

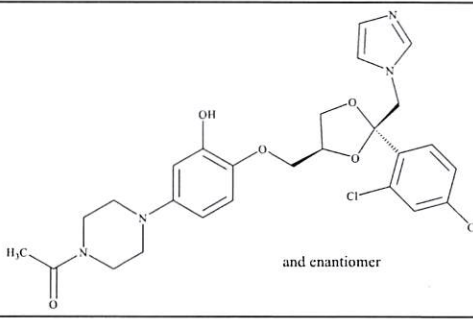
## Certificate of Analysis

Certificate No.: **20230324005**

Date: March 24, 2023



Retest date: March 1, 2026

<b>Compound Name:</b> Ketoconazole Metabolite (M8)	
<b>Synonyms:</b>	<i>rel</i> -1-(4-(4-(((2R,4S)-2-((1 <i>H</i> -imidazol-1-yl)methyl)-2-(2,4-dichlorophenyl)-1,3-dioxolan-4-yl)methoxy)-3-hydroxyphenyl)piperazin-1-yl)ethan-1-one
<b>TLC Catalogue Number:</b>	K-0169
<b>CAS Number:</b>	1253852-48-0
<b>Molecular Weight:</b>	547.43
<b>Molecular Formula:</b>	C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>5</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	5454-060A3
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO, Acetonitrile, Ethanol



and enantiomer

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>Purity (HPLC)</b>	Not less than 95.0%	<b>98.1%</b>
<b>Impurity (HPLC)</b>	RT 4.47, 0.53%; RT 16.90, 0.64%; RT 17.28, 0.26%	
<b>Water Content (KF)</b>	N/A	<b>0.2%</b>
<b>Residual Solvents (NMR)</b>	0.9% diethyl ether and 0.1% acetone	
<b>Assay (%)</b>	Not less than 90.0%	<b>96.9%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03 / 28 / 2023
Approved by:	Quality Assurance		03 / 28 / 2023

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