

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY
REPORT FOR YEAR 2011**

9 TH LIST

Bil (8)dlm.BPFK/PPP/01/03 Jilid 1 (10/01/2011)

| Bil. | TEST PRODUCTS (Pharmaceutical name) | Comparator Products | | Effective Date for Submission of BE Study Report | Closing Date for Submission of BE Study Report of Registered Products | |
|------|--|--|--|--|---|----------------|
| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 1. | Letrozole | i) Femara 2.5mg Film-Coated Tablet (MAL19973303ARZ) | Novartis Pharma Stein AG, Switzerland | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 2. | Anagrelide | i) Agrylin 0.5mg Capsules (MAL20051337ACR) ii) Agrylin 0.5mg Capsules (MAL13055062ACRZ) | Mallinckrodt Inc, United States DSM Pharmaceuticals, Inc., United States | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 3. | Chlorpromazine | i) Largactil Tablet 25mg (PBKD861335A) ii) Largactil Tablet 100mg (PBKD8631345A) | May & Baker Ltd, United Kingdom May & Baker Ltd, United Kingdom | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | Products are available in East Europe, Tunisia and Africa. (Information obtained from Sanofi-Aventis (Malaysia) Sdn Bhd through an email dated 19 September 2011) and Australia (According to | | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | <p>information provided during upon Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013)</p> <p>However, as agreed upon Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013, Largactil® manufactured from other sites which are Sanofi Aventis, Spain and Famar Lyon, France can also be used as the comparator.</p> | | | | |
| 4. | Haloperidol | <p>i) Serenace Tablet 0.5mg (PBKD861361A)</p> <p>ii) Serenace Tablet 1.5mg (PBKD861365A)</p> <p>iii) Serenace Tablet 5mg (PBKD861368A)</p> | <p>Searle Labs, Australia</p> <p>Searle Labs, Australia</p> <p>Searle Labs, Australia</p> | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | <p>Products are available in Aruba, Bahrain, Iran, Kuwait, Macau, Oman, Philippines, Qatar, South Africa, UAE (Information obtained from Pfizer through an email dated 14/7/2011)</p> <p>As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: Serenace Tablet from Piramal Healthcare UK Limited & Sigma Australia can also be used as a comparator.</p> | | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 5. | Perphenazine | Trilafon Tablet 2mg (1986043353A) Trilafon Tablet 4mg (1986043352A) | Schering-Plough Pty. Ltd., Australia Schering-Plough Pty. Ltd., Australia | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 6. | Trifluoperazine | i) Stelazine Tablet 1mg (PBKD861375A) ii) Stelazine Tablet 5mg (PBKD861379A) iii) Stelazine Capsule 2mg (MAL19871465A) | Smith Kline & French (Aust) Ltd, Australia Smith Kline & French (Aust) Ltd, Australia Smith Kline & French Labs, United Kingdom | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | Products are available in Singapore (Information obtained during Mesyuarat JKKBE 02/2011) | | | | |
| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2017”, 24 May 2017, the following product is being added to the existing list of comparator:- | | | | |
| | | i) Apo-Trifluoperazine 5mg (MAL19984755AZ) | Apotex Inc, Canada | | | |

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|------|---|--|---|--|---|----------------|
| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 7. | Aripiprazole | Abilify Tablet 10mg (MAL07021401ARS) | Otsuka Pharmaceutical Co Ltd., Japan | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | Abilify Tablet 15mg (MAL07021403ARS) | Otsuka Pharmaceutical Co Ltd., Japan | | | |
| | | Abilify Tablets 10mg (MAL05023433AR) | Bristol-Myers Squibb Manufacturing Company, United States | | | |
| | | Abilify Tablets 15mg (MAL05023434AR) | Bristol-Myers Squibb Manufacturing Company, United States | | | |
| | | Products are available in Singapore, Australia and New Zealand (Information obtained through an email from Bristol-Myers Squibb, Korea dated 22/6/2011) | | | | |
| 8. | Olanzapine | i) Zyprexa 5mg Tablet (MAL19986933AZ) | Lilly Del Caribe Inc., Puerto Rico | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | | Basingstoke UK | | | |
| | | ii) Zyprexa Tablet 5mg (MAL08061564ARSZ) | Lilly S.A., Spain | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | iii) Zyprexa 10mg Tablet (MAL19986935AZ) | Lilly Del Caribe Inc., Puerto Rico | | | |
| | | | Basingstoke UK | | | |
| | | iv) Zyprexa Tablet 10mg (MAL08061565ARSZ) | Lilly S.A., Spain | | | |
| | | v) Zyprexa Tablet 15mg (MAL04125528AR) | Lilly Del Caribe Inc., United States | | | |
| | | vi) Zyprexa Tablet 20mg (MAL04125532AR) | Lilly Del Caribe Inc., United States | | | |
| | | Products are available in Canada, USA, Denmark and Sweden (Information obtained from Eli Lilly dated 23rd January 2013 via email) | | | | |
| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013, 2 nd September 2013, the following products are being added to the existing list of comparator: | | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | i) Oleanz 5 Tablet (MAL10100139AZ) ii) Oleanz 10 Tablet (MAL10100143AZ) iii) Olenza 5mg Tablet (MAL10100149AZ) iv) Olenza 10mg Tablet (MAL10100148AZ) | Sun Pharmaceutical, India Sun Pharmaceutical, India Noripharma Sdn. Bhd. Noripharma Sdn. Bhd. | | | |
| 9 | Quetiapine | i) Seroquel Tablet 25mg (MAL20000261AZ) ii) Seroquel Tablet 100mg (MAL20000262AZ) iii) Seroquel Tablet 200mg (MAL20000263AZ) iv) Seroquel Tablet 300mg (MAL06041484AZ) | Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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|------|--|---|--|--|---|----------------|
| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 10. | Ziprasidone | i) Zeldox Capsule 20mg (MAL20032622A) ii) Zeldox Capsule 40mg (MAL20032623AZ) iii) Zeldox Capsule 60mg (MAL20032624AZ) iv) Zeldox Capsule 80mg (MAL20032625AZ) | Pfizer Australia Pty Ltd, Australia Pfizer Australia Pty Ltd, Australia Pfizer Australia Pty Ltd, Australia Pfizer Australia Pty Ltd, Australia | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 11. | Citalopram | i) Cipram Tablets 10mg (MAL19950393A) ii) Cipram Tablets 20mg (MAL19950394AZ) iii) Cipram Tablets 40mg (MAL19950392A) | H. Lundbeck A/S, Denmark H. Lundbeck A/S, Denmark H. Lundbeck A/S, Denmark | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 12. | Escitalopram | i) Lexapro 5mg Tablet (MAL20041159AZ) ii) Lexapro 10mg Tablet (MAL20041160AZ) | H. Lundbeck A/S, Denmark H. Lundbeck A/S, Denmark | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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|---|---|---|--|--|---|----------------|
| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | iii) Lexapro 15mg Tablet (MAL20041161AZ) iv) Lexapro 20mg Tablet (MAL20041162AZ) | H. Lundbeck A/S, Denmark H. Lundbeck A/S, Denmark | | | |
| 13. | Paroxetine | i) Seroxat 20mg Tablet (MAL19930146A) | Glaxo Wellcome Production, France | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| Product is available in Hong Kong, Thailand and Philippines (Information obtained via an email from GSK dated 5th October 2015) | | | | | | |
| As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2018’ – 25 May 2018: Seroxat 20mg Tablet manufactured by S.C Europharm S.A, Romania and GlaxoSmithKline Pharmaceuticals S.A, Poland can also be used as a comparator. | | | | | | |
| 14. | Duloxetine | i) Cymbalta Capsule 30mg (MAL05092473AZ) | Lilly del Caribe Inc., Puerto Rico Lilly S.A, Spain | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | ii) Cymbalta Capsule 60mg (MAL05092474AZ) | Lilly del Caribe Inc., Puerto Rico Lilly S.A, Spain | | | |
| 15. | Venlafaxine | i) Efexor Tablets 37.5mg (MAL19973300A) ii) Efexor Tablets 50mg (MAL19973301A) iii) Efexor Tablets 75mg (MAL19973302A) | Wyeth Canada, Canada Wyeth Canada, Canada Wyeth Canada, Canada | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | Products are available from Ireland, Italy, Spain, Malta, Ireland, France (Information obtained through an email from Pfizer Malaysia dated 3rd October 2012) This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information. | | | | |
| 16. | Mirtazapine | i) Remeron 15mg Tablet (MAL19990905A) ii) Remeron 30mg Tablet (MAL19990903A) | N.V. Organon, Netherlands N.V. Organon, Netherlands | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | iii) Remeron 45mg Tablet (MAL19990904A) | N.V. Organon, Netherlands | | | |
| 17. | Imipramine | i) Tofranil Tablet 25mg (PBKD861457A) | Novartis Pharma Stein AG., Switzerland | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | <p>Product is available in Afghanistan, Argentina Aruba, Bahrain, Bangladesh, Bolivia, Brazil, Cameroon, Colombia, Costa Rica, Curacao, Dominican Republic, El Salvador Ethiopia, Guatemala, Honduras, Indonesia, Iraq, Israel, Jamaica, Jordan, Kenya, Kuwait, Madagascar, Mauritius, Mexico, Nicaragua, Oman, Pakistan, Palestine, Palestine, Panama, Paraguay, Qatar, Saudi Arabia, Senegal, Sudan, Switzerland, Trinidad and Tobago, Turkey, United Arab Emirates, Uruguay, Venezuela, Yemen, Zambia, Zimbabwe (Information obtained through an email from Novartis Malaysia dated 13/7/2011)</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015, this active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information.</p> | | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 18. | Maprotiline | i) Ludiomil 25mg Tablets (MAL20001251A) ii) Ludiomil Tablet50mg (MAL19861465A) | Novartis Urunleri, Turkey Novartis Farmaceutica S.A., Spain | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 19. | Nortriptyline | i) Nortrilen Tablet 10mg (PBKD1986043197A) ii) Nortrilen Tablet 25mg (PBKD861452A) Products are available in Belgium, Czee Republic, Iceland, Italy, Germany, Denmark, Estonia, Hong Kong, Finland, Latvia, Lithuania, Luxemburg, Malta, Netherland, Norway, Saudi Arabia, Sweden, Switzerland (Information obtained through a letter from IDS Services (M) Sdn Bhd dated 25/8/2011) This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information. | H. Lundbeck A/S., Denmark H. Lundbeck A/S., Denmark | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 20. | Pregabalin | i) Lyrica 75mg Capsules (MAL20081831AZ) | Pfizer manufacturing Deutschland GmbH., Germany | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | ii) Lyrica 50mg Capsules (MAL20081830AZ) | Pfizer manufacturing Deutschland GmbH., Germany | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | iii) Lyrica 150mg Capsules (MAL20081832AZ) | Pfizer manufacturing Deutschland GmbH., Germany | | | |
| 21. | Diazepam | i) Valium Roche Tablet 2mg (PBKD861254A) | F. Hoffman-La Roche., Switzerland | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | ii) Valium Roche Tablet 5mg (PBKD861263A) | F. Hoffman-La Roche., Switzerland | | | |
| | | iii) Valium Roche Tablet 10mg (PBKD861274A) | F. Hoffman-La Roche., Switzerland | | | |
| | | As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013 – 13 March 2013: Valium Tablet from France, USA & Spain can also be used as a comparator. | | | | |

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|------|--|--|---|--|---|----------------|
| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014, 23 April 2014, the following products are being added to the existing list of comparator: | | | | |
| | | i) Diazepam 10mg Tablet (MAL19860207AZ) | Idaman Pharma Manufacturing Sdn Bhd, Malaysia | | | |
| | | ii) Diazepam 5mg Tablet (MAL19860211AZ) | Idaman Pharma Manufacturing Sdn Bhd, Malaysia | | | |
| 22. | Nitrazepam | i) Mogadon 5mg Tablets (MAL06091378ACR) | Labiana Pharmaceuticals SL, Spain | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015: This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information. | | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 23. | Zolpidem | i) Stilnox 10mg Film Coated Tablet (MAL19940650AZ) | Sanofi Winthrop Industrie, France | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 24. | Chlordiazepoxide | i) Librium Roche Dragee 5mg (PBKD861319A) | F. Hoffman-La Roche., Switzerland | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | ii) Librium Roche Dragee 10mg (PBKD861317A) | F. Hoffman-La Roche., Switzerland | | | |
| | | <p>Products are available in United States of America (Information obtained through an email from Inova Pharma dated 27/12/2012)</p> <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information.</p> | | | | |
| 25. | Alprazolam | i) Xanax Tablet 0.25mg (MAL05121165ACRSZ) | Sanico N.V., Belgium | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | ii) Xanax Tablet 0.5mg (MAL05121161ACRSZ) | Sanico N.V., Belgium | | | |
| | | iii) Xanax Tablet 1mg (MAL05121166ACRSZ) | Sanico N.V., Belgium | | | |
| | | iv) Xanax 0.5mg Tablets (MAL20021408A) | Pfizer Manufacturing Belgium NV | | | |
| | | v) Xanax Tablet 0.25mg (MAL19861297A) | Pfizer Manufacturing Belgium NV | | | |
| | | vi) Xanax 1.0mg Tablets (MAL20021409A) | Pfizer Manufacturing Belgium NV | | | |
| | | vii) Xanax Tablet 0.25MG (MAL19861296A) | Pfizer Pharmaceuticals LLC, Puerto Rico | | | |
| | | viii) Xanax Tablet 1mg (MAL19861299A) | Pfizer Pharmaceuticals LLC, Puerto Rico | | | |
| | | ix) Xanax Tablet 0.5mg (MAL19861301A) | Pfizer Pharmaceuticals LLC, Puerto Rico | | | |
| 26. | Lorazepam | i) Ativan Tablet 0.5mg (MAL19871462A) | Wyeth Pharma GmbH, West Germany | | | |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| | | ii) Ativan 0.5mg Tablet (MAL19991388A) iii) Ativan 1mg Tablet (MAL19991389A) | Wyeth Medica Ireland, Ireland Wyeth Medica Ireland, Ireland | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| | | Products are available in Europe . (Information obtained through an email from Pfizer Malaysia dated 12/7/2011) | | | | |
| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2013, 2 nd December 2013, the following product is being added to the existing list of comparator:- | | | | |
| | | Apo-Lorazepam Tablet 1mg (MAL19984741ARZ) | Apotex Inc, Canada | | | |
| 27. | Bromazepam | i) Lexotan Roche Tablet 1.5mg (MAL19861302ARZ) | Roche S.P.A., Italy | 01/07/2011 | 01/07/2011 | 01/07/2011 |
| 28. | Clobazam | i) Frisium Tablet 10mg (MAL19861330AZ) | Sanofi Winthrop Industrie, France | 01/07/2011 | 01/07/2011 | 01/07/2011 |

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| | | Trade Mark/Registration No./ Reference No. | Manufacturer | New Application | Imported Products | Local Products |
| 29. | Zopiclone | i) Imovane Tablet 7.5mg (MAL19900140AZ) | Sanofi Winthrop Industrie, France | 01/07/2011 | 01/07/2011 | 01/07/2011 |

*Note:

1) Bioequivalence study requirement is also applied for Fixed Dose Combination product which contains the listed active substance as above.

Updated on 21/08/2018