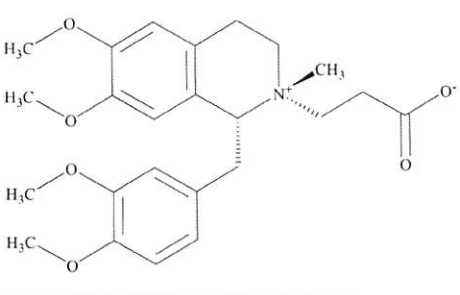


## Certificate of Analysis



Certificate No.: 20220318021

Date: March 18, 2022

Retest date: March 15, 2025

<b>Compound Name:</b>	<b>Cisatracurium Besilate EP Impurity A</b>	
<b>Synonyms:</b>	3-((1R,2R)-1-(3,4-dimethoxybenzyl)-6,7-dimethoxy-2-methyl-1,2,3,4-tetrahydroisoquinolin-2-ium-2-yl)propanoate	
<b>TLC Catalogue Number:</b>	A-753	
<b>CAS Number:</b>	1075727-04-6	
<b>Molecular Weight:</b>	429.52	
<b>Molecular Formula:</b>	C <sub>24</sub> H <sub>31</sub> NO <sub>6</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	3611-001A9	
<b>Storage Conditions:</b>	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>99.3%</b>
<b>Impurity (HPLC)</b>	RT 8.98, 0.33%; RT 12.81, 0.22%	
<b>Water Content (KF)</b>	N/A	<b>14.5%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{20.0}(c=0.56, \text{DMSO}): -85.1^\circ$
<b>Residual Solvents (NMR)</b>	0.3% methanol	
<b>Assay (%)</b>	Not less than 80.0%	<b>84.6%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03 / 21 / 2022
Approved by:	Quality Assurance		03 / 21 / 2022

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