

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC20120120

REGISTER NO: SMR-QC-018a0

PRODUCT	CLOZAPINE	PHARMACOPOEIA	EP10.0
BATCH NO.	A-71012012001	GROSS WEIGHT	27.5Kg/Drum
BATCH QUANTITY	1011.1Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE	DEC.02,2020	RETEST DATE	NOV. 2025
ANALYSIS DATE	DEC.04,2020	REPORT DATE	DEC.21, 2020
TESTS	SPECIFICATION	OBSERVATION	
Characters			
Appearance	Yellow,crystalline powder	Yellow,crystalline powder	
Solubility	Practically insoluble in water, freely soluble in Methylene chloride,soluble in ethanol(96%).It dissolves in dilute acetic acid.	Complies	
Identification			
(a)Melting point	182°C~186°C(2.2.14)	183.8°C	
(b) IR	Conforms to clozapine CRS(2.2.24)	Complies	
Test			
Related substances	(2.2.29)		
Impurity A	≤ 0.1%	Not detected	
Impurity B	≤ 0.2%	Not detected	
Impurity C	≤ 0.2%	0.05%	
Impurity D	≤ 0.2%	Not detected	
unspecified impurities	≤ 0.10%	0.07%	
Total Impurities	≤ 0.6%	0.1%	
Loss on drying	≤ 0.5%(2.2.32)	0.07%	
Sulphated ash	≤ 0.1%(2.4.14)	0.02%	
Assay(on dried basis)	99.0-101.0%(2.2.20)	100.1%	

Conclusion: The commodity meets the standard of EP10.0. CEP No. R1-CEP 2012-006-Rev 00.

Examiner: Huang Shasha

Checker: Hu Yue

QA : Li Wenguang

2020.12.21

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