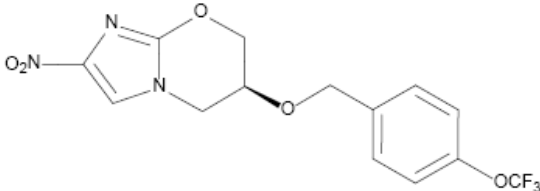


Pretomanid (PA-824)

Catalog No. NR-59591

Product Description:

Pretomanid [PA-824; (S)-PA-824; Dovprela®] is a novel antimycobacterial used in treating multidrug-resistant tuberculosis (MDR-TB) and is a member of the nitroimidazooxazine class (whereas delamanid is a member of the nitroimidazooxazole class). Its mechanism of action is complex and has not been fully elucidated.

Chemical Name	(6S)-2-Nitro-6-[[4-(trifluoromethoxy)benzyl]oxy]-6,7-dihydro-5H-imidazo[2,1-b][1,3]oxazine
Structure	
Formula	C ₁₄ H ₁₂ F ₃ N ₃ O ₅
Molecular Weight	359.26
CAS Number	187235-37-6

Lot: 70066565

Manufacturing Date: FEB2022

All information below was provided by Mylan Laboratories Limited for the bulk material [Batch No. PTM-IV RS (SA-012) 1], which was analyzed on 07SEP2022 and has a retest date of 07AUG2024.

TEST	SPECIFICATIONS	RESULTS
Appearance	White to off-white to yellow powder	Off-white powder
Content per Vial	Report results	40 mg ± 0.3 mg
NMR	Spectrum conforms to structure	Spectrum conforms to structure
IR	Spectrum conforms to structure	Spectrum conforms to structure
Mass	Spectrum conforms to structure	Spectrum conforms to structure
UV	Report results	Peaks at 207 nm and 320 nm
Powder X-Ray Diffraction (PXRD)	Report results	Spectrum conforms to structure
Water Content by KF	< 0.50% w/w	0.17% w/w
Sulfated Ash	< 0.14% w/w	0.07% w/w
Related Impurities by HPLC¹		
Benzyloxy propyl pivalate	< 0.15% w/w	0.00% w/w (BQL: 0.015%)
Benzyloxy propanol	< 0.15% w/w	0.00% w/w (BQL: 0.012%)
Ortho isomer	< 0.15% w/w	0.03% w/w
Meta isomer	< 0.15% w/w	Not detected
Methoxy impurity	< 0.15% w/w	0.00% w/w (BQL: 0.015%)
Pretomanid dimer	< 0.15% w/w	0.02% w/w (BQL: 0.012%)
Pretomanid enantiomer	< 0.15% w/w	0.01% w/w (BQL: 0.027%)
Any major unspecified impurity	< 0.10% w/w	0.07% w/w
Total impurities	< 1.0% w/w	0.17% w/w

TEST	SPECIFICATIONS	RESULTS
Residual Solvents by GC-HS^{1,2}		
Methanol	< 3000 ppm	17 ppm (BQL: 38.7 ppm)
Dichloromethane	< 600 ppm	Not detected
<i>t</i> -Butyl methyl ether	< 5000 ppm	Not detected
Ethyl acetate	< 5000 ppm	3 ppm (BDL: 6.6 ppm)
Cyclohexane	< 3880 ppm	Not detected
<i>n</i> -Heptane	< 5000 ppm	24 ppm
Toluene	< 890 ppm	2 ppm (BDL: 4.1 ppm)
N-methyl-2-pyrrolidone (NMP)	< 530 ppm	Not detected
Potency by HPLC³	> 99.0% w/w	99.6% w/w

¹Below Quantitation Limit (BQL)

²Below Detection Limit (BDL)

³Potency is calculated as follows: 100 - (% Water Content by KF + % Sulfated Ash + % Pretomanid enantiomer by HPLC + % Total impurities by HPLC + % Total Residual Solvents by GC-HS).

/Sonia Bjorum Brower/

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26 MAR 2024

Technical Manager or designee, ATCC Federal Solutions

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