

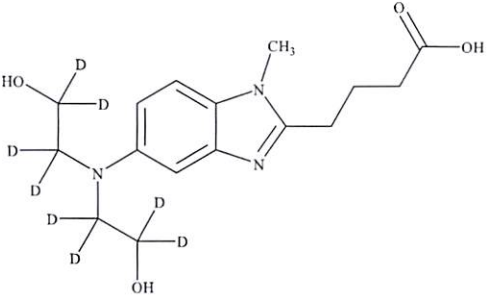
## Certificate of Analysis

Certificate No.: 20230131012


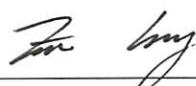
Date: January 31, 2023

Retest date: January 29, 2026

<b>Compound Name:</b> Bendamustine Impurity 4-d <sub>8</sub> (Dihydroxy Impurity-d <sub>8</sub> )	
<b>Synonyms:</b>	4-(5-(bis(2-hydroxyethyl-1,1,2,2-d <sub>4</sub> )amino)-1-methyl-1H-benzo[d]imidazol-2-yl)butanoic acid
<b>TLC Catalogue Number:</b>	B-4350
<b>CAS Number:</b>	109882-30-6 (non-labelled)
<b>Molecular Weight:</b>	329.43
<b>Molecular Formula:</b>	C <sub>16</sub> H <sub>15</sub> D <sub>8</sub> N <sub>3</sub> O <sub>4</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	3717-066A6
<b>Storage Conditions:</b>	Hygroscopic, store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO, Water



Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Elemental Analysis</b>	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>100.0%</b>
<b>Impurity (HPLC)</b>	N/A	
<b>Isotopic Enrichment</b>	Not less than 98.0%	<b>99.5%</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (qNMR)</b>	Not less than 90.0%	<b>94.4%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		02/02/2023
Approved by:	Quality Assurance		02/02/2023

**Attachments:** HPLC, IR, MS and NMR spectra.