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CERTIFICATE OF ANALYSIS

PRODUCT NAME	Risperidone	SAMPLE SOURCE	Workshop One
BATCH NO.	103230301	PACKAGE SIZE	5.00kg per bag
BATCH QTY	19.70kg	MFG. DATE	Mar.29, 2023
PACKAGING QTY	4	RECEIPT DATE	Mar.30, 2023
TEST ITEMS	Full test	REPORT DATE	Apr.17, 2023
TEST REFERENCE	EP 10.0	RETEST DATE	Mar.28, 2026
CERTIFICATE OF ANALYSIS			
TEST	SPECIFICATION	RESULTS	
Characters	Appearance: White or almost white powder	Almost white powder	
	Solubility: practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 per cent).	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 per cent)	
Identification Infrared Absorption	Conforms to spectrum of Risperidone CRS	Conforms to spectrum of Risperidone CRS	
Appearance of solution	The solution is clear and colourless	complies	
Loss on drying	NMT 0.5%	0.03%	
Sulfated ash	NMT 0.1%	0.04%	
Residual solvents	Ethanol NMT 0.5%	0.1%	
	N,N-dimethylformamide NMT 0.088%	Undetected	
Related substances	Impurity A NMT 0.2%	0.01%	
	Impurity B NMT 0.2%	0.02%	
	Impurity C NMT 0.2%	Undetected	
	Impurity D NMT 0.2%	Undetected	
	Impurity E NMT 0.2%	Undetected	
	Impurity K NMT 0.15%	Undetected	
	Single unknown impurity NMT 0.10%	RRT=1.11:0.01%;RRT=1.19:0.02%; RRT=1.23:0.03%	
Total impurities NMT 0.3%	0.09%		
Assay	99.0 per cent to 101.0 per cent (dried substance)	100.5%	
Hydroxylamine hydrochloride	NMT 90ppm	Undetected	
Remark: N/A			
Conclusion: The above material complies with EP 10.0			

