

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY REPORT
FOR YEAR 2009 - 2010**

8 TH LIST

| 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. | Manufacturer | New Application | Imported Products | Local Products |
| 1. | Amoxicillin | i) Ospamox 250mg Capsule (MAL19890611AZ) ii) Ospamox 500mg Film-Coated Tablet (MAL19890612AZ) iii) Ospamox 1000mg Film-Coated Tablet (MAL19890613AZ) iv) Moxilen Capsule 250mg (MAL19860458AZ) v) Moxilen Capsule 500mg (MAL19860465AZ) | Sandoz GmbH, Austria Sandoz GmbH, Austria Sandoz GmbH, Austria Medochemie Ltd, Cyprus Medochemie Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 2. | Ampicillin | i) Pamecil Capsule 250mg (MAL19860391AZ) ii) Pamecil Capsule 500mg (MAL19860396AZ) | Medochemie Ltd, Cyprus Medochemie Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 3. | Cephalexin | i) Ospexin Capsule 250mg (MAL19890449AZ) | Sandoz GmbH, Austria | | | |

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|----|------------------------------------|---|---|------------|------------|------------|
| | | ii) Ospexin 500mg F/C Tablet (MAL19890448AZ) | Sandoz GmBH, Austria | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| | | iii) Ospexin 1000mg Film-Coated Tablet (MAL19890610AZ) | Sandoz GmBH, Austria | | | |
| 4. | Clindamycin | i) Dalacin C Capsule 150mg (MAL19871766ACZ) | Fareva Amboise, France Pfizer PGM, France | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| | | ii) Dalacin C Capsules 300mg (MAL19985498ACZ) | Fareva Amboise, France Pfizer, France Patheon Inc, Canada | | | |
| 5. | Cloxacillin | i) Monoclox Capsule 250mg (MAL19871957AZ) | Medochemie Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015, 7 th September 2015, the following products are being added to the existing list of comparator:- | | | | |
| | | i) Cloxacillin Capsule 250mg (MAL19930225AZ) | Dynapharm (M) Sdn Bhd | | | |
| | | ii) Cloxacillin Capsule 500mg (MAL07090901AZ) | Dynapharm (M) Sdn Bhd | | | |
| | | iii) Cloxacilla Cap 250mg (MAL19890418AZ) | Idaman Pharma Manufacturing Sdn Bhd (Seri Iskandar) | | | |
| 6. | Erythromycin Ethylsuccinate | i) E.E.S. 400 Filmtab (MAL19870265A) | Abbott Laboratories, US | 01/01/2010 | 01/07/2010 | 31/12/2010 |

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| | | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013, 2 nd September 2013, the following product is being added to the existing list of comparator:- | | | | |
| | | Axcel Erythromycin ES Tablet (MAL20020154AZ) | Kotra Pharma (M) Sdn. Bhd | | | |
| 7. | Erythromycin Stearate | Erythrocin Stearate Filmtab 250mg (MAL19871699AR) | Abbott Laboratories, US | | | |
| | | This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on NPRA website for more information. | | | | |
| 8. | Griseofulvin | i) Medofulvin Tablet 125mg (MAL19860841AZ) ii) Medofulvin 500 Tablet (MAL19860848AZ) | Medochemie Ltd, Cyprus Medochemie Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 9. | Levofloxacin | i) Cravit Tablet 100mg (MAL19985877A) ii) Cravit 250mg (MAL20041051AZ) iii) Cravit 500mg (MAL20041052A) | Daiichi Sankyo Propharma Co., Ltd., Shizuoka Plant, Japan Pt Kalbe Farma TBK, Indonesia Pt Kalbe Farma TBK, Indonesia | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 10. | Minocycline | i) Apo-Minocycline 50mg (MAL19984325AZ) ii) Apo-Minocycline 100mg Capsule (MAL19984324AZ) | Apotex Inc, Canada Apotex Inc, Canada | 01/01/2010 | 01/07/2010 | 31/12/2010 |

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| 11. | Nitrofurantoin | i) Apo-Nitrofurantoin Tablet 100mg (MAL19984749ARZ) | Apotex Inc, Canada | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 12. | Norfloxacin | i) Urobacid 400mg Film-Coated Tablets (MAL20021380AZ) ii) Trizolin 400 F.C. Tablets (MAL19913447A) | Merck Kommanditgesellschaft Auf Aktein & Co.Werk, Austria Remedica Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 13. | Oseltamivir Phosphate | i) Tamiflu Capsules 75mg (MAL20014188ARZ) ii) Tamiflu Capsule 75mg (MAL09082799ARSZ) iii) Tamiflu Capsules 75mg (MAL11030079ACRSZ) iv) Tamiflu Capsule 30mg (MAL09100495ARZ) v) Tamiflu Capsule 45mg (MAL09100496ARZ) | Roche S.P.A., Italy F.Hoffmann-LA Roche Ltd, Switzerland Cenexi SAS, France Catalent Pharma Solutions, Germany Roche S.P.A., Italy Roche S.P.A., Italy | 01/01/2010 | 01/07/2010 | 31/12/2010 |
| 14. | Phenoxymethyl penicillin | i) Ospen Tablet 250mg (MAL19860442AZ) ii) Ospen (KV) 1000 Film-Coated Tablet (MAL19872227AZ) | Sandoz GmbH, Austria Biochemie GmbH, Austria Sandoz GmbH, Austria | 01/01/2010 | 01/07/2010 | 31/12/2010 |

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| 15. | Terbinafine | i) Lamisil 125mg Tablet (MAL19930423A) | Novartis Pharm UK Ltd, United Kingdom | 01/01/2010 | 01/07/2010 | 31/12/2010 | |
| | | ii) Lamisil 250mg Tablet (MAL20000273ACRZ) | Novartis Pharm UK Ltd, United Kingdom | | | | |
| | | Lamisil Tablet 250mg is no longer marketed in Malaysia. It can be obtained from Singapore, Hong Kong, China and Australia (Information obtained from Novartis (M) Sdn. Bhd dated 26 th November 2014 via an email) | | | | | |
| As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2017’ – 24 May 2017: Lamisil 250mg Tablet manufactured by Novartis Pharma Produktions GmbH, Wehr, Germany can also be used as a comparator. | | | | | | | |
| 16. | Tetracycline | i) Tetracycline MC Capsule 250mg (MAL19860535AZ) | Medochemie Ltd, Cyprus | 01/01/2010 | 01/07/2010 | 31/12/2010 | |
| 17. | Tinidazole | i) Sporinex Tablet 500mg (MAL19900273A) | Medochemie Ltd, Cyprus | 01/07/2010 | 01/07/2010 | 31/12/2010 | |
| | | ii) Tinirem 500 Tablets (MAL19900270A) | Remedica Ltd, Cyprus | | | | |
| 18. | Trimethoprim | i) Alprim 300 Tablet (MAL19940099AZ) | Alphapharm Pty Ltd, Australia | 01/07/2010 | 01/07/2010 | 31/12/2010 | |
| | | Alprim 300mg Tablet can be obtained from Australia and New Zealand (Information obtained from Pahang Pharmacy dated 17 th February 2015 via an email) | | | | | |