

Certificate of analysis

Cisapride Monohydrate

CAS No	260779-88-2	Code	BIOJCPR001
Lot No	DK60-2404211	Manufacture Date	Apr.21, 2024
Retest Date	Apr. 20, 2027	Quantity	1Kg

Testing Items	Specifications	Results
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Optical rotation	Between -0.05° and $+0.05^{\circ}$	-0.001°
UV absorption coefficient	$E_{1\text{cm}}^{1\%}$ is between 248 and 274(at 308nm)	257.3
Identification	Primary aromatic amines: An orange or scarlet precipitation is produced	Complies
	UV: Max. absorptions at 237nm and 308nm; Min. absorptions at 291nm and 249nm	Complies Complies
	IR: The spectrum of sample consists with that of the reference substance	Complies
	Organic fluorides: The solution appears royal purple colour	Complies
Appearance of solution	Clear or not more opalescent than turbidity standard solution I	Complies
	The colour is not more intensely coloured than No.7 orange yellow reference solution	
Related substances	Single impurity: $\leq 0.5\%$	0.03% (RRT:0.7) 0.02% (RRT:1.08) 0.04% (RRT:1.11) 0.11% (RRT:1.4)
	Sum of impurities: $\leq 1.0\%$	0.20%
Residual solvents	Methanol: $\leq 0.01\%$	$<0.0001\%$
	Toluene: $\leq 0.089\%$	$<0.0001\%$
	Chloroform: $\leq 0.006\%$	$<0.0001\%$
Water	3.4%~4.0%	3.7%
Residue on ignition	$\leq 0.1\%$	0.02%
Heavy metals	$\leq 20\text{ppm}$	$<20\text{ppm}$
Assay(on dried basis)	$\geq 99.0\%$	99.4%
Conclusion	This product conforms to China SFDA standard	

***Storage condition: Store below 25°C, Protect from moisture and light.**