

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Drug Submission Status

Report for November 2021

## Complete Streamlined Multiple-Source

Submissions for Off-Formulary Interchangeability

The Ministry of Health and Long-Term Care 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 a DDD Notice.

Manufacturer	Product	Reference Product	Generic Name	Strength	Dosage Form	DIN
Sanis Health Inc.	Paroxetine	Paxil	PAROXETINE HCL	10 mg	FC tablet	02282844
Sanis Health Inc.	Valacyclovir	Valtrex	VALACYCLOVIR	1000 mg	tablet	02519585
Sanis Health Inc.	Vardenafil	Levitra	VARDENAFIL	10 mg	tablet	02520397
Sanis Health Inc.	Vardenafil	Levitra	VARDENAFIL	20 mg	tablet	02520400
Accord Healthcare Inc.	ACH-Dimethyl Fumarate	TECFIDERA	DIMETHYL FUMARATE	120 mg	DR capsule	02495341
Accord Healthcare Inc.	ACH-Dimethyl Fumarate	TECFIDERA	DIMETHYL FUMARATE	240 mg	DR capsule	02495368
KVR Pharmaceuticals	Bipazen	DDAVP INJ 4MCG/ML	DESMOPRESSIN ACETATE	4 mcg/mL	IV, SC, IM solution	02513579

Jamp Pharma	Jamp Dimethyl Fumarate	Tecfidera	DIMETHYL FUMARATE	120 mg	DR capsule	02516047
Jamp Pharma	Jamp Dimethyl Fumarate	Tecfidera	DIMETHYL FUMARATE	240 mg	DR capsule	02516055