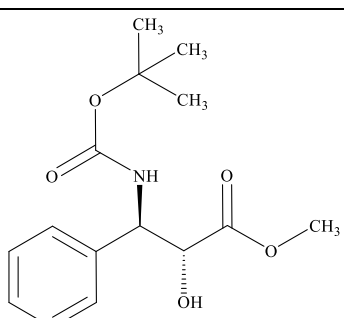


Certificate of Analysis

Certificate No.: 20200806005

Date: August 6, 2020

Retest date: July 31, 2023

Compound Name:	Docetaxel Impurity 33	
Synonyms:	methyl (2R,3R)-3-((<i>tert</i> -butoxycarbonyl)amino)-2-hydroxy-3-phenylpropanoate	
TLC Catalogue Number:	D-1957	
CAS Number:	959123-35-4	
Molecular Weight:	295.34	
Molecular Formula:	C ₁₅ H ₂₁ NO ₅	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4016-031A5	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF, Acetonitrile	

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
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Purity (Chiral HPLC)	Not less than 98.0%	100.0%
Water Content (KF)	N/A	0.2%
Optical Rotation	[α] _D ^{26.0} (c=0.50, CHCl ₃): -33.0°	[α] _D ^{25.0} (c=0.43, CHCl ₃): -30.5°
Residual Solvents (NMR)	0.3% dichloromethane	
Assay (%)	Not less than 90.0%	99.5%
Recommendation:	Released.	

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

Attachments: HPLC, IR, MS and NMR spectra.