

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

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
1.	<b>Pseudoephedrine hydrochloride 60mg + triprolidine hydrochloride 2.5mg</b>	1. Actifed Tablet (MAL19860267A)	The Wellcome Foundation Ltd, UK
		2. Actifed Tablet (MAL19989031AC)	Parke Davis Pty Ltd, Australia
		3. Actifed Tablet (MAL19940560A)	Wellcome Ltd, Australia
Products are available in <b>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 )			
2.	<b>Chlordiazepoxide 5mg + clidinium bromide 2.5mg</b>	Librax Roche Dragee (MAL19880019A)	F. Hoffman La Roche Switzerland
		Product is available in <b>Canada</b> (Information obtained through an email from Inova Pharma dated 27/12/2012)	
3.	<b>Losartan 100mg + Hydrochlorothiazide 25mg</b>	Fortzaar Tablet (MAL20013017AR)	Merck Sharp & Dohme Ltd, UK
4.	<b>Amoxicillin + Clavulanic Acid</b>	1. Augmentin Tablet 375mg (MAL19871292A)	Smithkline Beecham Pharmaceuticals United Kingdom
		2. Augmentin Tablet 625mg (MAL19986474A)	Smithkline Beecham Pharmaceuticals United Kingdom
		3. Augmentin Tablet 1g (MAL19972945A)	Smithkline Beecham Pharmaceuticals United Kingdom
5.	<b>Triamterene + hydrochlorothiazide</b>	1. Dyazide Tablet MAL19950581A	SmithKline Beecham Pharm, UK
		2. Dyazide Tablet MAL19871039A	SmithKline & French (Aust), Australia
6.	<b>Levonorgestrel 0.15mg + Ethinylestradiol 0.03mg</b>	Microgynon 30 Tablet (MAL19900570A)	Schering AG Berlin, Germany

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7.	<b>Levonorgestrel 0.15mg + Ethinyl estradiol 0.03mg + Ferrous Fumarate 75mg</b>	Microgynon 30 ED FE Tablet (MAL19900571A)	Schering AG Berlin, Germany
8.	<b>Cyproterone Acetate 2.0mg + Ethinyl Estradiol 0.035mg</b>	1. Diane 35 Tablet (MAL19900568A)  2. Diane-35 Tablet (MAL20001806ASC)	Schering GHBH & Co Productions KG, Germany  PT Schering Indonesia
9.	<b>Amiloride Hydrochloride 5mg + Hydrochlorothiazid e 50mg</b>	Moduretic 50/5 Tablet MAL19920200AR	Frosst Iberica S.A, Spain
10.	<b>Chlordiazepoxide 5mg + Clidinium Bromide 2.5mg</b>	Librax Roche Dragee MAL19880019A	F. Hoffman La-Roche, Switzerland
11.	<b>Sulphamethoxazole 400mg + Trimethorprim 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.			
12.	<b>Trimethoprim 90mg + Sulphadiazine 410mg Tablet</b>	Triglobe Tablet 500mg, MAL19870919AR,	Astrazeneca Sweden
13.	<b>Paracetamol 500mg + Dihydrocodeine 10mg</b>	Codopar 118 Tablet, MAL1986042938A + DF 118 Tablet 30mg. MAL19962828AS	Glaxosmithkline Pharmaceutical Sdn Bhd, Malaysia  GlaxoSmithKline South Africa
14.	<b>Chlorpheniramine Maleate 2 mg, Paracetamol 500 mg, Phenylephrine Hydrochloride 10 mg</b>	Piriton Tablet 4mg, MAL07082871AC + Codral Relief Decongestant	Haupt Pharma Wulfing Gmbh, Germany  Johnson & Johnson Australia

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15.	<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
16.	<b>Atropine Sulphate 0.025mg + Diphenoxylate Hydrochloride 25mg</b>	Lomotil Tablet 2.5mg MAL20000044AR	Pharmacia Ltd, United Kingdom
		Product is available in <b>Botswana and South Africa.</b> (Information obtained via a letter from Johnson & Johnson dated 9 <sup>th</sup> August 2012)	
		Lomotil Tablet PBKD871651A	Searle Labs, Australia
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2013, 2 <sup>nd</sup> December 2013:-  1. Lomotil Tablet manufactured by Pfizer Canada is being added to the existing list of comparator.  2. Analytes to measure: Diphenoxylate HCl.	
17.	<b>Atenolol 100mg + Chlorthalidone 25mg</b>	Tenoretic Tablet MAL19871032A	Astrazeneca UK Ltd, United Kingdom
18.	<b>Irbesartan + Hydrochlorothiazid e</b>	1. Coaprovel 150mg/12.5mg Tablet MAL20014479A	Sanofi Winthrop Industrie, France
		2. Coaprovel 300mg Tablet MAL20014478A	Sanofi Winthrop Industrie, France
		3. Coaprovel 300/25mg Tablet	Sanofi Winthrop Industrie, France
19.	<b>Orphenadrine Citrate 35mg + Paracetamol 450mg</b>	Norgesic Tablet MAL19871086A,	iNova Pharmaceuticals (Australia) Pty Ltd, Australia
20.	<b>Paracetamol 500mg + Phenylephrine HCl 5mg</b>	Paracetamol Sinus Relief PE Caplet MAL09062126A	Glaxosmithkline Australia Pty Ltd, Australia

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21.	<b>Uracil 224mg + Tegafur 100mg</b>	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 )	
22.	<b>Buprenorphine + Naloxone</b>	1. Suboxone 2mg Sublingual Tablets, MAL20061581A  2. Suboxone 8mg Sublingual Tablets, MAL20061582A	Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom  Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom
23.	<b>Telmisartan + Hydrochlorothiazid e</b>	1. Micardis Plus 80/25mg Tablet, MAL09032035A  2. Micardis Plus 40/12.5mg Tablet, MAL20034439A  3. Micardis Plus 80/12.5mg Tablet MAL20034440A	Boehringer Ingelheim, West Germany  Boehringer Ingelheim, West Germany  Boehringer Ingelheim, West Germany
24.	<b>Drospirenone 3mg + Ethinyl Estradiol 30mcg</b>	Yasmin Tablet MAL20040023AR	Schering Gmbh, Germany
25.	<b>Paracetamol 325mg + Tramadol 37.5mg</b>	Ultracet Tablet MAL20051462A	Janssen Korea Ltd, Korea
26.	<b>Ethinylestradiol 20mcg + Desogestrel 150mcg</b>	1. Mercilon Tablet MAL19962539A  2. Mercilon Tablets MAL19900640A	Organon (Ireland) Ltd., Ireland  N.V. Organon, Netherlands
27.	<b>Desogestrel 0.15mg + Ethinyl estradiol 0.03mg</b>	Marvelon Tablet, MAL19872093A	N.V. Organon, Netherlands
28.	<b>Drosperinone 3mg + Ethinylestradiol 0.02mg</b>	Yaz Tablets , MAL20091884ACR	Schering Gmbh & Co. Germany

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29.	<b>Ezetimibe + Simvastatin</b>	Vytorin 10/10mg Tablet MAL20041212AR	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/20mg Tablet, MAL20041213AR	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/40mg Tablet, MAL20041214AR	MSD International Gmbh (Singapore), Singapore
		Vytorin 10/80mg Tablet MAL20041215AR	MSD International Gmbh (Singapore), Singapore
30.	<b>Valsartan + Hydrochlorothiazid e</b>	Co-Diovan 80/12.5mg Film-Coated Tablet MAL09062164AS	Novartis Farma S.P.A, Italy
		Co-Diovan 320/12.5mg Film-Coated Tablet MAL09051533A	Novartis Pharma Stein AG, Switzerland
		Co-Diovan 320/25mg Film-Coated Tablet MAL09051534A	Novartis Pharma Stein AG, Switzerland
		Co-Diovan Tablets MAL20000246A	Novartis Pharma AG, Switzerland
		Co-Diovan 160/12.5mg Film-Coated Tablet MAL09062165AS	Novartis Pharma S.P.A, Italy
		Co-Diovan 160/25mg Film Coated Tablet MAL09062166AS	Novartis Pharma S.P.A, Italy
31. .	<b>Ethinylestradiol (0.04mg, 0.03mg, 0.03mg)+ Levonorgestrel (0.0075mg, 0.125mg, 0.05mg)</b>	Trinordiol 21 Tablet MAL20000740A	Pfizer Ireland Pharmaceuticals Ireland
32.	<b>Rifampicin 300mg + Isoniazid 150mg</b>	Rimactazid 300mg Sugar Coated Tablet MAL19871621A	Novartis South Africa (Pty) Ltd, South Africa

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33.	<b>Metformin + Glibenclamide</b>	Glucovance 500mg/2.5mg MAL20051296A	Merck Sante SAS, France
		Glucovance 500mg/1.25mg MAL20051295A	Merck Sante SAS, France
		Glucovance 500/5mg MAL20051297A	Merck Sante SAS, France
34.	<b>Levonorgestrel + Estradiol</b>	Loette 21 Tablet MAL19992674A	Pfizer Ireland Pharmaceuticals, Ireland
35.	<b>Aliskiren Hemihydrate + Hydrochlorothiazid e</b>	Rasilez HCT 150/12.5mg Film-Coated Tablet MAL20091951A	Novartis Pharma S.P.A, Italy
		Rasilez HCT 300/12.5mg Film-Coated Tablet MAL20091953A	Novartis Pharma S.P.A, Italy
		Rasilez HCT 300/25mg Film-Coated Tablet MAL20091954A	Novartis Pharma S.P.A, Italy
		Rasilez HCT 150/25mg Film-Coated Tablet MAL20091952A	Novartis Pharma S.P.A, Italy
36.	<b>Metformin + Glimepiride</b>	Amaryl M 1/250mg Tablet MAL20091866A	Handok Pharmaceuticals Co. Ltd., Korea
		Amaryl M 2/500mg Tablet MAL20091867A	Handok Pharmaceuticals Co. Ltd., Korea
37.	<b>Perindopril tert- butylamine + Indapamide</b>	Coversyl Plus Tablet MAL20013354A	Les Labs Industrie, France
		Coversyl Plus Tablet MAL09011458ACS	Kotra Pharma (M) Sdn. Bhd., Malaysia
38.	<b>Paracetamol + Codeine</b>	Panadeine Forte Tablet MAL19871079A	Winthrop Labs, Australia
		Panadeine Tablet	Aventis Pharma Limited, India

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		MAL19950068A	
39.	<b>Lamivudine 150mg + Zidovudine 300mg</b>	Combivir Tablet MAL19991350AR	Glaxo Wellcome Operations UK Ltd, United Kingdom
40.	<b>Fexofenadine Hydrochloride 60mg + Pseudoephedrine Hydrochloride 120mg</b>	Telfast-D Tablet MAL20040553AR	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)
41.	<b>Simethicone 300mg + Alverine Citrate 60mg</b>	Meteospasmyl Capsule MAL19990251AC	LGV Capsules 20,Rue Louis Charles Vernin,77190 Dammarie Les Lys, France
42.	<b>Estradiol Valerate 2mg + Cyproterone Acetate 1mg</b>	Climen 28 Sugar Coated Tablet MAL20040218A	Delpharm Lille SAS, France
43.	<b>Vildagliptin + Metformin</b>	Glavus Met 50/850mg Film-Coated Tablet MAL20091864A  Glavus 50/1000mg Film-Coated Tablet MAL20091865A	Novartis Pharma Stein AG, Switzerland  Novartis Pharma Stein AG, Switzerland
44.	<b>Bisoprolol hemifumarate + hydrochlorothiazide</b>	Lodoz 10mg Tablet MAL05051114A  Lodoz 5mg Tablet MAL05051113A  Lodoz 2.5mg Tablet MAL05051115AA  Lodoz MAL20040552A	Merck KgaA, Germany       Pt Merck Indonesia

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45.	<b>Dydrogestrone + estradiol</b>	Femoston Conti Tablet MAL20040952A  Femoston 2/10 Tablet MAL06021201A  Femoston 2/20 Tablet MAL19991348A  Femoston 1/10 Tablet MAL20040819A	Abbott Biological B. V, Netherlands  Abbott Biological B. V, Netherlands  Solvay Pharmaceuticals B.V 1, Netherlands  Abbott Biological B. V, Netherlands
46.	<b>Paracetamol + Dextrometorphan + Pseudoephedrine Hydrochloride</b>	Panadol-CF Tablet MAL19930413A	Winthrop Labs, Australia
47.	<b>Perindopril + Amlodipine</b>	Coveram 10mg/10mg Tablet MAL20091913A  Coveram 10mg/5mg Tablet MAL20091912A  Coveram 5mg/10mg Tablet MAL20091911A  Coveram 5mg/5mg Tablet MAL20091910A	Servier (Ireland) Industries Ltd., Ireland
48.	<b>Allopurinol + Benzbromarone</b>	Harpagin Tablet MAL19871347A	Merz Pharma Gmbh & Co. KGAA, Germany
49.	<b>Olmesartan Medoxomil + Hydrochlorothiazid e</b>	Olmetec Plus 20/12.5mg Film-Coated Tablet MAL20071700AR  Olmetec Plus 40/12.5mg Film-Coated Tablet MAL20071701AR	Daiichi Sankyo Europe Gmbh, Germany  Daiichi Sankyo Europe Gmbh, Germany

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		Olmetec Plus 40/25mg Film-Coated Tablet MAL20071702AR	Daiichi Sankyo Europe Gmbh, Germany
50.	<b>Olmesartan Medoxomil + Amlodipine Besilate</b>	Azoren 20 Mg/5 mg Film-Coated Tablets Mal12055003A  Azoren 40 Mg/10 mg Film-Coated Tablets Mal12055005A  Azoren 40 Mg/5 mg Film-Coated Tablets Mal12055004A	Daiichi Sankyo Europe Gmbh, Germany  Daiichi Sankyo Europe Gmbh, Germany  Daiichi Sankyo Europe Gmbh, Germany
51.	<b>Levodopa + Carbidopa</b>	Sinemet 25/100 Tablet MAL19913441A  Sinemet 25/250 Tablet MAL19913442A  Sinemet Tablet 25/250mg MAL19871095AR  Sinemet 25/100 Tablet MAL19871096AR	Merck Sharp & Dohme (Australia) Pty. Ltd., Australia  Merck Sharp & Dohme (Australia) Pty. Ltd., Australia  Merck Sharp & Dohme Int, United States  Merck Sharp & Dohme Int, United States

**Note:**

If you need further clarification, kindly email to [mazuwin@bpfk.gov.my](mailto:mazuwin@bpfk.gov.my) and [muikiat@bpfk.gov.my](mailto:muikiat@bpfk.gov.my)

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