



Hangzhou Huarong Pharmaceutical Co., Ltd.

ADD: Room1101, Hakim International Building, Gongshu District,

Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

Website: www.huarongpharm.com

Certificate of Analysis for Olanzapine /OZP(U)

Test sheet No.: C₉₁-220006

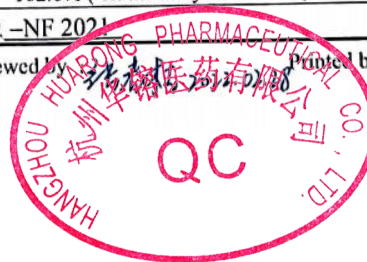
Product Code	OZP(U)	Batch No.	OZP-2202003
Batch Size	15.41kg	Type of Product	API
Manufacturing Date	Feb.15,2022	Package Size	5.0Kg/Drum
Report Date	Feb.28,2022	Retest date	Feb.14,2024
Standard	USP		
Tests	Acceptance criteria	Results	
Appearance	Yellow crystalline powder	Yellow crystalline powder	
Identification			
Infrared absorption	Infrared spectrum is concordant with that of the reference standard	Conforms	
HPLC	The retention time of the major peak of the Sample Solution corresponds to that of the standard Solution, as obtained in the Assay	Conforms	
Tests			
water	Not more than 1.0%	0.16%	
Residue on ignition	Not more than 0.1%	0.03%	
Related substances			
Olanzapine Related compound A	Not more than 0.10%	ND	
Olanzapine Related compound B	Not more than 0.10%	ND	
Olanzapine Related compound C (Chloromethyl Olanzapinium chloride)	Not more than 0.15%	ND	
Olanzapine Related compound D	Not more than 0.10%	ND	
Any unknown impurity	Not more than 0.10%	ND	
Total Impurities	Not more than 0.4%	ND	
Residual solvents			
Acetone	Not more than 5000ppm	389ppm	
Microbial limit			
TAMC	Not more than 10 ³ cfu/g	<10cfu/g	
TYMC	Not more than 10 ² cfu/g	<10cfu/g	
Escherichia coli	No detected/g	ND	
Assay	98.0%~102.0% (on the anhydrous basis)	100.3%	

Conclusion: The test results comply with USP. -NF 2021

Approved by: [Signature] 2022.02.28

Reviewed by: [Signature]

Printed by: [Signature] 2022.02.28



*Means the document is under process
Product under patent is for R&D purpose.