Biological B. V, Netherlands
22.	Dutasteride + Tamsulosin HCl	Duodart 0.5mg/0.4mg Capsules MAL20112150ACRZ	Catalent Germany Schorndorf GmbH, Germany
23.	Emtricitabine + Elvitegravir + Tenofovir alafenamide fumarate + Cobicistat	Genvoya (Elvitegravir 150mg/ Cobicistat 150mg/ Emtricitabine 200mg/ Tenofovir alafenamide 10mg) Film-Coated Tablets MAL17025022ACZ	Patheon Inc, Canada
24.	Emtricitabine + Rilpivirine + Tenofovir alafenamide fumarate	Odefsey (200mg Emtricitabine/ 25mg Rilpivirine/ 25mg Tenofovir alafenamide) Film Coated Tablets MAL18116091ACZ	Patheon Inc, Canada
25.	Emtricitabine + Tenofovir alafenamide	Descovy (Emtricitabine 200mg/ Tenofovir alafenamide 25mg) Film Coated Tablets MAL18116088ACZ	Patheon Inc, Canada

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		Descovy (Emtricitabine 200mg/ Tenofovir alafenamide 10mg) Film Coated Tablets MAL18116089ACZ	
26.	Estradiol Hemihydrate 1mg + Norethisterone Acetate 0.5mg	Activelle Tablet MAL20001814AZ	Novo Nordisk A/S, Denmark
27.	Estradiol Valerate 2mg + Cyproterone Acetate 1mg	Climen 28 Sugar Coated Tablet MAL20040218AZ	Delpharm Lille SAS, France
28.	Estradiol Valerate + Norgestrel	Progyluton Tablets MAL20021014AZ	Bayer Weimar GmbH und Co. KG, Germany
29.	Ethinylestradiol 20mcg + Desogestrel 150mcg	Mercilon Tablet MAL19962539AZ Mercilon Tablets MAL19900640AZ	Organon (Ireland) Ltd., Ireland N.V. Organon, Netherlands
30.	Ethinylestradiol 0.03mg + Gestodene 0.075mg	Gynera Tablet MAL09122026ACZ	Schring do Brasil Quimica e Farmaceutica Ltda., Brazil
31.	Ethinylestradiol 0.02mg + Gestodene 0.075mg	Meliane Sugar Coated Tablet MAL20001807AZ	Delpharm Lille S.A.S., France
32.	Ethinylestradiol (0.04mg, 0.03mg, 0.03mg)+ Levonorgestrel (0.0075mg, 0.125mg, 0.05mg)	Trinordiol 21 Tablet MAL20000740A	Pfizer Ireland Pharmaceuticals Ireland

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33.	Ezetimibe + Simvastatin	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
		This product is available in Australia (Information obtained via an email from Merck dated 22 nd January 2016)	
34.	Fexofenadine Hydrochloride 60mg + Pseudoephedrine Hydrochloride 120mg	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)
35.	Irbesartan + Hydrochlorothiazide	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
36.	Lamivudine 150mg + Zidovudine 300mg	Combivir Tablet MAL19991350ARZ	GlaxoSmithKline Pharmaceuticals SA, Poland Glaxo Wellcome Operations UK Ltd, United Kingdom
37.	Ledipasvir + Sofosbuvir	HARVONI (Ledipasvir 90mg/Sofosbuvir 400mg) Film-coated Tablets MAL16035013AZ	Gilead Sciences Ireland UC, Ireland

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38.	Levodopa + Carbidopa	Sinemet Tablet 25/100 mg MAL12085068ACRZ	Mylan Pharmaceuticals Inc., United States
		Sinemet Tablet 25/250 mg MAL12085069ACRZ	Mylan Pharmaceuticals Inc., United States
		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
		Sinemet 25/100 Tablet MAL19871096AR	Merck Sharp & Dohme Int, United States
39.	Levodopa + Carbidopa Monohydrate + Entacapone	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

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40.	Levonorgestrel + Estradiol	Loette 21 Tablet MAL19992694AZ	Pfizer Ireland Pharmaceuticals, Ireland
41.	Levonorgestrel 0.15mg + Ethinylestradiol 0.03mg	Microgynon 30 Tablet (MAL19900570AZ) Nordette 21 Tablet (MAL20013009AZ)	Schering AG Berlin, Germany Pfizer Ireland Pharmaceuticals, Ireland
42.	Levonorgestrel 0.15mg + Ethinyl estradiol 0.03mg + Ferrous Fumarate 75mg	Microgynon 30 ED FE Tablet (MAL19900571AZ)	Schering AG Berlin, Germany
43.	Losartan 100mg + Hydrochlorothiazide 25mg	Fortzaar Tablet (MAL20013017ARZ)	Merck Sharp & Dohme Ltd, UK
44.	Losartan 100mg + Hydrochlorothiazide 12.5mg	Hyzaar Tablet 100/12.5mg (MAL06081219ARZ)	Merck Sharp & Dohme Ltd, UK
45.	Losartan 50mg + Hydrochlorothiazide 12.5mg	Hyzaar Tablet (MAL19990960ARZ)	Merck Sharp & Dohme Ltd, UK
46.	Metformin + Glibenclamide	Glucovance 500mg/2.5mg MAL20051296AZ Glucovance 250mg/1.25mg MAL20051295A Glucovance 500/5mg MAL20051297AZ	Merck Sante SAS, France Merck Sante SAS, France Merck Sante SAS, France
47.	Metformin + Glimepiride	Amaryl M 1/250mg Tablet MAL20091866AZ Amaryl M 2/500mg Tablet MAL20091867AZ	Handok Pharmaceuticals Co. Ltd., Korea Handok Pharmaceuticals Co. Ltd., Korea
48.	Olmesartan Medoxomil + Hydrochlorothiazide	Olmetec Plus 20/12.5mg Film-Coated Tablet MAL20071700ARZ	Daiichi Sankyo Europe Gmbh, Germany

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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.	Olmesartan Medoxomil + Amlodipine Besilate	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.	Orphenadrine Citrate 35mg + Paracetamol 450mg	Norgesic Tablet MAL19871086A	iNova Pharmaceuticals (Australia) Pty Ltd, Australia
		Norgesic Tablet MAL13115130ACZ	Adcock Ingram Limited - A Medreich Group Company (India)
51.	Paracetamol + Codeine	Panadeine Forte Tablet MAL19871079A	Winthrop Labs, Australia
		This product is available in Australia, United Kingdom, Finland, Sweeden, Ireland & Malta . (Information obtained from Sanofi Aventis (M) Sdn. Bhd dated 8 th August 2017 via an email)	
		As agreed upon 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2017 – 27 September 2017: Panadeine Forte Tablet manufactured by Sanofi India Limited, India can be used as comparator.	
		Panadeine Tablet MAL19950068AZ	Sanofi India Limited, India Aventis Pharma Limited, India
52.	Paracetamol 500mg + Dihydrocodeine 10mg	Codopar 118 Tablet 1986042938A	Glaxosmithkline Pharmaceutical Sdn Bhd, Malaysia

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		Trade Mark/Registration Reference No.	No./ Manufacturer
53.	Paracetamol 500mg + Phenylephrine HCl 5mg	Panadol Sinus Relief PE Caplet MAL09062126AZ	Glaxosmithkline Australia Pty Ltd, Australia
54.	Paracetamol + Pseudoephedrine	Panadol C Tablet MAL19950231AZ	Sterling Drug (M) Sdn Bhd
55.	Paracetamol + Pseudoephedrine Hydrochloride + Dextromethorphan	Panadol CC Caplet MAL19950383AZ	Sterling Drug (M) Sdn Bhd
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.	
56.	Paracetamol 325mg + Tramadol 37.5mg	Ultracet Tablet MAL20051462AZ	Janssen Korea Ltd, Korea Janssen Cilag SPA, Italy
57.	Perindopril + Amlodipine	Coveram 10mg/10mg Tablet MAL20091913AZ Coveram 10mg/5mg Tablet MAL20091912AZ Coveram 5mg/10mg Tablet MAL20091911AZ Coveram 5mg/5mg Tablet MAL20091910AZ	Servier (Ireland) Industries Ltd., Ireland Servier (Ireland) Industries Ltd., Ireland Servier (Ireland) Industries Ltd., Ireland Servier (Ireland) Industries Ltd., Ireland
58.	Perindopril tert- butylamine + Indapamide	Coversyl Plus 4mg/1.25mg Tablet MAL20013354AZ Coversyl Plus 4mg/1.25mg Tablet MAL09011458ACSZ Preterax Tablet MAL20020003AZ	Les Labs Servier Industrie, France Kotra Pharma (M) Sdn. Bhd., Malaysia Les Labs Servier Industrie, France
59.	Perindopril arginine + Indapamide	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

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		Trade Mark/Registration Reference No.	No./ Manufacturer
60.	Phenylephrine HCL 10mg + Triprolidine HCL 2.5mg.	Actidil Tablet 2.5mg MAL19890070A + Codral Relief Decongestant	The Wellcome Foundation LTD, London, United Kingdom Johnson & Johnson Australia
61.	Pseudoephedrine hydrochloride 60mg + triprolidine hydrochloride 2.5mg	Actifed Tablet (MAL19860267A)	The Wellcome Foundation Ltd, UK
		Actifed Tablet (MAL19989031AC)	Parke Davis Pty Ltd, Australia
		Actifed Tablet (MAL19860267A)	Wellcome Ltd, Australia
		Products are available in Korea, Singapore, Vietnam, Cambodia, Indonesia, Sri Lanka, India and Thailand (Information obtained via an email from GSK dated 26 th Sept 2012)	
		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.	
		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:-	
62.	Pseudoephedrine Sulphate + Loratadine	Fedac Tablet (MAL19900594AZ)	PT Actavis, Indonesia Drug Houses of Australia Pte Ltd, Singapore
		As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016’ – 13 January 2017: Actifed Tablet from Glaxo Wellcome GmbH & Co., Bad Oldesloe, Germany can also be used as a comparator.	
63.	Rifampicin + Ethambutol HCl + Pyrazinamide + Isoniazide	Akurit-4 Tablet MAL20051429AZ	Lupin Limited, India

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64.	Rifampicin 300mg + Isoniazid 150mg	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 st March 2016)	
65.	Simethicone 300mg + Alverine Citrate 60mg	Meteospasmyl Capsule MAL19990251ACZ	LGV Capsules 20,Rue Louis Charles Vernin,77190 Dammarie Les Lys, France
66.	Sitagliptin phosphate + Metformin HCl	Janumet 50/500mg MAL20081789ACRZ Janumet 50/850mg MAL20081790ACRZ Janumet 50/1000mg MAL20081791ACRZ Janumet XR 50mg/500mg Film Coated Tablets MAL14125082ARZ Janumet XR 50mg/1000mg Film Coated Tablets MAL14125083ARZ Janumet XR 100mg/1000mg Film Coated Tablets MAL14125081ARZ	Patheon Puerto Rico, Inc, United States Patheon Puerto Rico, Inc, United States Patheon Puerto Rico, Inc, United States MSD International GmbH (Puerto Rico Branch) LLC, Puerto Rico MSD International GmbH (Puerto Rico Branch) LLC, Puerto Rico MSD International GmbH (Puerto Rico Branch) LLC, Puerto Rico
67.	Sulfadoxine + Pyrimethamine	Fansidar Roche Tablet MAL19871340ARZ	F.Hoffmann-La Roche Ltd, Switzerland
68.	Sulphamethoxazole 400mg + Trimethoprim 80mg.	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.	

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		Pharmaniaga Co-Trimoxazole Tablet (MAL19871882AZ)	Pharmaniaga Manufacturing Berhad
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014, 18 th August 2014:- 1. Co-Trimoxazole Tablet manufactured by Pharmaniaga Manufacturing Berhad is being added to the existing list of comparator.	
69.	Tegafur + Gimeracil + Oteracil Potassium	TS-ONE Capsule 20 MAL12075066ARZ TS-ONE Capsule 25 MAL12075067ARZ	Taiho Pharmaceutical Co. Ltd., Japan
70.	Telmisartan + Amlodipine Besilate	Twynsta Tablet 40/5mg MAL20112135ACZ Twynsta Tablet 40/10mg MAL20112136ACZ Twynsta Tablet 80/5mg MAL20112137ACZ Twynsta Tablet 80/10mg MAL20112138ACZ	Cipla Limited, India Cipla Limited, India Cipla Limited, India Cipla Limited, India
71.	Telmisartan + Hydrochlorothiazide	Micardis Plus 80/25mg Tablet, MAL09032035A	Boehringer Ingelheim, West Germany
		This product is available in Philippines, Korea, Hong Kong, Germany, Switzerland, Poland, Netherlands, Belgium, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, Norway, Portugal, Cyprus, Slovakia, Slovenia, Austria, Sweden, Bulgaria, Canada, United States (Information obtained via an email from Boehringer Ingelheim dated 3 rd December 2018).	
		Micardis Plus 40/12.5mg Tablet, MAL20034439AZ	Boehringer Ingelheim Ellas A.E, Greece Boehringer Ingelheim, West Germany
		Micardis Plus 80/12.5mg Tablet MAL20034440AZ	Boehringer Ingelheim Ellas A.E, Greece

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			Boehringer Ingelheim, West Germany
72.	Triamterene + hydrochlorothiazide	Dyazide Tablet (MAL19950581A) Dyazide Tablet (MAL19871039A)	SmithKline Beecham Pharm, UK SmithKline & French (Aust), Australia
73.	Trimethoprim 90mg + Sulphadiazine 410mg Tablet	Triglobe Tablet 500mg (MAL19870919AR)	Astrazeneca Sweden
74.	Uracil 224mg + Tegafur 100mg	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 :- i) Validation process report for 3 consecutive batches ii) Comparative dissolution profile for 3 consecutive batches (time points : 0, 5, 15, 30 & 45 minutes) Kindly refer biowaiver page on NPRA website for more information.	
75.	Valsartan + Hydrochlorothiazide	Co-Diovan 80/12.5mg Film-Coated Tablet MAL09062164ARSZ Co-Diovan 320/12.5mg Film-Coated Tablet MAL09051533ARZ Co-Diovan 320/25mg Film-Coated Tablet MAL09051534ARZ Co-Diovan Tablets MAL20000246A Co-Diovan 160/12.5mg Film-Coated Tablet MAL09062165ARSZ Co-Diovan 160/25mg Film Coated Tablet MAL09062166ARSZ	Novartis Farma S.P.A, Italy Novartis Pharma Stein AG, Switzerland Novartis Pharma Stein AG, Switzerland Novartis Pharma AG, Switzerland Novartis Pharma S.P.A, Italy Novartis Pharma S.P.A, Italy

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76.	Vildagliptin + Metformin	Galvus Met 50/500mg Film-coated Tablet MAL12035005ARZ		Novartis Pharma Stein AG, Switzerland	
		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	

Note:

If you need further clarification, kindly email to be_sug@npra.gov.my

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