

Avantor™ Performance Materials

100 Matsonford Rd #200

Radnor, PA 19087 USA

Technical Service Department

Toll free 1 855 282 6867, select option 5

Outside U.S. 1 610 573 2600, select option 5

technical.service@avantorsciences.com

Date: March 25, 2024

Re: Manufacturer's Certificate of Analysis

A number of the cGMP-manufactured products that are sold by Avantor Performance Materials may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures in place at our facilities, we can ensure and take complete responsibility for the traceability and quality of the finished, packaged product. Since Avantor Performance Materials is accountable as the manufacturer of the final tested and packaged product, we do not share the product codes, Certificates of Analysis, or other documentation from the original manufacturing site with our customers.

As of April 24, 2006, the original manufacturer name and address is referenced on the Certificate of Analysis as an alpha or alpha-numeric manufacturer code rather than listing the full name and address for the regulated products designated with Management of Change (MOC) codes RL- Regulated Limited, R - Regulated and HR - Highly Regulated. This practice is compliant with ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs), the International Pharmaceutical Excipients Council (IPEC) guidelines and cGMP requirements

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

Revision History

Rev. 0; March 25, 2024 – New Document. No alteration in data.

Prepared by the Avantor
Technical Service Department

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