

Reduced L-Glutathione Injection

200 mg/mL, 30mL Multiple Dose Vial



Summary of Long-Term Storage Data (Real-Time at 5°C ± 3°C)

Test	Method	Months					
		0	1	2	3	5	6
Product Appearance (Description)	Visual	PASS	PASS	PASS	PASS	PASS	PASS
Package Appearance (Seal)		PASS	PASS	PASS	PASS	PASS	PASS
Package Appearance (Vial)		PASS	PASS	PASS	PASS	PASS	PASS
Container Closure Integrity	Bonfiglioli Leak Tester	PASS	PASS	PASS	PASS	PASS	PASS
Foreign Matter (Visible)	USP <1> and USP <790>	PASS	PASS	PASS	PASS	PASS	PASS
pH	USP <791>						
Assay	HPLC / UPLC	207 mg/mL	208 mg/mL	200 mg/mL	199 mg/mL	197 mg/mL	195 mg/mL
Identification		PASS	PASS	PASS	PASS	PASS	PASS
Benzyl Alcohol		0.9%	0.9%	0.9%	0.9%	0.9%	0.9%
Impurities		Conforms to Specification					
Particulate Matter (Sub-Visible)	USP <788> Method I	PASS	PASS	PASS	PASS	PASS	PASS
Bacterial Endotoxin	USP <85>	PASS	PASS	PASS	PASS	PASS	PASS
Sterility	USP <71>	PASS	PASS	PASS	PASS	PASS	PASS
Antimicrobial Effectiveness Test	USP <51>	PASS	PASS	PASS	PASS	PASS	PASS