

Avantor™ Performance Materials

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Re: J.T.Baker® and Macron Fine Chemicals™ Parenteral/Injectable Grade Biopharmaceutical
Chemicals

Parenteral or injectable pharmaceutical ingredients are used in formulations that are administered directly into the body, bypassing the digestive system.

Avantor adheres to compendial and regulatory testing requirements for GMP-manufactured biopharmaceutical chemicals. Testing criteria for ingredients intended for parenteral applications are evaluated and applied to finished goods. The tests include but are not limited to Bacterial Endotoxins and Peroxide Value. Products that meet the required standards are labeled as "suitable for use in the manufacture of injectable or parenteral dosage forms" on the Avantor Certificate of Analysis (CoA). This designation confirms compliance with applicable standards for parenteral use. While these specifications may indicate suitability for use in the manufacture of sterile products, the performance of these tests or processes does not imply that the product supplied by Avantor is sterile. Sterility testing is only conducted when explicitly stated on the CoA.

Avantor's comprehensive approach ensures product quality and regulatory compliance, supporting the development and manufacture of high-performance parenteral formulations.

If you have any questions or require additional information, please contact Technical Services.

Revision History:

Rev 0: Aug 27, 2025 – New document.

Prepared by the Technical Service Department

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