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Certificate of Analysis for Olanzapine /OZP(U)

Test sheet No.: C$_{81}$-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 10^3cfu/g	<10cfu/g
TYMC	Not more than 10^2cfu/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: 2022.02.28 Reviewed by: 2022.02.28 Printed by: 2022.02.28

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. 杭州华荣医药有限公司 QC

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