

## **Bioequivalence Requirements for Generic Products Containing Scheduled Poison in Dosage Forms of Effervescent, Dispersible, Orodispersible, Sublingual, Lozenges, Buccal and Chewable Tablets/ Capsules**

The Drug Control Authority (DCA) in their 284<sup>th</sup> meeting, has decided to enforce the bioequivalence (BE) requirements on generic products containing scheduled poison in dosage forms of effervescent, dispersible, orodispersible, sublingual, buccal and chewable tablets/ capsules effective from 1<sup>st</sup> January 2018 for all new product application/submission. This requirement is also applicable for registered products with renewal due date from 1<sup>st</sup> January 2019 onwards.

### **LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES**

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS                                      |                                                   |
|-----|----------------------------------------|----------------------------------------------------------|---------------------------------------------------|
|     |                                        | PRODUCT NAME AND MAL NO.                                 | MANUFACTURER                                      |
| 1   | ACYCLOVIR 800MG                        | ZOVIRAX TABLET 800MG (DISPERSIBLE)<br><br>MAL19950570ARZ | GLAXO WELLCOME S.A., SPAIN                        |
|     | ACYCLOVIR 400MG                        | ZOVIRAX DISPERSIBLE TABLETS 400MG<br><br>MAL19962830A    | THE WELLCOME FOUNDATION LTD, UNITED KINGDOM       |
|     | ACYCLOVIR 200MG                        | ZOVIRAX DISPERSIBLE TABLET 200MG<br><br>MAL19962829ARZ   | GLAXO WELLCOME S.A., SPAIN                        |
| 2   | ARIPIPIRAZOLE                          | ARISA 10MG ORODISPERSIBLE TABLET<br><br>MAL23056005AZ    | PHARMATHEN INTERNATIONAL S.A. (GREECE)            |
|     |                                        | ARISA 15MG ORODISPERSIBLE TABLET<br><br>MAL23056006AZ    | PHARMATHEN INTERNATIONAL S.A. (GREECE)            |
| 3   | ASENAPINE MALEATE (EQ 5MG BASE)        | SAPHRIS SUBLINGUAL TABLET 5MG<br><br>MAL20112129ACRZ     | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |
|     | ASENAPINE MALEATE (EQ 10MG BASE)       | SAPHRIS SUBLINGUAL TABLET 10MG<br><br>MAL20112130ACRZ    | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)                                               | COMPARATOR PRODUCTS                                   |                                                                |
|-----|--------------------------------------------------------------------------------------|-------------------------------------------------------|----------------------------------------------------------------|
|     |                                                                                      | PRODUCT NAME AND MAL NO.                              | MANUFACTURER                                                   |
| 4   | BILASTINE 10MG                                                                       | BILAXTEN 10MG ORODISPERSIBLE TABLETS<br>MAL21046009AZ | A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY |
| 5   | BUPRENORPHINE HYDROCHLORIDE (EQ 0.2MG BASE)                                          | TEMGESIC SUBLINGUAL TABLET 0.2MG<br>MAL19860975AZ     | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM          |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE)                                            | SUBUTEX SUBLINGUAL TABLET 8MG<br>MAL20013547A         | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM          |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE)                                            | SUBUTEX SUBLINGUAL TABLET 2MG<br>MAL20013546A         | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM          |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 0.4MG BASE)                                          | SUBUTEX SUBLINGUAL TABLET 0.4MG<br>MAL20013545A       | RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM          |
| 6   | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE)   | SUBOXONE 8 MG SUBLINGUAL TABLETS<br>MAL20061582ACZ    | RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM     |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE) | SUBOXONE 2MG SUBLINGUAL TABLETS<br>MAL20061581ACZ     | RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM     |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE)   | SUBOXONE SUBLINGUAL FILM 8MG/2MG<br>MAL13075058ACZ    | MONOSOL RX, UNITED STATES                                      |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)                                               | COMPARATOR PRODUCTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                       |
|-----|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
|     |                                                                                      | PRODUCT NAME AND MAL NO.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | MANUFACTURER                          |
|     | BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE) | SUBOXONE SUBLINGUAL FILM 2MG/0.5MG<br><br>MAL13075057ACZ                                                                                                                                                                                                                                                                                                                                                                                                                                   | MONOSOL RX, UNITED STATES             |
| 7   | BUPROPION HYDROCHLORIDE 150MG                                                        | WELLBUTRIN SR TABLETS<br><br>MAL20081803ARZ                                                                                                                                                                                                                                                                                                                                                                                                                                                | GLAXOSMITHKLINE LLC, UNITED STATES    |
| 8   | DEFERASIROX 125MG                                                                    | EXJADE 125MG DISPERSIBLE TABLETS<br><br>MAL20061603ARZ                                                                                                                                                                                                                                                                                                                                                                                                                                     | NOVARTIS PHARMA STEIN AG, SWITZERLAND |
|     | DEFERASIROX 250MG                                                                    | EXJADE 250MG DISPERSIBLE TABLETS<br><br>MAL20061604A                                                                                                                                                                                                                                                                                                                                                                                                                                       | NOVARTIS PHARMA STEIN AG SWITZERLAND  |
|     | DEFERASIROX 500MG                                                                    | EXJADE 500MG DISPERSIBLE TABLETS<br><br>MAL20061605ARZ                                                                                                                                                                                                                                                                                                                                                                                                                                     | NOVARTIS PHARMA STEIN AG, SWITZERLAND |
|     |                                                                                      | Exjade Dispersible Tablets manufactured by Novartis Pharma Stein AG, Switzerland can be obtained from <b>United Arab Emirates, Bahrain, Brazil, Canada, Switzerland, Chile, China, Ecuador, Indonesia, Jordan, Kuwait, Kazakhstan, Morocco, Macedonia, New Zealand, Oman, Panama, Philippines, Palestine, Paraguay, Qatar, Serbia, Thailand, Turkey, Taiwan, Ukraine, United States and South Africa.</b><br><i>(Source of information: Novartis Corporation (Malaysia) Sdn Bhd, 2022)</i> |                                       |
| 9   | DESLORATADINE 2.5MG                                                                  | AJALORIN 2.5MG ORODISPERSIBLE TABLET<br><br>MAL19016047ACZ                                                                                                                                                                                                                                                                                                                                                                                                                                 | GENEPHARM S.A., GREECE                |
|     | DESLORATADINE 5MG                                                                    | AJALORIN 2.5MG ORODISPERSIBLE TABLET<br><br>MAL19016044ACZ                                                                                                                                                                                                                                                                                                                                                                                                                                 | GENEPHARM S.A., GREECE                |

**LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES**

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS                                         |                                                  |
|-----|----------------------------------------|-------------------------------------------------------------|--------------------------------------------------|
|     |                                        | PRODUCT NAME AND MAL NO.                                    | MANUFACTURER                                     |
| 10  | DONEPEZIL HYDROCHLORIDE 10MG           | ARICEPT EVESS ORODISPERSIBLE TABLET 10MG<br>MAL09042405ACRZ | BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN |
|     | DONEPEZIL HYDROCHLORIDE 5MG            | ARICEPT EVESS ORODISPERSIBLE TABLET 5MG MAL09042397ACRZ     | BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN |
| 11  | ERDOSTEINE 300MG                       | ERDOMED® 300MG DISPERSIBLE TABLETS<br>MAL20076015ARZMA      | EDMOND PHARMA S.R.L, ITALY                       |
| 12  | ESCITALOPRAM OXALATE (EQ 20MG BASE)    | AJALOPRAM 20 MG ORODISPERSIBLE TABLET<br>MAL18086103ACZ     | GENEPHARM S.A., GREECE                           |
|     | ESCITALOPRAM OXALATE (EQ 15MG BASE)    | AJALOPRAM 15MG ORODISPERSIBLE TABLET<br>MAL18086104ACZ      | GENEPHARM S.A., GREECE                           |
|     | ESCITALOPRAM OXALATE (EQ 10MG BASE)    | AJALOPRAM 10MG ORODISPERSIBLE TABLET<br>MAL18086106ACZ      | GENEPHARM S.A., GREECE                           |
|     | ESCITALOPRAM OXALATE (EQ 5MG BASE)     | AJALOPRAM 5MG ORODISPERSIBLE TABLET<br>MAL18086105ACZ       | GENEPHARM S.A., GREECE                           |
| 13  | FENTANYL CITRATE (EQ 400MCG BASE)      | ABSTRAL 400 MICROGRAM SUBLINGUAL TABLETS<br>MAL17085057ACZ  | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM      |
|     | FENTANYL CITRATE (EQ 200MCG BASE)      | ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS<br>MAL17085056ACZ  | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM      |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)                       | COMPARATOR PRODUCTS                                                  |                                                                         |
|-----|--------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------|
|     |                                                              | PRODUCT NAME AND MAL NO.                                             | MANUFACTURER                                                            |
|     | FENTANYL CITRATE (EQ 100MCG BASE)                            | ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS<br><br>MAL14025004ACZ       | RECIPHARM STOCKHOLM AB, SWEDEN                                          |
|     |                                                              | ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS<br><br>MAL17085055ACZ       | AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM                             |
|     |                                                              | ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS<br><br>MAL14025003ACZ       | RECIPHARM STOCKHOLM AB, SWEDEN                                          |
| 14  | FLURBIPROFEN 8.75MG                                          | STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE<br><br>MAL13045049AZ  | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM      |
|     |                                                              | STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE<br><br>MAL18016023ASZ | RECKITT BENCKISER HEALTHCARE MANUFACTURING (THAILAND) LIMITED           |
| 15  | GIMERACIL 7.28MG, OTERACIL POTASSIUM 24.5MG AND TEGAFUR 25MG | TS-ONE OD TABLET 25<br><br>MAL19071005ARZ                            | TAIHO PHARMACEUTICAL CO.,LTD, JAPAN                                     |
|     | GIMERACIL 5.8MG, OTERACIL POTASSIUM 19.6MG AND TEGAFUR 20MG  | TS-ONE OD TABLET 20<br><br>MAL19071004ARZ                            | TAIHO PHARMACEUTICAL CO.,LTD, JAPAN                                     |
| 16  | GLYCERYL TRINITRATE 0.5MG                                    | GTN ACTAVIS TABLET 500 MCG<br><br>MAL19871706ACZ                     | ACCORD-UK LTD, UNITED KINGDOM<br><br>ACTAVIS UK LIMITED, UNITED KINGDOM |
| 17  | LAMOTRIGINE 50MG                                             | LAMICTAL DISPERSIBLE TABLET 50MG<br><br>MAL19930433ACRZ              | DELPHARM POZNAN SPOLKA AKCYJNA(POLAND)                                  |

**LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES**

| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS                                                                                                                                                                                                                                                  |                                                                                                     |
|-----|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
|     |                                        | PRODUCT NAME AND MAL NO.                                                                                                                                                                                                                                             | MANUFACTURER                                                                                        |
|     | LAMOTRIGINE 25MG                       | LAMICTAL DISPERSIBLE TABLET 25MG<br>MAL19970262ACRZ                                                                                                                                                                                                                  | GLAXO SMITH KLINE<br>PHARMACEUTICALS SA,<br>POLAND<br><br>DELPHARM POZNAN SPOLKA<br>AKCYJNA(POLAND) |
|     | LAMOTRIGINE 5MG                        | LAMICTAL DISPERSIBLE TABLET 5MG<br>MAL19970261ACRZ                                                                                                                                                                                                                   | GLAXO SMITH KLINE<br>PHARMACEUTICALS SA,<br>POLAND<br><br>DELPHARM POZNAN SPOLKA<br>AKCYJNA(POLAND) |
|     | LAMOTRIGINE 2MG                        | LAMICTAL CHEWABLE DISPERSABLE<br>2MG TABLETS<br>MAL20061515ARZ                                                                                                                                                                                                       | GLAXO WELLCOME INC,<br>UNITED STATES<br><br>DELPHARM POZNAN SPOLKA<br>AKCYJNA(POLAND)               |
| 18  | LANSOPRAZOLE<br>15MG                   | PREVACID FDT 15 MG TABLET<br>MAL08042459ARZ                                                                                                                                                                                                                          | KOKANDO CO. LTD (JAPAN)                                                                             |
|     | LANSOPRAZOLE<br>30MG                   | PREVACID FDT 30MG TABLET<br>MAL08042460ARZ                                                                                                                                                                                                                           | KOKANDO CO. LTD (JAPAN)                                                                             |
| 19  | LORATADINE 10MG                        | CLARITYNE RAPID TABLET 10MG<br>MAL20014313ACZ                                                                                                                                                                                                                        | SCHERER DDS LTD, UNITED<br>KINGDOM                                                                  |
|     |                                        | As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2019” – 19 November 2019, Clarityne Rapid Tablet and Claritin Reditabs manufactured by <b>Catalent U.K. Swindon Zydis Limited, United Kingdom</b> is allowed to be used as a comparator. |                                                                                                     |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API) | COMPARATOR PRODUCTS                                                                                                                                                                                                                                                                                               |                                                                |
|-----|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
|     |                                        | PRODUCT NAME AND MAL NO.                                                                                                                                                                                                                                                                                          | MANUFACTURER                                                   |
| 20  | MIRTAZAPINE 45MG                       | REMERON SOLTAB 45MG<br>MAL05023179ACR                                                                                                                                                                                                                                                                             | CIMA LABS INC , UNITED STATES                                  |
|     | MIRTAZAPINE 30MG                       | REMERON SOLTAB 30MG<br>MAL14015019ACRZ                                                                                                                                                                                                                                                                            | ANESTA LLC, UNITED STATES<br><br>CEPHALON, INC (UNITED STATES) |
|     | MIRTAZAPINE 15MG                       | REMERON SOLTAB 15MG<br>MAL14015018ACRZ                                                                                                                                                                                                                                                                            | ANESTA LLC, UNITED STATES<br><br>CEPHALON, INC (UNITED STATES) |
| 21  | MONTELUKAST SODIUM (EQ 5MG BASE)       | SINGULAIR CHEWABLE TABLET 5MG<br>MAL19990956ARZ                                                                                                                                                                                                                                                                   | MERCK SHARP & DOHME LTD, UNITED KINGDOM                        |
| 22  | MONTELUKAST SODIUM (EQ 4MG BASE)       | SINGULAIR 4MG CHEWABLE TABLET<br>MAL20020121ARZ                                                                                                                                                                                                                                                                   | MERCK SHARP & DOHME LTD, UNITED KINGDOM                        |
| 23  | NICOTINE 4MG                           | NICOTINELL FRUIT 4MG, CHEWING-GUM<br><br>MAL06011709ACRZ                                                                                                                                                                                                                                                          | FERTIN PHARMA A/S , DENMARK                                    |
|     |                                        | This product can be obtained from <b>Denmark, Iceland, Israel, New Zealand, Switzerland and United Kingdom.</b><br>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)                                                                                                                         |                                                                |
|     | NICOTINE 2MG                           | NICOTINELL FRUIT 2MG, CHEWING-GUM<br><br>MAL06011708ACRZ                                                                                                                                                                                                                                                          | FERTIN PHARMA A/S, DENMARK                                     |
|     |                                        | This product can be obtained from <b>Austria, Belgium, Denmark, Finland, France, Iceland, Ireland, Israel, Republic of Korea, Luxembourg, Netherland, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.</b><br>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019) |                                                                |
|     | NICOTINE 4MG                           | NICOTINELL MINT 4MG, CHEWING-GUM<br><br>MAL06011711ACRZ                                                                                                                                                                                                                                                           | FERTIN PHARMA A/S, DENMARK                                     |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)      | COMPARATOR PRODUCTS                                                                                                                                                                                                                                   |                                                            |
|-----|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
|     |                                             | PRODUCT NAME AND MAL NO.                                                                                                                                                                                                                              | MANUFACTURER                                               |
|     |                                             | This product can be obtained from <b>Denmark, Finland, Iceland, Israel, New Zealand, Norway, Sweden and United Kingdom.</b><br>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)                                                 |                                                            |
|     | NICOTINE 2MG                                | NICOTINELL MINT 2MG, CHEWING-GUM<br><br>MAL06011710ACRZ                                                                                                                                                                                               | FERTIN PHARMA A/S ,<br>DENMARK                             |
|     |                                             | This product can be obtained from <b>Denmark, Finland, Hong Kong, Iceland, Israel, Japan, Republic of Korea, New Zealand, Norway, Sweden, Thailand &amp; United Kingdom.</b><br>Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019) |                                                            |
|     | NICOTINE RESINATE (EQ 4MG BASE)             | NICORETTE ICY MINT 4 MG GUM<br><br>MAL15045059ARZ                                                                                                                                                                                                     | MCNEIL AB, SWEDEN                                          |
|     | NICOTINE RESINATE (EQ 2MG BASE)             | NICORETTE ICY MINT 2 MG GUM<br><br>MAL15045076ARZ                                                                                                                                                                                                     | MCNEIL AB, SWEDEN                                          |
|     | NICOTINE POLACRILEX (EQ 4MG BASE)           | NIQUITIN 4MG LOZENGES<br><br>MAL06100577ARZ                                                                                                                                                                                                           | GLAXO SMITH KLINE<br>CONSUMER HEALTHCARE,<br>UNITED STATES |
|     | NICOTINE POLACRILEX (EQ 2MG BASE)           | NIQUITIN 2MG LOZENGES<br><br>MAL06100578ARZ                                                                                                                                                                                                           | GLAXO SMITH KLINE<br>CONSUMER HEALTHCARE,<br>UNITED STATES |
|     | NICOTINE POLACRILEX (EQ 4MG BASE)           | NIQUITIN 4MG MINT LOZENGES<br><br>MAL09051546AZ                                                                                                                                                                                                       | GLAXO SMITH KLINE<br>CONSUMER HEALTHCARE,<br>UNITED STATES |
|     | NICOTINE POLACRILEX (EQ 2MG BASE)           | NIQUITIN 2MG MINT LOZENGES<br><br>MAL09051545AZ                                                                                                                                                                                                       | GLAXO SMITH KLINE<br>CONSUMER HEALTHCARE,<br>UNITED STATES |
|     | NICOTINE BITARTRATE DIHYDRATE (EQ 1MG BASE) | NICOTINELL MINT 1MG LOZENGE<br><br>MAL06011707ACRZ                                                                                                                                                                                                    | SANICO N.V., BELGIUM                                       |



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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)           | COMPARATOR PRODUCTS                                                        |                                                   |
|-----|--------------------------------------------------|----------------------------------------------------------------------------|---------------------------------------------------|
|     |                                                  | PRODUCT NAME AND MAL NO.                                                   | MANUFACTURER                                      |
|     | NICOTINE<br>POLACRILEX 10MG<br>(EQ 2MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 2MG<br>(CHERRY FLAVOUR)<br><br>MAL25026002AZ   | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
|     | NICOTINE<br>POLACRILEX 10MG<br>(EQ 2MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 2MG<br>(CINNAMON FLAVOUR)<br><br>MAL25026003AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
|     | NICOTINE<br>POLACRILEX 10MG<br>(EQ 2MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 2MG<br>(MINT FLAVOUR)<br><br>MAL25026001AZ     | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
|     | NICOTINE<br>POLACRILEX 20MG<br>(EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG<br>(CHERRY FLAVOUR)<br><br>MAL25026005AZ   | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
|     | NICOTINE<br>POLACRILEX 20MG<br>(EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG<br>(CINNAMON FLAVOUR)<br><br>MAL25026006AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
|     | NICOTINE<br>POLACRILEX 20MG<br>(EQ 4MG NICOTINE) | SKIIP NICOTINE MINI LOZENGE 4MG<br>(CINNAMON FLAVOUR)<br><br>MAL25026004AZ | RUBICON RESEARCH PRIVATE LIMITED, INDIA           |
| 24  | OLANZAPINE 10MG                                  | ZYPREXA ZYDIS 10MG<br>ORODISPERSIBLE TABLET<br><br>MAL04125491ACRZ         | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |
|     | OLANZAPINE 5MG                                   | ZYPREXA ZYDIS 5MG<br>ORODISPERSIBLE TABLET<br><br>MAL04125490ACRZ          | CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)                    | COMPARATOR PRODUCTS                                                                                              |                                                  |
|-----|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
|     |                                                           | PRODUCT NAME AND MAL NO.                                                                                         | MANUFACTURER                                     |
| 25  | PERINDOPRIL ARGININE 10MG                                 | COVERSYL OD 10MG,<br>ORODISPERSIBLE TABLETS<br><br>MAL13095087AZ                                                 | SERVIER ( IRELAND)<br>INDUSTRIES LTD, IRELAND    |
|     | PERINDOPRIL ARGININE 5MG                                  | COVERSYL OD 5MG,<br>ORODISPERSIBLE TABLETS<br><br>MAL13095085AZ                                                  | SERVIER ( IRELAND)<br>INDUSTRIES LTD, IRELAND    |
|     | PERINDOPRIL ARGININE 2.5MG                                | COVERSYL OD 2.5MG,<br>ORODISPERSIBLE TABLETS<br><br>MAL13095086AZ                                                | SERVIER ( IRELAND)<br>INDUSTRIES LTD, IRELAND    |
| 26  | PIROXICAM 20MG                                            | FELDENE DISPERSIBLE TABLET<br><br>MAL19962549ACZ                                                                 | FAREVA AMBOISE, FRANCE<br><br>PFIZER PGM, FRANCE |
| 27  | RANITIDINE HYDROCHLORIDE (EQ 150MG BASE)                  | ZANTAC EFFERVESCENT TABLET 150MG<br><br>MAL07011019AZ                                                            | GLAXOWELLCOME PRODUCTION , FRANCE                |
| 28  | RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG | RHZ KID DT (RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS)<br><br>MAL25056006ACZ | OXALIS LABS (INDIA)                              |
| 29  | SILDENAFIL CITRATE (EQ 100MG BASE)                        | AJENAFIL 100MG CHEWABLE TABLET<br><br>MAL18046144AZ                                                              | GENEPHARM S.A., GREECE                           |
|     | SILDENAFIL CITRATE (EQ 50MG BASE)                         | AJENAFIL 50MG CHEWABLE TABLET<br><br>MAL18046145AZ                                                               | GENEPHARM S.A., GREECE                           |
|     | SILDENAFIL CITRATE (EQ 25MG BASE)                         | AJENAFIL 25MG CHEWABLE TABLET<br><br>MAL18046146AZ                                                               | GENEPHARM S.A., GREECE                           |

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| NO. | ACTIVE PHARMACEUTICAL INGREDIENT (API)  | COMPARATOR PRODUCTS                                                            |                                  |
|-----|-----------------------------------------|--------------------------------------------------------------------------------|----------------------------------|
|     |                                         | PRODUCT NAME AND MAL NO.                                                       | MANUFACTURER                     |
| 30  | TADALAFIL 20MG                          | LEBIVA ODS-20 TADALAFIL ORALLY DISINTEGRATING STRIPS 20MG<br><br>MAL2309611ACZ | ZIM LABORATORIES LIMITED (INDIA) |
| 31  | TADALAFIL 5MG                           | CALIBERI ORODISPERSIBLE FILM 5MG<br><br>MAL21036001AZ                          | CTCBIO INC, SOUTH KOREA          |
| 32  | TADALAFIL 10MG                          | HOVID ERETAF ORODISPERSIBLE FILMS 10MG                                         | ZIM LABORATORIES LIMITED, INDIA  |
| 33  | TADALAFIL 20MG                          | HOVID ERETAF ORODISPERSIBLE FILMS 20MG                                         | ZIM LABORATORIES LIMITED, INDIA  |
| 34  | VERDANAFIL HYDROCHLORIDE (EQ 10MG BASE) | LEVITRA 10 MG ORODISPERSIBLE TABLETS<br><br>MAL12035080ARZ                     | BAYER AG (LEVERKUSEN), GERMANY   |

**Note:**

This list is non-exhaustive and will be updated from time to time. For further clarification, kindly email to [be\\_sug@npra.gov.my](mailto:be_sug@npra.gov.my)

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