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Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (40 CFR Part 439)

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U.S. Environmental Protection Agency
Office of Water
Engineering and Analysis Division
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Executive Summary

On September 21, 1998, the U.S. Environmental Protection Agency (EPA) promulgated revised regulations for the pharmaceutical industry to control both effluent discharges and air emissions. The purpose of this guidance document is to help permit writers and pretreatment coordinators develop appropriate National Pollutant Discharge Elimination System (NPDES) permits and pretreatment requirements for pharmaceutical facilities with the following types of operations: fermentation, extraction, chemical synthesis, mixing, compounding and formulating and research. For an overview of the NPDES and National Pretreatment Programs, refer to the *U.S. EPA NPDES Permit Writer's Manual* (EPA-833-B-96-003) as well as the *Industrial User Permitting Guidance Manual* (EPA-833/R-89-001).