

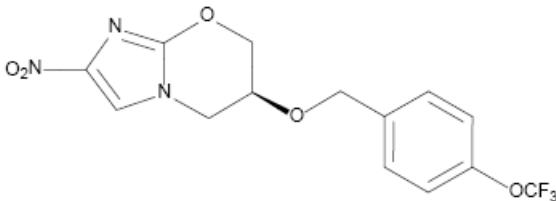
**Pretomanid (PA-824)**

**Catalog No. NR-59591**

This reagent is the property of the U.S. Government.

**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.

<b>Chemical Name</b>	(6S)-2-Nitro-6-[[4-(trifluoromethoxy)benzyl]oxy]-6,7-dihydro-5H-imidazo[2,1-b][1,3]oxazine
<b>Structure</b>	
<b>Formula</b>	C <sub>14</sub> H <sub>12</sub> F <sub>3</sub> N <sub>3</sub> O <sub>5</sub>
<b>Molecular Weight</b>	359.26
<b>CAS Number</b>	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
<b>Appearance</b>	White to off-white to yellow powder	Off-white powder
<b>Content per Vial</b>	Report results	40 mg ± 0.3 mg
<b>NMR</b>	Spectrum conforms to structure	Spectrum conforms to structure
<b>IR</b>	Spectrum conforms to structure	Spectrum conforms to structure
<b>Mass</b>	Spectrum conforms to structure	Spectrum conforms to structure
<b>UV</b>	Report results	Pending
<b>Powder X-Ray Diffraction (PXRD)</b>	Report results	Spectrum conforms to structure
<b>Water Content by KF</b>	< 0.50% w/w	0.17% w/w
<b>Sulfated Ash</b>	< 0.14% w/w	0.07% w/w
<b>Related Impurities by HPLC<sup>1</sup></b>		
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
<b>Residual Solvents by GC-HS<sup>1,2</sup></b>		
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
<b>Potency by HPLC<sup>3</sup></b>	> 99.0% w/w	99.6% w/w

<sup>1</sup>Below Quantitation Limit (BQL)

<sup>2</sup>Below Detection Limit (BDL)

<sup>3</sup>Potency 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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