b|e|i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH

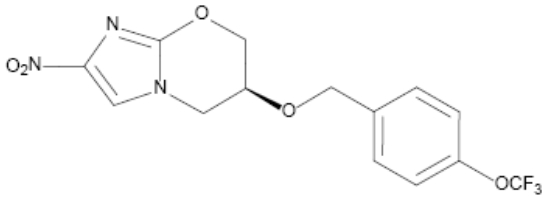
Certificate of Analysis for NR-59591

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	(6*S*)-2-Nitro-6-{[4-(trifluoromethoxy)benzyl]oxy}-6,7-dihydro-5H-imidazo[2,1-b][1,3]oxazine
Structure	
Formula	$C_{14}H_{12}F_3N_3O_5$
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 reanalyzed on 08MAR2024 and has a retest date of 07MAR2026.

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	Consistent with structure	Consistent with structure
IR Spectrum	Consistent with structure	Consistent with structure
Mass Spectrum	Consistent with structure	Consistent with structure
UV Spectrum	Report results	Peaks at 207 nm and 320 nm
Powder X-Ray Diffraction (PXRD)	Consistent with structure	Consistent with structure
Water Content by KF	< 0.50% w/w	0.19% w/w
Residue on Ignition	< 0.30% w/w	0.07% w/w
Related Impurities by HPLC[1]		
Benzyloxy propyl pivalate	< 0.15% w/w	Not detected
Benzyloxy propanol	< 0.15% w/w	Not detected
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	0.01% w/w (BQL: 0.012%)
Pretomanid enantiomer	< 0.15% w/w	Not detected
Any major unspecified impurity	< 0.10% w/w	0.05% w/w
Total impurities	< 1.0% w/w	0.18% w/w

BEI Resources
www.beiresources.org

E-mail: contact@beiresources.org
Tel: 800-359-7370
Fax: 703-365-2898

Certificate of Analysis for NR-59591

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

[1]Below Quantitation Limit (BQL)
[2]Below Detection Limit (BDL)
[3]Potency is calculated as follows: 100 - (% Water Content by KF + % Residue on Ignition + % Pretomanid enantiomer by HPLC + % Total impurities by HPLC + % Total Residual Solvents by GC-HS).

/Sonia Bjorum Brower/
Sonia Bjorum Brower 24 OCT 2025
Technical Manager or designee, ATCC Federal Solutions

ATCC®, on behalf of BEI Resources, hereby represents and warrants that the material provided under this certificate has been subjected by ATCC® and the manufacturer to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and accurate to the best of ATCC®'s knowledge.

Support Provided by NIAID

BEI Resources
www.beiresources.org
E-mail: contact@beiresources.org
Tel: 800-359-7370
Fax: 703-365-2898