

Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

TCERTIFICATE OF ANALYSIS

Product : 4-[4-[[2-(4-Chlorophenyl)-4,4-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[3-nitro-4-[[[(tetrahydro-2H-pyran-4-yl)methyl]amino]phenyl]sulfonyl]-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)-benzamide (**Venetoclax**)

Quantity : 25kg

Manufacturing Date : May. 13, 2022

CAS NO.: 1257044-40-8

Suggest Retest Date : May. 13, 2024

Batch NO. : RD-VCL-202205131

Test Basis : SOP-T-API-080-1

Tests	Specifications	Results
Appearance	Yellow powder	Yellow powder
Identification	A. Retention Time: Similar to Reference Substance	Complies
	B.IR: Similar to Reference Substance	Complies
Loss on drying	≤1.0%	0.36%
Residue on ignition	≤0.5%	0.04%
Related substances	DMAP≤0.15%	Undetected
	VLP-A≤0.15%	Undetected
	VCLM3≤0.15%	Undetected
	VLP-9≤0.15%	Undetected
	VCL-B≤0.15%	Undetected
	Deschloro of VCL≤0.15%	0.01%
	VCL-J≤0.15%	Undetected
	VCL-F≤0.15%	0.01%
	Any individual impurity≤0.10%	0.07%
	Total impurities≤1.0%	0.18%
Residual solvents 1	Methanol≤0.3%	Undetected
	Ethanol≤0.5%	Undetected
	Hexane≤0.029%	0.0011%
	Ethyl acetate≤0.5%	0.3836%
	Tetrahydrofuran≤0.072%	0.0058%
	Triethylamine≤0.5%	Undetected
	Dimethyl sulfoxide≤0.5%	Undetected
Residual solvents 2	Dichloromethane≤0.06%	Undetected
	1,2-dimethoxyethane≤0.01%	0.0007%
Acetic acid	≤0.5%	Undetected
Assay	98.0%~102.0% (Calculated on the dried basis)	100.0%

The results above meet all requirements under **Venetoclax** in **In-House Standard**

