

CERTIFICATE OF ANALYSIS

Product Name:	Voriconazole		
Batch No.	220601		
CAS No.	137234-62-9	Specification No.	LB-TS-ZL0058-LBS-05
Quantity	169.31kg	Manufacturing Date	June 7, 2022
Report Date	June 28, 2022	Expiry Date	June 6, 2024
Analytical Results			
Items	Specifications		Results
Appearance	White to almost white crystalline powder		White crystalline powder
Identification	A: IR		Conforms
	B: HPLC		Conforms
Voriconazole Related Compound C&D	Impurity C: NMT 0.2%		0.009%
	Impurity D: NMT 0.1%		ND
	Any unknown impurity: NMT 0.1%		0.009%
	Total impurities: NMT 0.5%		0.036%
Voriconazole Related Compound B	Impurity B: NMT 0.2%		ND
Voriconazole Related Compound F	Impurity F: NMT 0.1%		ND
Water (By K.F)	Not more than 0.4%		0.046%
Residue on ignition	Not more than 0.1%		0.01%
Heavy metals	Not more than 10ppm		Conforms
Assay (on dried basis, by HPLC)	97.5%~102.0%		99.45%
Remark	Impurity B: (2S,3R)-2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol(voriconazole enantiomer)		
	Impurity C: 1-(2,4-difluorophenyl)-2-(1H,1,2,4-triazol-1-yl) ethanone		
	Impurity D: (2RS,3RS)-2-(2,4-difluorophenyl)-3-(pyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl) butan-2-ol		
	Impurity F: [(1RS,4RS)7,7-Dimethyl-2-oxobicyclo[2,2,1]hept-1-yl]methanesulfonic acid ((±)-10-camphorsulfonic acid)		
Storage	In an airtight container, protected from light.		
Conclusion	Conforms to the above specifications.		

Inspector: Carlifor Wu

Verifier: Jack He

