

# SINOWAY INDUSTRIAL CO.,LTD.

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## Certificate of Analysis

<b>Product name:</b> Posaconazole		<b>MFG. date:</b> 2021.09.14
<b>Batch No.:</b> C033-2109002		Test Date: 2021.09.16
<b>Batch Quantity:</b> 27.300 kg		<b>Retest date:</b> 2023.09.13
<b>Inspection standards:</b> Enterprise Standard		
TEST ITEM	SPECIFICATION	RESULTS
Appearance	White to Off white powder.	White powder
Melting point	167 ~ 171°C	167.5 ~ 168.0C
Specific optical rotation	-28.5. ~-24.5.	-27.2°
Identification	The retention time of the major peak of the test solution corresponds to that of the standard solution, as obtained in the <i>Assay</i> .	Conform
	The infrared absorption spectrum of this product should corresponds to the reference spectrum.	Conform
Crystallinity	There are characteristic peaks at $7.7^{\circ}\pm 0.2^{\circ}$ , $9.9^{\circ}\pm 0.2^{\circ}$ , $17.8^{\circ}\pm 0.2^{\circ}$ , $19.5^{\circ}\pm 0.2^{\circ}$ , $20.0^{\circ}\pm 0.2^{\circ}$ (Crystal form 1).	Conform
Water content (%w/w)	$\leq 0.5\%$	0.1%
Residue on ignition	$\leq 0.1\%$	0.02%
Related substances	QR0005DS-IN-01: $\leq 0.10\%$	Not detected
	QR0005DS-IN-02: $\leq 0.10\%$	0.01%
	QR0005DS-IM-08: $\leq 0.10\%$	Not detected
	QR0005DS-IN-02-IM-06: $\leq 0.10\%$	Not detected
	Other maximum unknown impurity $\leq 0.10\%$	0.02%
	Total impurities: $\leq 0.40\%$	0.07%
Enantiomeric and diastereoisomer	QR0005DS-IM-02: $\leq 0.10\%$	0.01%
	QR0005DS-IM-03: $\leq 0.10\%$	Not detected
	QR0005DS-IM-04: $\leq 0.10\%$	Not detected
	QR0005DS-IM-01+QR0005DS-IM-05+QR0005DS-IM-06: $\leq 0.10\%$	Not detected
	QR0005DS-IM-07: $\leq 0.10\%$	0.02%
	Total isomer impurities: $\leq 0.50\%$	0.04%

TEST ITEM	SPECIFICATION	RESULTS
Residual solvents	Methanol: $\leq 3000$ ppm	31 ppm
	Dichloromethane: $\leq 600$ ppm	53 ppm
	Acetone: $\leq 5000$ ppm	Not detected
	Ethanol: $\leq 5000$ ppm	Not detected
	Dimethyl sulfoxide: $\leq 5000$ ppm	Not detected
Benzene	$\leq 2$ ppm	Not detected
Heavy metals	$\leq 10$ ppm	Conform
Bacterial endotoxin	$\leq 0.25$ EU/mg	Conform
Microbial limit	Total Aerobic Microbial Count (TAMC): $\leq 10^2$ cfu/g	10 cfu/g
	Total molds and Yeast Count (TYMC): $\leq 10^1$ cfu/g	<10 cfu/g
	Escherichia Coli: Absence	Not detected
Assay	C <sub>37</sub> H <sub>42</sub> F <sub>2</sub> N <sub>8</sub> O <sub>4</sub> : 98.0% ~ 102.0% (on the anhydrous basis)	101.0%
Conclusion	Conform to Enterprise Standard	

**Reported by/date:**Zhang Yixuan    **Reviewed by/date:**You Feng    **Issued by/date:**Xiao Yuan

Sep. 26,2021

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