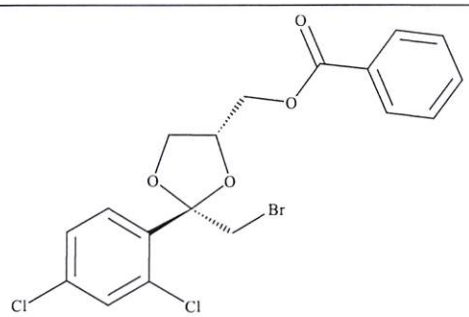
TLC PHARMACEUTICAL STANDARDS

Certificate of Analysis

Certificate No.: **20221221006**

Date: December 21, 2022 Retest date: December 15, 2025

Compound Name:	**Ketoconazole Impurity 4**	
Synonyms:	((2R,4R)-2-(bromomethyl)-2-(2,4-dichlorophenyl)-1,3-dioxolan-4-yl)methyl benzoate	
TLC Catalogue Number:	K-0121	
CAS Number:	170210-39-6	
Molecular Weight:	446.12	
Molecular Formula:	$C_{18}H_{15}BrCl_2O_4$	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	5232-044A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	DMSO, solution of Methanol and Acetonitrile	

Test Description	**Specifications**	**Results**
Visual Description	White to off-white solid	**Conforms**
Identification **IR** **MS** **^{1}H NMR**	 Conforms to structure Conforms to structure Conforms to structure	 **Conforms** **Conforms** **Conforms**
Purity (HPLC)	Not less than 95.0%	**99.8%**
Impurity (HPLC)	RT 12.30, 0.24%	
Purity (Chiral HPLC)	Not less than 98.0%	**99.9%**
Water Content (KF)	N/A	**0.0%**
Optical Rotation	N/A	$[\alpha]_D^{20.0}$(c=0.39, $CHCl_3$): **+29.1°**
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	**99.7%**
Recommendation:	**Release.**	

Name	**Department**	**Signature**	**Date**
Reviewed and approved by:	Quality Control	Kelvin Zhu	12/22/2022
Approved by:	Quality Assurance	Karl	12/22/2022

Attachments: HPLC, IR, MS and NMR spectra.

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