

Ministry of Health

Health Programs and Delivery Division

Drug Submission Status

Report for February 2025

Complete Streamlined Multiple-Source

Submissions for Off-Formulary Interchangeability

The Ministry of Health has received complete submissions for the following streamlined multiple-source drug products for Off-Formulary Interchangeability (OFI) designation. 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 designated as OFI drugs in a future Formulary update. Final OFI designation 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
Apotex Inc.	Apo-Butalbital-Acetylsalicylic Acid-Caffeine-Codeine-C ¼	Acetylsalicylic Acid/ Butalbital/ Caffeine/ Codeine Phosphate	ACETYLSALICYLIC ACID/ BUTALBITAL/ CAFFEINE/ CODEINE PHOSPHATE	50 mg/ 330 mg/ 40 mg/ 15 mg	capsule	02554615
Apotex Inc.	Apo-Butalbital-Acetylsalicylic Acid-Caffeine-Codeine-C ½	Acetylsalicylic Acid/ Butalbital/ Caffeine/ Codeine Phosphate	ACETYLSALICYLIC ACID/ BUTALBITAL/ CAFFEINE/ CODEINE PHOSPHATE	50 mg/ 330 mg/ 40 mg/ 30 mg	capsule	02554623
Marcan Pharmaceuticals Inc.	Mar-Afatinib	Giotrif	AFATINIB	20 mg	tablet	02517019

Marcan Pharmaceuticals Inc.	Mar-Afatinib	Giotrif	AFATINIB	30 mg	tablet	02517027
Marcan Pharmaceuticals Inc.	Mar-Afatinib	Giotrif	AFATINIB	40 mg	tablet	02517035
Sanis Health Inc.	Amlodipine	Norvasc	AMLODIPINE	2.5 mg	tablet	02478587
Marcan Pharmaceuticals Inc.	Mar-Amlodipine	Norvasc	AMLODIPINE BESYLATE	2.5 mg	tablet	02371707
Marcan Pharmaceuticals Inc.	Mar-Citalopram	Celexa	CITALOPRAM HYDROBROMIDE	10 mg	tablet	02371871
Sivem Pharmaceuticals	Mirtazapine	Remeron	MIRTAZAPINE	15 mg	tablet	02496666
Sivem Pharmaceuticals	Mirtazapine	Remeron	MIRTAZAPINE	45 mg	tablet	02496682
Apotex Inc.	Apo-Nilotinib	Tasigna	NILOTINIB HYDROCHLORIDE MONOHYDRATE	150 mg	capsule	02550881
Apotex Inc.	Apo-Nilotinib	Tasigna	NILOTINIB HYDROCHLORIDE MONOHYDRATE	200 mg	capsule	02550903
Mantra Pharma Inc.	M-Pirfenidone	Esbriet	PIRFENIDONE	267 mg	tablet	02550644
Mantra Pharma Inc.	M-Pirfenidone	Esbriet	PIRFENIDONE	801 mg	tablet	02550652
Pharmascience Inc.	PMS-Rupatadine	Rupall	RUPATADINE	10 mg	tablet	02552604
Apotex Inc	Apo-Rupatadine	Rupall	RUPATADINE	10 mg	tablet	02553155