

Alpha-Lipoic Acid Injection

40 mg/mL, 15mL Single Dose Vial



Summary of Long-Term Storage Data (25°C ± 2°C / 60%RH ± 5%RH)

Test	Method	Months			
		0	3	6	9
Product Appearance (Description)	Visual	PASS	PASS	PASS	PASS
Package Appearance (Seal)		PASS	PASS	PASS	PASS
Package Appearance (Vial)		PASS	PASS	PASS	PASS
Container Closure Integrity	Bonfiglioli Leak Tester	PASS	PASS	PASS	PASS
Foreign Matter (Visible)	USP <1> and USP <790>, supplement with USP <1790>	PASS	PASS	PASS	PASS
pH	USP <791>	7.3	7.1	7.0	6.8
Assay	HPLC / UPLC	39 mg/mL	39 mg/mL	39 mg/mL	39 mg/mL
Identification		PASS	PASS	PASS	PASS
Impurities		Conforms to Specification			
Particulate Matter (Sub-Visible)	USP <788> Method I	PASS	PASS	PASS	PASS
Bacterial Endotoxin	USP <85>	PASS	PASS	PASS	PASS
Sterility	USP <71>	PASS	PASS	PASS	PASS