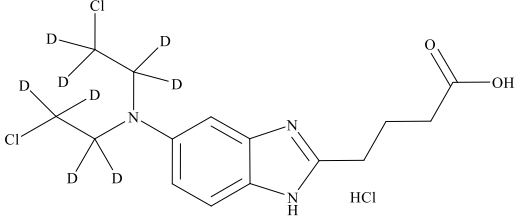


Certificate of Analysis

Certificate No.: 20200716005

Date: July 16, 2020

Retest date: July 9, 2023

Compound Name:	Bendamustine Impurity 5-d₈ HCl (Bendamustine Desmethyl Impurity-d₈ HCl)	
Synonyms:	4-(5-(bis(2-chloroethyl-1,1,2,2-d ₄)amino)-1 <i>H</i> -benzo[<i>d</i>]imidazol-2-yl)butanoic acid, hydrochloride (1:1)	
TLC Catalogue Number:	B-4352	
CAS Number:	31349-38-9 (non-labelled)	
Molecular Weight:	352.28 36.46	
Molecular Formula:	C ₁₅ H ₁₁ D ₈ Cl ₂ N ₃ O ₂ · HCl	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3973-018A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.3%
Impurity (HPLC)	RT 9.19, 0.96%; RT 11.42, 0.14%; RT 12.32, 0.35%	
Isotopic Enrichment	Not less than 98.0%	99.7%
Water Content (KF)	N/A	0.5%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	97.8%
Recommendation:	Released.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.