Avantor™ Performance Materials
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Re: Manufacturing License information for Avantor™ Performance Materials Manufacturing and Repackaging Sites

The FDA (Food and Drug Administration) registration is mandatory for drug manufacturers to produce, repack, or relabel drug products in the United States. The Avantor Performance Materials site in Paris, Kentucky, USA, is registered with the FDA for analysis, labeling, packaging, relabeling, and repackaging operations. The Phillipsburg, New Jersey, USA site is registered with the FDA for analysis and active pharmaceutical ingredients (API) manufacturing. In addition to Federal requirements, we hold state/county-specific manufacturing licenses to perform manufacturing operations. Avantor Paris, KY, is ISO 9001:2015 certified, and the Avantor Phillipsburg, NJ, site is 9001:2015 and FSSC 22000:2018 certified. The manufacturing license is confidential and is available for review during an on-site audit. For regulatory drug submissions and China support packages, it can be obtained under a non-disclosure agreement.

The Avantor Performance Materials site in Gliwice, Poland, is registered with the FDA for analysis operations. No Active Pharmaceutical Ingredients are manufactured or repackaged at this location. This site is not registered with the Polish Health Authority; therefore, the manufacturing license does not apply to this site. The Gliwice site is ISO 9001:2015, FSSC 22000, ISO 13485:2016 & EN ISO 13485:2016, and AQAP 2110:2016 certified.

The Avantor Performance Materials site in India, Panoli is registered with the FDA for analysis operations. Additionally, this site is ISO 9001:2015 certified, GMP, GLP certified by the Food & Drug Control Administration, Gujarat State, India. The local FDA Form 25 and Form 25B licenses can be obtained under a non-disclosure agreement for regulatory drug submissions.

The ISO certificates for the respective production facilities are available on the Avantor website at Avantor® ISO Certifications | Avantor. The FDA registrations can be verified at the Drug Establishments Current Registration Site

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