



上海遐瑞医药科技有限公司

SHANGHAI T&W PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Name	Clozapine	CAS No.	5786-21-0
Batch No.	Q03Y160402	Mfg. Date	20160402
Quantity	175.0 kg	Report Date	20160412
Test Specification	EP 9.2		

ITEMS	STANDARD	RESULT	
Appearance	Yellow crystalline powder	Complies	
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96%). It dissolves in dilute acetic acid	Complies	
Identification			
(1)Melting point	182-186°C	Complies	
(2)IR	IR Spectrum of sample complies with that of clozapine CRS	Complies	
Tests			
Related substances	Impurity A	Not more than 0.1%	0.06%
	Impurity B	Not more than 0.2%	ND
	Impurity C	Not more than 0.3%	ND
	Impurity D	Not more than 0.2%	0.06%
	Single impurity	Not more than 0.1%	0.05%
	Total impurities	Not more than 0.6%	0.22%
Loss on drying	Not more than 0.5%	0.07%	
Sulfated ash	Not more than 0.1%	0.04%	
Assay	99.0-101.0% (dried substance)	99.2%	

Conclusion: Complies with prescribed standard of EP 9.2.

Analyst: *Xiao Mei Sun*

Checker: *Jong Wang*

Approve: *Jong Wang*

