



CERTIFICATE OF CONFORMANCE

General Product Information			
Product Name	Glutathione Preservative Free 200 mg/mL (30 mL) Injection		
Empower NDC:	72627-2402-1	Empower Lot Number:	615893
Container Description & Fill Volume:	30 mL fill in 30 mL amber glass vial with black flip-off seal	Compounding Date (DOM):	29-Oct-2025
Storage Conditions:	2°C-8°C (36°F-46°F)	Beyond Use Date (BUD):	24-Sep-2026

Glutathione Preservative Free 200 mg/mL (30 mL) Final Product Quality Attributes			
Test	Method	Specification	Results
Appearance	Visual Inspection	Clear, colorless solution with no visible particulates	Pass
Assay-Glutathione (L)	UHPLC (USP<621>)	103.0-110.0%	Pass
pH	USP<791>	6.5-7.0	Pass
Subvisible Particulates	USP<788>	≥ 10 µm: NMT 6000 particles per container ≥ 25 µm: NMT 600 particles per container	Pass
Endotoxin	USP<85>	≤11 EU/mL	Pass
Sterility	USP<71> / Rapid Sterility (SCANRDI)	No Growth / 0 Microbes	Pass

Glutathione (L) Lot: B240323, Raw Material Quality Attributes			
Test	Method	Specification	Results
Endotoxin	USP<85>	NMT 0.1 EU/mg	Pass
Total Aerobic Microbial Count	USP<61>	NMT 100 CFU/g	Pass
Total Yeast and Mold Count	USP<61>	NMT 10 CFU/g	Pass

Sodium Hydroxide NF Lot: 2312662009, Raw Material Quality Attributes			
Test	Method	Specification	Results
Endotoxin	USP<85>	NMT 5 EU/mg	Pass

Sodium Hydroxide NF Lot: 23I2662009, Raw Material Quality Attributes			
Test	Method	Specification	Results
Endotoxin Validation	MBI-135	Complete/Incomplete	Pass
Total Aerobic Microbial Count	USP<61>	NMT 1000 EU/g	Pass
Total Aerobic Microbial Count Suitability	USP<61>	Pass/Fail	Pass
Total Yeast and Mold Count	USP<61>	NMT 1000 EU/g	Pass
Total Yeast and Mold Count Suitability	USP<61>	Pass/Fail	Pass

Empower Pharma, 5980 W Sam Houston Pkwy N, Suite 300, Houston, TX 77041, is an FDA-registered 503B compounding facility. This Certificate of Conformance confirms that the product was manufactured under current Good Manufacturing Practices (cGMP). This lot met all applicable specifications and was approved for release by the Quality Unit.