

检 验 报 告

CERTIFICATE OF ANALYSIS

Product Name: Risperidone Batch NO.:20120108 Report Date :2012/01/12 Perform Standard: EP 6.0		
Test	Specification	Result of analysis
Appearance	White or almost white power	Conforms
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol(96%). It dissolves in dilute acid solutions.	Conforms
Identification(HPLC)	Comparing with the spectrum obtained with risperidone CRS	Conforms
Appearance of solution	The solution is clear and colourless	Conforms
Residual solvents	DCM Not more than 600PPM	N.D.
	Acetone Not more than 5000PPM	313PPM
	DMF Not more than 880 PPM	245PPM
Palladium	Not more than 5 PPM	2 PPM
Related substance(HPLC)	Impurity A Not more than 0.2%	0.09%
	Impurity B Not more than 0.2%	N.D.
	Impurity C Not more than 0.2%	N.D.
	Impurity D Not more than 0.2%	N.D.
	Impurity E Not more than 0.2%	N.D.
	Any other Impurity Not more than 0.1%	Conforms
	Total Impurity Not more than 0.3%	0.09%
Loss on drying	Not more than 0.5%	0.035%
Residue on ignition	Not more than 0.1%	0.07%
Assay	Between 99.0 % and 101.0 % calculated on the dried basis	99.9%
Conclusion: Conforming to EP6.0 审查者 (Exam) 化验者 (Analyst) 复核者 (Checker)		