

## **Certificate of Analysis for NR-51636**

## **Delamanid (Reference Standard)**

Catalog No. NR-51636

Lot: 70049844 (Otsuka S21E95) Manufacturing Date: 26MAY2021

All information provided by Otsuka Pharmaceutical Co., Ltd. The date of analysis for the bulk material (Otsuka lot S21E95) was 25JUN2021.

Chemical Name	(R)-2-Methyl-6-nitro-2-[(4-{4-[4-(trifluoromethoxy)phenoxy]piperidin-1-yl}phenoxy)methyl]-2,3-dihydroimidazo[2,1-b]oxazole
Structure	$O_2N$ $N$ $O_2N$ $O_2N$ $O_3$ $O_2N$ $O_3$ $O_4$ $O_4$ $O_5$ $O_7$ $O_8$
Formula	C <sub>25</sub> H <sub>25</sub> F <sub>3</sub> N <sub>4</sub> O <sub>6</sub>
Molecular Weight	534.48
Content per Vial	20 mg ± 0.3 mg
Appearance	Pale yellowish white crystalline powder
<sup>1</sup> H NMR	Spectrum consistent with structure
MS	Spectrum consistent with structure
IR	Absorptions at 222-226 nm, 241-245 nm, and 318-322 nm
uv	Absorptions at 3130, 1610, 1514, 1240, 1038 and 827 cm <sup>-1</sup>
Purity	100.00%
Optical Purity by HPLC	100.0%ee
Melting Point	196.1°C (decomposition)
Water Content	0.1%
Drug-Related Impurities by HPLC	Individual: < 0.05% Total: < 0.05%
Residual Solvents by GC	Ethanol: 62 ppm Acetone: 44 ppm

## /Heather Couch/

Heather Couch 25 MAR 2022

Program Manager or designee, ATCC Federal Solutions

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