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Wastewater Monitoring for the Pharmaceutical Manufacturing Industry

The U.S. Environmental Protection Agency issued a final regulation in 1998 (63 FR 50388) that established standards for wastewater discharges for new and existing Pharmaceutical Manufacturing Industry (PMI) facilities. These regulations, the Pharmaceutical Effluent Guidelines found in 40 CFR Part 439, include nontraditional analytes and analytical methods specific to the pharmaceutical industry. These contaminants and appropriate methods are listed in the attached table.

EPA has developed four different subcategories in the regulations based on the type of operations performed at the facility:

Subcategory A—Fermentation Operations

Subcategory B—Biological and Natural Extraction Operations

Subcategory C—Chemical Synthesis Operations

Subcategory D—Mixing, Compounding or Formulating Operations

The specific subcategory then determines the contaminants required for monitoring.

Eurofins Lancaster Laboratories Environmental has validated two of the specific methods required for determination of nontraditional analytes as part of the Pharmaceutical Effluent Guidelines (see below). Coupled with other wastewater and drinking water methods (EPA Method 524.2 for example), these can provide monitoring for all the contaminants listed in the regulation. We have certification for these analyses through the NELAP program in Pennsylvania.

Methods for nontraditional contaminants:

- Method 1666 Revision A—Volatile Organic Compounds Specific to the Pharmaceutical Manufacturing Industry by Isotope Dilution GC/MS (for the purge-and-trap analysis).

- Method 1671 Revision A—Volatile Organic Compounds Specific to the Pharmaceutical Manufacturing Industry by GC/FID.

A baseline monitoring program as well as routine monitoring for a PMI wastewater is required under these regulations for many facilities. Eurofins Lancaster Laboratories Environmental has the equipment and experience to provide the analytical services needed for this program.

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Contaminants* and Methods for the Analysis of Wastewater in the Pharmaceutical Manufacturing Industry

Pollutant	CAS #	EPA Analytical Method
acetone (2-propanone)	67-64-1	524.2
acetonitrile	75-05-8	1671
n-amyl acetate	628-63-7	1666
n-amyl alcohol	71-41-0	1666
benzene	71-43-2	524.2
n-butyl acetate	123-86-4	1666
tert-butyl alcohol	75-65-0	1666
chlorobenzene	108-90-7	524.2
chloroform	67-66-3	524.2
1,2-dichlorobenzene	95-50-1	524.2
1,2-dichloroethane	107-06-2	524.2
diethylamine	109-89-7	1671
dimethyl sulfoxide (DMSO)	67-68-5	1671
ethanol	64-17-5	1671
ethyl acetate	141-78-6	1666
heptane	142-82-5	1666
hexane	110-54-3	1666
isobutyraldehyde	78-84-2	1666
isopropyl acetate	108-21-4	1666
isopropyl ether	108-20-3	1666
methanol	67-56-1	1671
methyl cellosolve	109-86-4	1671
methylene chloride	75-09-2	524.2
methyl formate	107-31-3	1666
4-methyl-2-pentanone (MIBK)	108-10-1	1666
2-propanol	67-63-0	1666
n-propanol	71-23-8	1671
tetrahydrofuran (THF)	109-99-9	1666
toluene	108-88-3	524.2
triethylamine	121-44-8	1671
xylenes (total)		1666

*Other traditional analyses may also be required (e.g., cyanide and ammonia).

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Organic Acids
Aldehydes
1,4-Dioxane (low level)
Low-Level Mercury
PMI
Method 25D

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