

CERTIFICATE of ANALYSIS




This example calls itself a Certificate of Analysis but it is not a Certificate of Analysis. It is a Certificate of Conformance. There are no numerical specifications or actual test results, only a note of conformance.

Formulation ID - Product Name:	458: Bevacizumab 1.25 mg/0.05 mL Inj
NDC#	XXXXX-XXX-XX
Concentration	25 mg/mL
Lot Number	XXXXX
Expiration Date	XX/XX/2024
Storage Conditions	2°C - 8°C (35.6°F - 46.4°F); Light Protect

Assay	Method	Specifications	Results
Appearance - Color & Clarity	Internal Method	Clear, colorless solution	Conforms
Particulate Matter (visible)	Internal Method	Visibly particulate-free	Conforms
Particulate Matter (sub-visible)	USP <788> Method I	Limits per USP <788>	Conforms
Bacterial Endotoxins	USP <85>	<20EU/mL	Conforms
Sterility	USP <71> ¹	Sterile	Conforms

¹Or equivalent validated alternative test method.

 **Particulate Matter (visible and sub-visible): Note there are no numerical limits stated for the standards, although they exist. There are also no numerical results.**

Date Reported: XX/XX/2024

Approval - Quality Control

Date Reported: XX/XX/2024

Approval - Quality Assurance