

Ministry of Health

Health Programs and Delivery Division

## Drug Submission Status

Report for March 2024

### Complete Streamlined Multiple-Source Submissions for Future Formulary Listing

The Ministry of Health has received complete submissions for the following streamlined multiple-source drug products for listing on the Ontario Drug Benefit Formulary. Subject to confirmation of Drug Identification Numbers (DIN) and prices by the manufacturers, as well as review and approval by the Executive Officer, these products may be listed as benefits in a future Formulary update. Final listing status will be communicated when the Formulary update is published on the Ministry website and via an HPDD Notice.

| Manufacturer      | Product                 | Reference Product | Generic Name                                | Strength        | Dosage Form | DIN      |
|-------------------|-------------------------|-------------------|---|-----------------|-------------|----------|
| Sanis Health Inc. | Amoxicillin/Clav        | Clavulin          | AMOXICILLIN & CLAVULANIC ACID               | 500mg & 125mg   | tablet      | 02536021 |
| Sanis Health Inc. | Amoxicillin/Clav        | Clavulin          | AMOXICILLIN & CLAVULANIC ACID               | 875mg & 125mg   | tablet      | 02536048 |
| Apotex Inc.       | Apo-Candesartan Tablets | Atacand           | CANDESARTAN CILEXETIL                       | 4 mg            | tablet      | 02541289 |
| Apotex Inc.       | Apo-Candesartan Tablets | Atacand           | CANDESARTAN CILEXETIL                       | 8 mg            | tablet      | 02541297 |
| Apotex Inc.       | Apo-Candesartan Tablets | Atacand           | CANDESARTAN CILEXETIL                       | 16 mg           | tablet      | 02541300 |
| Apotex Inc.       | Apo-Candesartan Tablets | Atacand           | CANDESARTAN CILEXETIL                       | 32 mg           | tablet      | 02541319 |
| Sanis Health Inc. | Candesartan/HCTZ        | Atacand Plus      | CANDESARTAN CILEXETIL & HYDROCHLOROTHIAZIDE | 32 mg & 12.5 mg | tablet      | 02536064 |

|                             |  |                              |                        |               |                                   |          |
|-----------------------------|--|------------------------------|------------------------|---------------|-----------------------------------|----------|
| Mint Pharmaceuticals Inc    | Mint-Carbamazepine                     | TEGRETOL                     | CARBAMAZEPINE          | 200 mg        | tablet                            | 02541238 |
| Lupin Pharma Canada Limited | Lupin-Cephalexin                       | Keflex                       | CEPHALEXIN MONOHYDRATE | 125 mg & 5mL  | powder for suspension             | 02469170 |
| Lupin Pharma Canada Limited | Lupin-Cephalexin                       | Keflex                       | CEPHALEXIN MONOHYDRATE | 250 mg & 5 mL | powder for suspension             | 02469189 |
| Nora Pharma                 | NRA-Ezetimibe Tablets                  | Ezetrol                      | EZETIMIBE              | 10 mg         | tablet                            | 02536420 |
| Laboratoire Riva Inc.       | Riva-Fluconazole                       | Diflucan-150                 | FLUCONAZOLE            | 150 mg        | capsule                           | 02255510 |
| Jamp Pharma Corporation     | Jamp Gabapentin Capsules               | Neurontin                    | GABAPENTIN             | 100 mg        | capsule                           | 02535246 |
| Jamp Pharma Corporation     | Jamp Gabapentin Capsules               | Neurontin                    | GABAPENTIN             | 300 mg        | capsule                           | 02535254 |
| Jamp Pharma Corporation     | Jamp Gabapentin Capsules               | Neurontin                    | GABAPENTIN             | 400 mg        | capsule                           | 02535262 |
| Sanis Health Inc.           | Hydralazine                            | Apresoline                   | HYDRALAZINE HCL        | 10 mg         | tablet                            | 02539802 |
| Sanis Health Inc.           | Hydralazine                            | Apresoline                   | HYDRALAZINE HCL        | 25 mg         | tablet                            | 02539810 |
| Sanis Health Inc.           | Hydralazine                            | Apresoline                   | HYDRALAZINE HCL        | 50 mg         | tablet                            | 02539829 |
| Jamp Pharma Corporation     | Jamp Ipratropium HFA                   | Atrovent HFA                 | IPRATROPIUM BROMIDE    | 20 mcg/ACT    | Metered-Dose Aerosol (Inhalation) | 02542587 |
| Jamp Pharma Corporation     | Jamp Letrozole Tablets                 | Femara                       | LETROZOLE              | 2.5 mg        | tablet                            | 02541912 |
| Jamp Pharma Corporation     | Jamp Levofloxacin                      | Levaquin                     | LEVOFLOXACIN           | 250 mg        | tablet                            | 02508443 |
| Jamp Pharma Corporation     | Jamp Levofloxacin                      | Levaquin                     | LEVOFLOXACIN           | 500 mg        | tablet                            | 02508451 |
| Jamp Pharma Corporation     | Metoclopramide Hydrochloride Injection | Metoclopramide HCL Injection | METOCLOPRAMIDE HCL     | 5 mg/mL       | IM solution                       | 02537397 |

|                         |                          |               |                    |          |                  |          |
|-------------------------|--------------------------|---------------|--------------------|----------|------------------|----------|
| Jamp Pharma Corporation | Jamp Raloxifene          | Evista        | RALOXIFENE HCL     | 60 mg    | tablet           | 02540681 |
| Jamp Pharma Corporation | Jamp Silodosin           | Rapaflo       | SILODOSIN          | 4 mg     | capsule          | 02539519 |
| Jamp Pharma Corporation | Jamp Silodosin           | Rapaflo       | SILODOSIN          | 8 mg     | capsule          | 02539527 |
| Auro Pharma Inc.        | Auro-Tamsulosin CR       | Flomax CR Tab | TAMSULOSIN HCl     | 0.4 mg   | tablet           | 02545179 |
| Jamp Pharma Corporation | Tobramycin Injection USP | Nebcin        | TOBRAMYCIN SULFATE | 40 mg/mL | IV, IM, solution | 02533103 |
| Jamp Pharma Corporation | Jamp Topiramate Tablets  | Topamax       | TOPIRAMATE         | 100 mg   | tablet           | 02345269 |
| Nora Pharma             | NRA-Topiramate           | Topamax       | TOPIRAMATE         | 25 mg    | tablet           | 02538466 |
| Nora Pharma             | NRA-Topiramate           | Topamax       | TOPIRAMATE         | 100 mg   | tablet           | 02538458 |
| Nora Pharma             | NRA-Topiramate           | Topamax       | TOPIRAMATE         | 200 mg   | tablet           | 02538474 |