

SECTION 7

DESCRIPTION OF THE CONTROL AND TREATMENT OPTIONS

7.1 Introduction

This describes the control and treatment options considered by the Agency for promulgation of BPT, BCT, BAT, NSPS, PSES and PSNS effluent limitations guidelines and standards for the pharmaceutical manufacturing industry. The following information is presented in this section:

- 7.2 discusses the pollution prevention measures and major wastewater treatment technologies used by the industry; and
- Section 7.3 discusses the development of control and treatment options.

7.2 Pollution Prevention Measures and Wastewater Treatment Technologies in the Pharmaceutical Manufacturing Industry

This describes pollution prevention practices and major wastewater treatment technologies used in the pharmaceutical manufacturing industry according to responses to the Detailed Questionnaire. 7.2.1 defines pollution prevention and describes how pollution prevention techniques are implemented in the industry. Sections 7.2.2 through 7.2.11 describe the major wastewater treatment technologies used in the industry based on responses to the Detailed Questionnaire. These treatment technologies include:

- Advanced biological treatment (7.2.2);
- Multimedia filtration (7.2.3);
- Polishing pond treatment (7.2.4);
- Cyanide destruction (7.2.5);
- Steam Stripping and Steam Stripping with Rectification (7.2.6);
- Granular activated carbon adsorption (7.2.7);
- pH adjustment/neutralization (7.2.8);
- Equalization (7.2.9);
- Air stripping (7.2.10); and
- Incineration (7.2.11).

Each technology includes a general description of how the technology works, what types of pollutants the technology treats, and how the pharmaceutical manufacturing industry currently uses the technology.

Table 7-1 presents the total number of facilities (out of the 244 facilities responding to the Detailed Questionnaire) that reported using each of these major technologies.

7.2.1 Pollution Prevention

The Agency examined pollution prevention practices in an effort to incorporate pollution prevention into the regulatory options developed. Although shown to be effective at reducing pollutant loadings and volumes of wastes generated at pharmaceutical manufacturing facilities, pollution prevention measures were not incorporated into the various technology options considered as bases for the final limitations and standards because of obstacles specific to the pharmaceutical manufacturing industry. However, the Agency believes that numerous facilities will choose to integrate pollution prevention practices into a cost-effective strategy to comply with the final effluent limitations guidelines and standards, where site-specific circumstances allow them to do so. This provides a general description of pollution prevention as it applies to the pharmaceutical manufacturing industry, and discusses the Agency's efforts to incorporate pollution prevention into the regulatory development process.

7.2.1.1 General Description

Pollution prevention is defined as the use of materials, processes, or practices that reduce or eliminate the creation of pollutants or wastes at the source. Also known as source reduction, pollution prevention includes practices that reduce the use of hazardous and nonhazardous materials, energy, water, or other natural resources. With the Pollution Prevention Act of 1990, Congress established pollution prevention as a national policy, declaring that the creation of pollutants should be prevented or reduced during the production cycle whenever feasible. (1)

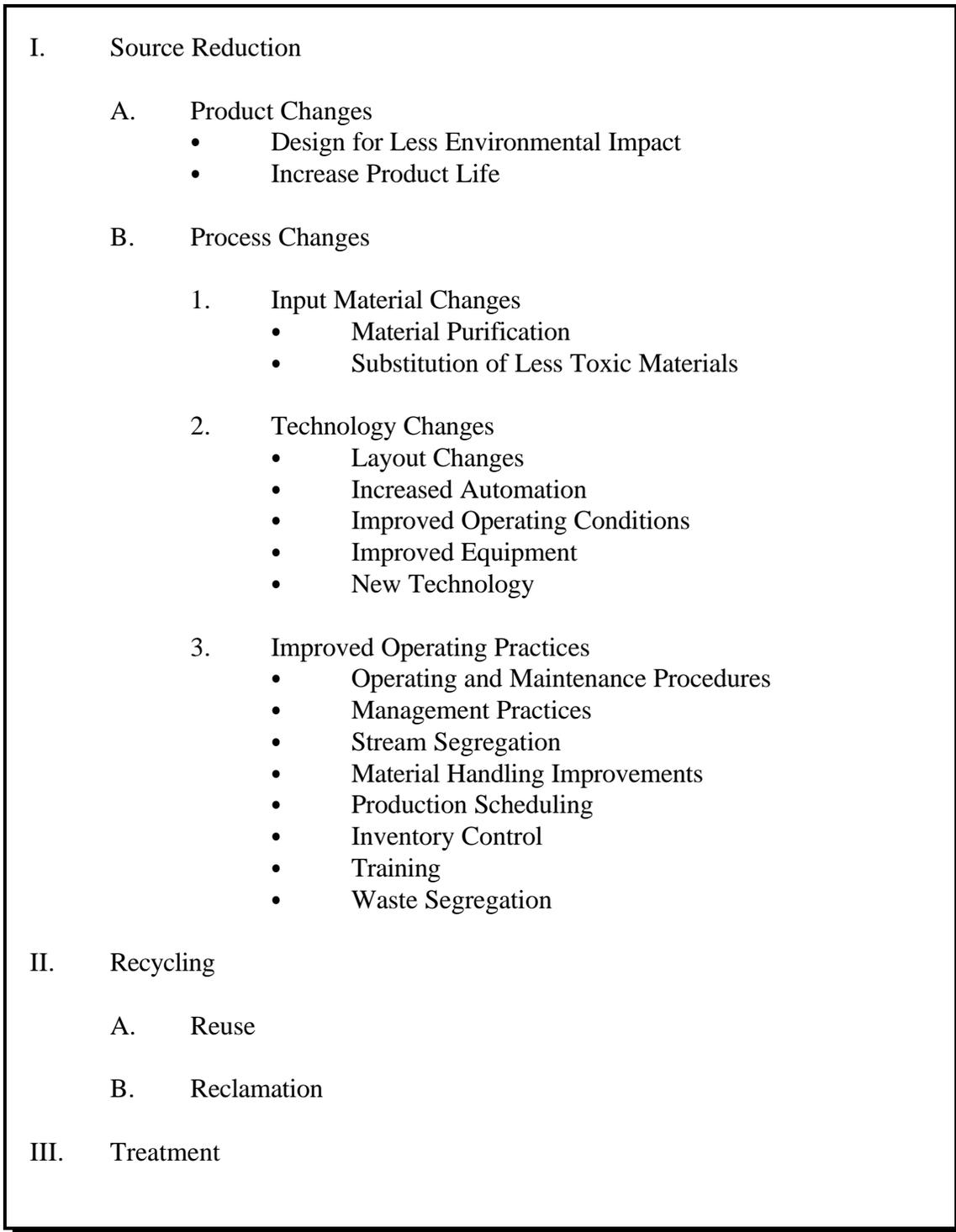
Pollution prevention in the manufacturing community can be achieved by changing production processes to reduce or eliminate the generation of waste at the source. Pollution control and waste handling measures (including waste treatment, off-site recycling, volume reduction, dilution, and transfer of constituents to another environmental medium) are not considered pollution prevention because such measures are applied only after wastes are generated.(1)

The Pollution Prevention Act of 1990 and EPA's 1991 Pollution Prevention Strategy establish an environmental management hierarchy that includes (in order of highest priority): source reduction, recycling, treatment, and disposal or release.(1) Essentially, the environmental hierarchy establishes a set of preferences, rather than an absolute judgment, that source reduction is always the most desirable option. Adoption of the source reduction option, for example, depends on applicable regulatory requirements, achievable levels of risk reduction, and cost effectiveness. As it applies to industry, the environmental management hierarchy stipulates that:

- Pollution should be reduced at the source whenever feasible;
- Pollution that cannot be reduced should be recycled in an environmentally safe manner whenever feasible;
- Pollution that cannot be reduced or recycled should be treated in an environmentally safe manner whenever feasible; and
- Disposal or other release into the environment should be used only as a last resort and should be conducted in an environmentally safe manner.

Figure 7-1 outlines the environmental management hierarchy, as applied to industry.

Examples of current pollution prevention initiatives in the pharmaceutical manufacturing industry are documented in the U.S. EPA Pollution Prevention Information Clearinghouse (PPIC). Source reduction was achieved at one plant by substituting a water-based material for an organic solvent-based material used to coat tablets. This process change reduced organic air emissions by 24 tons/year, eliminated potential risks associated with solvent inhalation by workers, saved organic solvent purchase costs, avoided potential costs for complying with emission standards, and resulted in a payback period of less than one year.



Reference: United States EPA, Office of Research and Development. Facility Pollution Prevention Guide, EPA/600/R-92/088, May 1992.

Figure 7-1. Environmental Management Options Hierarchy

In a similar case, another plant developed a process using a water-based solvent and new spray equipment for a tablet coating operation. By implementing these process changes, the plant avoided costs associated with purchasing and operating air pollution equipment and saved approximately \$15,000 in annual solvent make-up cost. And at another tablet coating operation, a plant converted from conventional film coating to aqueous film coating, resulting in a reduction of methylene chloride usage from approximately 60 tons/year to approximately 8 tons/year. (2)

Another plant used conventional separation processes to recover and reuse 70% of the acetone contained in the plant wastewater. Prior to recycling, the plant discharged wastewater containing approximately 200,000 lb/yr of acetone to a POTW. By recycling the acetone, the facility saves approximately \$70,000 in annual treatment costs, reduces the amount of acetone purchased, and reduces liabilities by generating less waste.

Additional examples of waste minimization and guidance on pollution prevention specific to the pharmaceutical manufacturing industry are provided in several documents published by the Agency, including *Guides to Pollution Prevention: The Pharmaceutical Industry* (EPA/625/7-91/017, October 1991) and *Pollution Prevention Assessment for a Manufacturer of Pharmaceuticals* (EPA/600/S-95/030, August 1995).

7.2.1.2 Efforts to Incorporate Pollution Prevention during the Regulatory Development Process

As demonstrated in the previous examples, pollution prevention initiatives can reduce the toxicity and volume of a pharmaceutical manufacturing facility's waste while lowering liability risk and operating costs. With such benefits in mind, EPA's Office of Water worked with the Food and Drug Administration (FDA) and EPA's Office of Pollution Prevention and Toxics (OPPT) to incorporate pollution prevention into the final pharmaceutical manufacturing industry effluent limitations guidelines and standards.

Prior to the implementation of a new drug manufacturing process the manufacturer must submit a new drug application to the FDA. During its review of a new drug application, the FDA assesses

the safety, efficacy, and quality of the drug. The FDA also examines the safety to the human environment from the manufacture and use of the drug. This examination includes an environmental assessment, review of clinical trials and animal trials of the drug. The FDA will also assess other factors such as the stability of the drug (shelf life) and the extent of drug absorption into the bloodstream.

Prior to the implementation of a change in a drug manufacturing process, that has already been approved by the FDA, a manufacturer must submit a supplement application to the FDA. During its review of a supplement application, the FDA assesses whether the proposed process change will produce a drug that equals or surpasses the efficacy and quality of the drug which was produced using the initial (unaltered) manufacturing process.

In the past, the length of time required by FDA to review and approve supplement applications (i.e., applications that propose changes to existing pharmaceutical manufacturing processes) has deterred the implementation of pollution prevention measures. However, since the enactment of the "Prescription Drug User Fee Act of 1992," 21 U.S.C. 379 et seq., Pub. L. 102-571, October 29, 1992, the FDA has committed to using the revenues generated under that Act to expedite the prescription drug review and approval process, including expediting decisions on supplements relating to pollution prevention-oriented process changes. EPA believes that such expeditious processing of supplements will eliminate impediments that presently discourage pharmaceutical plants from making process changes necessary to achieve source reductions. Additionally, EPA has transferred information collected from the pharmaceutical manufacturing industry via the Detailed Questionnaire to FDA, as stated in the August 23, 1993 Federal Register Notice (58 FR 44519). This information will enable FDA to develop a list of processes that could be the subject of supplement applications.

The Office of Water also worked with OPPT to develop 3b of the Detailed Questionnaire. This contains questions pertaining to waste minimization/pollution prevention efforts implemented at each facility in 1990. Two hundred and eighty Detailed Questionnaires were sent to pharmaceutical manufacturing facilities in 1991, and responses were received from 244 facilities. Three of the 244 facilities that responded to the questionnaire gave no response to 3b. Eighty-

nine of the 244 facilities indicated that they had no pollution prevention programs in place. One hundred and fifty-two of the 244 facilities claimed to have a pollution prevention program in place on site. Ninety of the 152 facilities with pollution prevention programs in place reported that their program did not include their pharmaceutical manufacturing processes. Sixty-two of the 152 facilities reported that the pollution prevention program implemented on site included their pharmaceutical manufacturing processes.

The 62 facilities that identified pollution prevention programs relevant to their pharmaceutical manufacturing processes reported 89 specific waste minimization/pollution prevention activities implemented at their facilities in 1990, and described these activities in the Detailed Questionnaire. The types of activities undertaken are summarized below.

Source Reduction				Number of Recycling Activities Reuse/Reclamation	Total Activities
Number of Product Changes	Number of Process Changes				
	Input Material Changes	Technology Changes	Improved Operating Practices		
3	22	16	16	32	89

Examples of pollution prevention activities reported by pharmaceutical manufacturing facilities include the following:

- **Product Changes** - Eliminate product packaging, and reformulate vitamin product filmcoats to remove volatile organic pollutants.
- **Input Material Process Changes** - Eliminate and/or reduce acetic acid, acetone, aerosols, chloroform, methanol, methylene chloride, toluene, and 1,1,1-trichloroethane from various production processes.
- **Technology Process Changes** - Install solvent recovery units; implement automated cleaning system for wastewater reduction; design closed-loop solvent recovery units for all new processes; and replace solvent-based cleaning units with water-based cleaning units.
- **Improved Operating Practices** - Separate nonquality products from batches earlier in production process; improve reclamation systems and

distillation capabilities; combine solvent waste streams to avoid need for multiple recovery systems; and reduce overall waste solvent generation.

- **Recycling/Reuse Activities** - Recycle/reuse alcohol, aqueous ammonia, dicyclohexylamine, dimethylaniline, freon, packaging materials, plastics, solvents, spent nickel catalyst wastes, steel drums, treated wastewater, 1,1,2-trichloroethane, triethylamine, and wooden pallets.

In addition to reporting pollution prevention activities, pharmaceutical manufacturing facilities reported quantities of chemicals that were recycled/reused. Table 7-2 summarizes the quantity of chemicals recycled/reused by pharmaceutical manufacturing facilities during 1990, as reported in the Detailed Questionnaire responses. As shown in the table, a total of approximately 335,000,000 pounds of 15 different chemicals were recycled/reused at the facilities during 1990.

The diversity of reported pollution prevention activities and recycled/reused chemicals demonstrate the facility-specific and/or process-specific nature of pollution prevention initiatives. Many of the examples listed are applicable to specific manufacturing processes and are not transferable to other operations. As reported in 3b of the Detailed Questionnaire, pollution prevention opportunities are generally site- and process-specific in the pharmaceutical manufacturing industry.

In the preamble to the proposed regulations, EPA discussed the possible pollution prevention alternatives available in pharmaceutical manufacturing. At that time, EPA indicated that pollution prevention opportunities were limited in the active ingredient manufacturing subcategories (namely, fermentation, natural extraction and chemical synthesis) but the use of water-based coatings in the formulation subcategory operations was a viable pollution prevention approach which eliminates the need for solvents in tablet coating operations. This approach may only be applicable to some and not most tablet coating operations, however. Since the proposal, EPA has received two suggestions for incorporation of pollution prevention into the final regulations which were discussed in the August 8, 1997 Notice of Availability at 62 FR 42720. One suggestion presented to the Agency was that Subcategories B and D dischargers that incorporate best management practices (BMPs), which reduce their discharge of any of the regulated pollutants should not have to monitor for the specific regulated pollutants, and possibly only monitor for the

conventional pollutants and COD. This pollution prevention approach is similar to the one adopted in the Pesticide Formulators, Packagers and Repackagers (PFPR) final regulation which was published in the Federal Register on November 6, 1996 at 61 FR 57518. (It should be noted that PFPR facilities that use the promulgated pollution prevention option have to assess their wastewater and may be required to treat wastewater prior to discharge). EPA evaluated this suggestion and decided that since EPA is not promulgating BAT limitations for specific organic pollutants (see 11.3), this pollution prevention suggestion was not relevant to compliance by subcategory B and D direct dischargers with final BAT limitations. For PSES, EPA believes the suggestion may be workable for indirect dischargers, since standards for specific organic pollutants are contained in the final rule, however, no information was submitted to identify the pollution prevention practices that would be incorporated into the rule, and EPA has been unable to identify any.

Another pollution prevention approach suggested to EPA was that Subcategories A and C facilities that can demonstrate a reduction in the use of a regulated pollutant and resultant lowered air emissions or water discharges should receive a higher effluent discharge limitation. As suggested, the higher effluent discharge limitation would be directly proportional to the amount of reduction achieved in the use of the regulated pollutant. Along with this suggestion, the commenters provided examples of how this pollution prevention suggestion could work in individual instances.

In evaluating this suggestion including the examples provided, EPA was concerned about the amount and type of process information that would have to be obtained from facilities and the methodology for estimating the pollutant reductions as the result of any pollution prevention practices. Another concern of the Agency had to do with the determination of when, in the new product development phase of work, the practice represents a pollution prevention activity or is just part of normal process development work in bringing a new product process to full scale production. EPA was also concerned that pollutant discharge or emission reductions achieved in the bench scale or pilot scale product development activities may not be realized during full scale production operations. In the period following publication of the NOA, the Agency did not

receive sufficient information relative to these concerns to enable it to develop a viable pollution prevention alternative based on this suggestion.

Furthermore, pollution prevention initiatives are not part of the technology basis of the final regulatory options for the pharmaceutical manufacturing industry because of several important constraints. First, Food and Drug Administration (FDA) review and approval is required before any modifications in manufactured pharmaceutical products or pharmaceutical manufacturing processes are permitted. EPA determined that it was not appropriate to include process modifications as part of the basis for regulatory options, when such modifications would need to be reviewed and approved by FDA on a case-by-case basis. Second, as discussed earlier in this section, the pharmaceutical manufacturing industry is complex and varied, and, therefore, EPA determined that the pollution prevention opportunities that exist are facility-, process-, and product-specific. EPA did not identify any specific pollution prevention techniques that could be incorporated into regulatory options and applied on a category- or subcategory-wide basis.

However, in addition to evaluating opportunities for reduced discharge and source reduction, EPA also examined potential treatment technologies to determine whether any might promote recovery, recycling, and reuse of process wastewater generated by pharmaceutical manufacturing operations, such as solvents. After evaluating the various technologies available to treat volatile-laden wastewaters, EPA concluded that for indirect discharging facilities, in-plant technologies such as steam stripping offered the best opportunity for recovery of solvents from wastewater. Steam stripping in plant not only avoids the dilution effects of commingling process wastewater streams and the transfer of volatile pollutants to air associated with other technologies, but it also allows the pharmaceutical manufacturing operation to recover the stripped solvents from the treatment process in an efficient and cost-effective manner from concentrated streams. These recovered solvents can then be recycled back into the process from which they were removed, reused in other manufacturing operations (e.g., in this industry or in other industries), or reused as "clean fuel" for boilers or other combustion devices. For a discussion of "clean fuels," see 12.4.3.

Thus, the Agency believes that the final regulation will foster the implementation of pollution prevention and recycle/reuse initiatives even though pollution prevention measures are not specifically part of the technologies upon which the final limitations and standards are based. Numerous facilities will use pollution prevention measures that reduce pollutant loadings and volumes of waste generated as part of a cost-effective strategy to comply with the final effluent limitations guidelines and standards.

7.2.2 Advanced Biological Treatment

7.2.2.1 General Description

Advanced biological treatment is used in the pharmaceutical manufacturing industry to treat BOD₅, COD, TSS, and to degrade various organic constituents. The term "advanced" is used to refer to treatment systems that consistently surpass, on a long-term basis, 90% BOD₅ reduction and 74% COD reduction in pharmaceutical manufacturing wastewater, as required by the existing BPT effluent limitations guidelines (40 CFR Part 439). To provide reduction of ammonia in the wastewater using advanced biological treatment, nitrification is necessary.

Biological systems can be divided into two basic types: aerobic (treatment takes place in the presence of oxygen) and anaerobic (treatment takes place in the absence of oxygen). According to responses to the Detailed Questionnaire, only two pharmaceutical manufacturing facilities reported using anaerobic biological treatment systems. The four most common aerobic treatment technologies in the industry are activated sludge systems, aerated lagoons, trickling filters, and rotating biological contactors (RBC).

In aerobic biological treatment processes, oxygen-requiring microorganisms decompose organic and nonmetallic inorganic constituents into carbon dioxide, water, nitrates, sulfates, organic byproducts, and cellular biomass. The microorganisms are maintained by adding oxygen and nutrients (usually nitrogen and phosphorous) to the system. Activated sludge and aerated lagoon processes are suspended-growth processes in which the microorganisms are maintained in suspension within the liquid being treated. The trickling filter and RBC processes are attached-

growth processes in which microorganisms grow on an inert medium (e.g., rock, wood, plastic). Three types of activated sludge processes were listed as choices in the Detailed Questionnaire: single, two-stage, and oxygen-activated sludge. Table 7-1 lists these processes under the heading "Biological Treatment." As can be seen in the table, the majority of biological treatment systems used in the industry are activated sludge systems.

An activated sludge treatment system normally consists of an equalization basin, a settling tank (primary clarifier), an aeration basin, a secondary clarifier, and a sludge recycle line. Equalization of flow, pH, temperature, and pollutant loads is necessary to perform consistent, adequate treatment. The settling tank is used to remove settleable solids prior to aeration. The aerobic bacterial population is maintained in the aeration basin, in which oxygen, recycled sludge, and nutrients are added to the system. Oxygen is normally supplied by aerators that also provide mixing to help keep microorganisms in suspension. Recycled sludge is added to keep an optimal concentration of acclimated microorganisms in the aeration basin. The secondary clarifier controls the amount of suspended solids discharged, as well as provides sludge for recycle to the aeration basin (3). Sludge produced by these systems generally consists of biological waste products and expired microorganisms. This sludge may accumulate under certain operating conditions and may therefore require periodic removal from the aeration basin.

Generated sludge will require some type of storage, handling, and disposal. Biological sludges are normally treated in a two-step process prior to disposal: thickening followed by dewatering. Other sludge treatment may also be performed, but these processes are the most common. The goal for each of these operations is to decrease the overall volume of sludge. Thickening of waste-activated sludge is normally performed in one of three ways: gravity separation, dissolved-air flotation, or centrifuging. Generally, thickeners will increase the solids content of sludge from 1% (typical from biological treatment) to 4 or 5%. Sludge dewatering is normally performed using some type of filter, including filter presses, vacuum filters, and belt filters. These units normally can increase the solids content in sludge from 5% up to 15 to 30%, which greatly reduces the shipping, handling and disposal costs associated with sludge generation from a biological treatment unit. (4)

Some key design parameters for activated sludge systems include nutrient-to-microorganism ratio, mixed liquor suspended solids (MLSS), sludge retention time, oxygen requirements, nutrient requirements, sludge production, substrate removal rate constant (K), and percent BOD₅ of effluent TSS. Pharmaceutical manufacturing industry averages for some of these parameters are presented in the following table.

Parameter	Subcategories A and C Average	Subcategories B and D Average
Food to Microorganism Ratio (lb/lb/day)	0.561	0.054
MLSS (mg/L)	5,521	3,443
Sludge Retention Time (hours)	33.0	22.9
K	11.14	2.06
%BOD ₅ of TSS	23	24

Ammonia treatment by nitrification is achieved in biological treatment units by incorporating two additional sets of autotrophic microorganisms. The first set of microorganisms (Nitrosomonas bacteria) converts ammonia to nitrites and the second set (Nitrobacter bacteria) converts nitrites to nitrates. These microorganisms are maintained in the treatment tank in a similar fashion as the microorganisms described above (addition of oxygen, nutrients, etc). Nitrification can be accomplished in either a single or two-stage activated sludge system. Indicators of nitrification capability are 1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and 2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate. Common design criteria for single and two-stage systems with nitrification capability are:

Parameter	Single Stage	Two-Stage
Suspended growth Food/Microorganism ratio (g BOD ₅ /g MLVSS/d)	0.05-0.15	<0.15
Sludge retention time (days)	20-30	10-20
MLVSS (mg/L)	2,000 - 3,000	1,500 - 2,500
pH (standard units)	7.2 - 8.5	7.2 - 8.5

7.2.2.2 Industry Application

Based on responses to the Detailed Questionnaire, 58 of 244 responding facilities in the pharmaceutical manufacturing industry use some form of activated sludge treatment process, 12 use aerated lagoons, 5 use trickling filters, and 3 use RBC treatment. Most of these facilities are operated at or near the facility off-site wastewater discharge point (end-of-pipe). There are no specific data regarding whether the treatment units are used primarily to reduce concentrations of conventional pollutants or organic constituents in the wastewater. However, it is likely that these systems were initially designed to treat BOD₅ and COD.

7.2.3 Multimedia Filtration

7.2.3.1 General Description

Multimedia filtration is used in the pharmaceutical manufacturing industry to reduce TSS in wastewater. This technology may also serve to treat BOD₅ in wastewater by removing BOD₅ associated with particulate matter. A multimedia filtration system operates by introducing a wastewater to a fixed bed of inert granular media. Suspended solids are removed from the wastewater by one or more of the following processes: straining, interception, impaction, sedimentation, and adsorption. This operation is continued until there is either solids "breakthrough" (solids concentration increases to an unacceptable level in the discharge from the bed), or the head loss across the bed becomes too great (due to trapped solids) to operate the bed efficiently.

If either of these conditions occurs, the bed must be cleaned by backwashing before it can be operated effectively again. Backwashing usually is accomplished by reversing the flow to the bed and introducing a "clean" stream of wash water. Wash water is introduced until the bed becomes fluidized (expanded). At this point, the solids are washed from the bed and carried away from the unit. It is common to return the backwashed solids stream to the biological treatment system (if applicable).

In multimedia filtration, a series of layers, each with a progressively smaller grain size medium (traveling from inflow to outflow of the bed) are used in the filtration bed. This design allows solids to penetrate deeper into the bed before becoming fixed, thus increasing the capacity of the bed and decreasing the buildup of head loss in the unit. Typical filtration media include garnet, crushed anthracite coal, resin beads, and sand. Though downflow (gravity flow) systems are the most common, upflow and biflow (influent is introduced above and below the filter medium, and the effluent discharges from the center of the filter medium) filtration units can also be used.

Figure 7-2 shows a cross-of a typical downflow, multimedia filtration bed. (4)

Some key design parameters associated with multimedia filtration units include wastewater flow rate, hydraulic loading rate, and filter medium depth. The following table shows ranges of values for each of these parameters for treatment units currently operated in the pharmaceutical manufacturing industry.

Parameter	Range	Units
Flow Rate	0.03 - 2.18	MGD
Hydraulic Loading Rate	2.0 - 5.0	gpm/ft ²
Depth of Medium	6 - 72	inches

7.2.3.2 Industry Application

Based on responses to the Detailed Questionnaire, 6 of 244 responding pharmaceutical manufacturing facilities use multimedia filtration treatment. This treatment is generally performed after biological treatment (if applicable) for additional TSS removal prior to wastewater discharge. Multimedia filtration can also provide limited treatment of BOD₅ by removing the BOD₅ load associated with suspended solids. The following is the breakdown of specific applications of multimedia filtration treatment in the industry: four facilities use multimedia filtration as a tertiary wastewater treatment, one facility uses it to treat noncontact cooling water prior to recycle, and one facility uses it as a treatment prior to granular activated carbon (GAC) treatment.

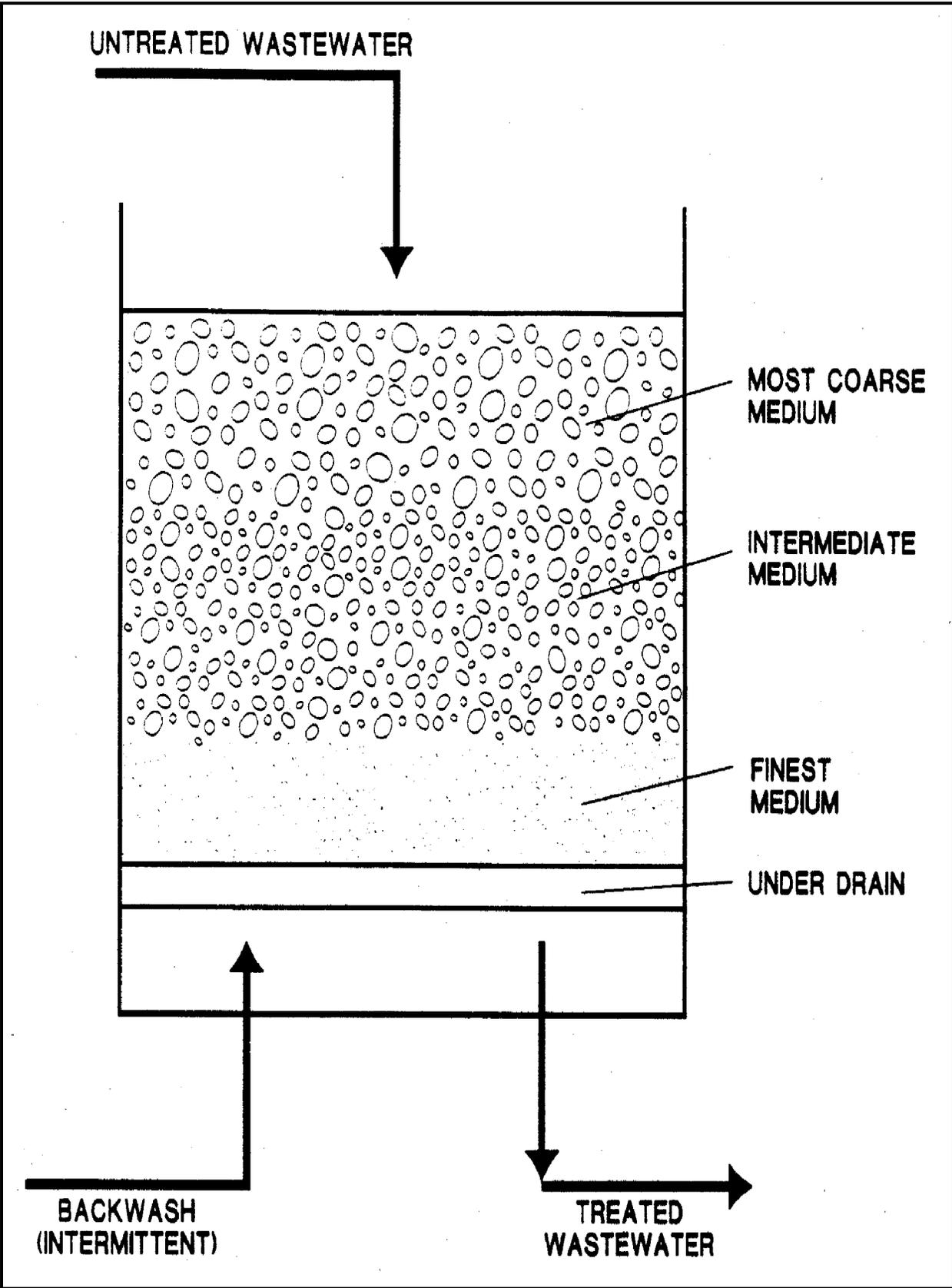


Figure 7-2. Typical Downflow Multimedia Filter Bed

7.2.4 Polishing Pond

7.2.4.1 General Description

Polishing ponds are used in the pharmaceutical manufacturing industry to remove TSS from wastewater using gravity settling. Some BOD₅ removal associated with the settling of suspended solids may also occur.

The wastewater is introduced at one end of the pond and ultimately flows out the other end. The pond is designed such that the water retention time is long enough and the water velocity is slow enough to allow solids to fall out of suspension. If the flow is too fast, or other mixing is added to the system, solids may be maintained in suspension and discharged from the pond.

To avoid anaerobic conditions in the bottom portion of the pond, these units must be designed to be shallow, which may require a large land area if flow to the unit is high. Depths of polishing ponds currently used in the industry range from 2.5 to 14 feet. Retention times range from 0.2 to 14.6 days. In the past, polishing ponds have been designed with an earthen liner only; however, current regulations require installation of a minimum of two liners and a leak detection system (40 CFR 264.221) for most new applications to this industry. Polishing ponds will accumulate solids over time and will therefore require periodic cleanout.

7.2.4.2 Industry Application

Based on responses to the Detailed Questionnaire, 8 of 244 responding pharmaceutical manufacturing facilities use polishing ponds to treat wastewater. This treatment is not currently common in the industry, and because of increasing regulatory requirements governing the use of ponds (surface impoundments), facilities have limited plans for installation of more of these units. For the facilities that use polishing ponds, this technology is generally used to treat wastewater just prior to discharge to the receiving stream or POTW.

7.2.5 Cyanide Destruction

7.2.5.1 General Description

Several cyanide destruction treatment technologies are currently used in the pharmaceutical manufacturing industry, including alkaline chlorination, hydrogen peroxide oxidation, and basic hydrolysis. The alkaline chlorination treatment process involves reacting free cyanide with hypochlorite (formed by reacting chlorine gas with an aqueous sodium hydroxide solution) to form nitrogen and carbon dioxide. The reaction is a two-step process and is normally performed separately in two reactor vessels. Because treatment is normally performed in batches, it is necessary to use an additional equalization tank to store accumulated wastewater during treatment. The reactors need to be equipped with agitators, and both reaction steps require close monitoring of pH and oxidation/reduction potential (ORP). These reactions are normally performed at ambient temperatures. (5)

Hydrogen peroxide treatment involves adding hydrogen peroxide to cyanide-bearing wastewater to convert free cyanide to ammonia and carbonate ions. This treatment is normally performed batch-wise in a reaction vessel or vessels. The treatment process consists of heating the wastewater to approximately 125°F and adjusting the pH in the reaction vessel to approximately 11. Hydrogen peroxide is added to the vessel and is allowed to react for approximately one hour. Required equipment for this process includes reaction vessel(s), storage vessels for hydrogen peroxide and a pH adjustment compound (typically sodium hydroxide), an equalization tank, and feed systems for hydrogen peroxide and sodium hydroxide.(5)

Hydrolysis treatment involves reacting free cyanide with water under basic conditions to produce formate and ammonia. This process requires approximately one hour to proceed and is typically performed at a temperature between 170 and 250°C, and at a pH of between 9 and 12.

Hydrolysis is normally performed in a reactor vessel equipped with a heat exchanger and a system to store and deliver sodium hydroxide (or other basic compound).

7.2.5.2 Industry Application

Based on responses to the Detailed Questionnaire, 10 of 244 responding pharmaceutical manufacturing facilities use cyanide destruction treatment. Of these, six use alkaline chlorination, three use hydrogen peroxide oxidation, and one uses hydrolysis. Most of these facilities apply the cyanide destruction technologies in the process area that generates the cyanide-bearing wastewater, and most of the treatment units are operated in batch mode.

7.2.6 Steam Stripping and Steam Stripping with Rectification

Steam stripping and steam stripping with rectification are used both in industrial chemical production (for chemical recovery and/or recycle) and in industrial waste treatment to remove gases and/or organic chemicals from wastewater streams by providing steam to a tray or packed column. Under both technologies, differences in relative volatility between the organic chemicals and water are used to achieve a separation. The more volatile components of the feed mixture concentrate in the vapor, while the less volatile components concentrate in the liquid residue (bottoms). Steam stripping and steam stripping with rectification are effective treatment for a wide range of aqueous streams containing organics and ammonia. Appropriately designed and operated columns can treat a variety of waste streams ranging from wastewaters containing a single volatile constituent to complex organic/inorganic mixtures. Steam stripping and steam stripping with rectification can be used both as in-plant processes to recover concentrated organics from aqueous streams and as end-of-pipe treatment to remove organics from wastewaters prior to discharge or recycle. For most effective wastewater treatment, columns should be placed after the process generating the wastewater and before the wastewater is combined with other wastewater that does not contain the pollutants being treated. Wastewater with high concentration and low flow is easier and less expensive to treat than wastewater with high flow and/or low concentration. In addition, the amount of volatiles emitted to the air can be minimized if columns are placed prior to exposure of the wastewater stream to the atmosphere.

7.2.6.1 General Description

Steam stripping and steam stripping with rectification can be conducted as either a batch or continuous operation in a packed tower or fractionating column (sieve tray or bubble cap) with more than one stage of vapor-liquid contact. In a steam stripping column, the wastewater feed enters near the top of the column and then flows downward by gravity, countercurrent to the steam which is introduced at the bottom of the column. In a steam stripping with rectification column, the wastewater feed enters lower down the column to allow for a rectification above the feed. In the rectification section, a portion of the condensed vapors are refluxed to the column to countercurrently contact the rising vapors. This process concentrates the volatile components in the overhead stream.

Steam may either be directly injected or reboiled, although direct injection is more common. The steam strips volatile pollutants from the wastewater, which are then included in the upward vapor flow. As a result, the wastewater contains progressively lower concentrations of volatile compounds as it moves toward the bottom of the column. The extent of separation is governed by physical properties of the volatile pollutants being stripped, the temperature and pressure at which the column is operated, and the arrangement and type of equipment used.

The difference between steam stripping columns and steam stripping with rectification columns is the location of the feed stream. Stripping columns have a feed stream located near the top of the column while steam stripping with rectification columns have a feed stream located further down the column. Pollutants that phase separate from water can usually be stripped from the wastewater in a steam stripper (a column without rectifying stages). Pollutants that are not phase-separable, such as methanol, need a column with rectifying stages to achieve a high concentration of the pollutants in the overhead stream.

The ancillary equipment used in conjunction with steam stripping and steam stripping with rectification columns includes a condenser and subcooler, pumps for the feed, overhead, bottoms, and reflux streams, a feed preheater and bottoms cooler, a decanter, a storage tank, a distillate tank, and an air pollution control device to contain any vapors from the condenser. The

condenser and subcooler condense and cool the overhead stream to a temperature amenable for storage and disposal. The pumps supply the force to move the waste stream: either into the column at the feed position or at a point above the feed in the case of a reflux stream. The bottoms pump moves the bottoms from the stripping column to the bottoms cooler, and the overheads distillate pump moves the distillate from the decanter to the distillate receiver tank. The feed preheater/bottoms cooler is a heat exchanger that heats the feed before it enters the column at the same time it cools the bottoms stream so that it can be sent to a storage area or treatment system. The decanter separates the aqueous layer from the organic layer after the stream comes from the condenser and subcooler. The aqueous layer can be refluxed back to the column while the organic layer is usually disposed of or reused. The storage tank provides a steady feed for the steam stripper column, equalizing flow and waste variability. An air pollution control device may be needed to contain any pollutants that do not condense in the condenser and would otherwise escape to the air. Wet scrubbers, carbon adsorption devices, or venting to a combustion device may be used to control air emissions. Figure 7-3 shows a flow diagram of a typical steam stripping treatment system and Figure 7-4 shows a flow diagram of a typical steam stripping with rectification treatment system.

The typical construction material for steam stripping and steam stripping with rectification columns in the pharmaceutical manufacturing industry is stainless steel. If a wastewater stream is highly corrosive, a more corrosion-resistant material, such as Hastelloy or Teflon®-lined carbon steel, may be required for construction of the column. The majority of pharmaceutical manufacturing facilities which currently use steam stripping and/or steam stripping with rectification columns to treat their wastewater use stainless steel.

Salts and other pollutants may contribute to scaling and corrosion inside the column. Timely maintenance should be provided to deter scaling problems. Costs of these measures are discussed in 10.

The key design parameters for stripping columns are the steam-to-feed ratio and the number of trays or equilibrium stages in packed columns. These parameters are calculated using the

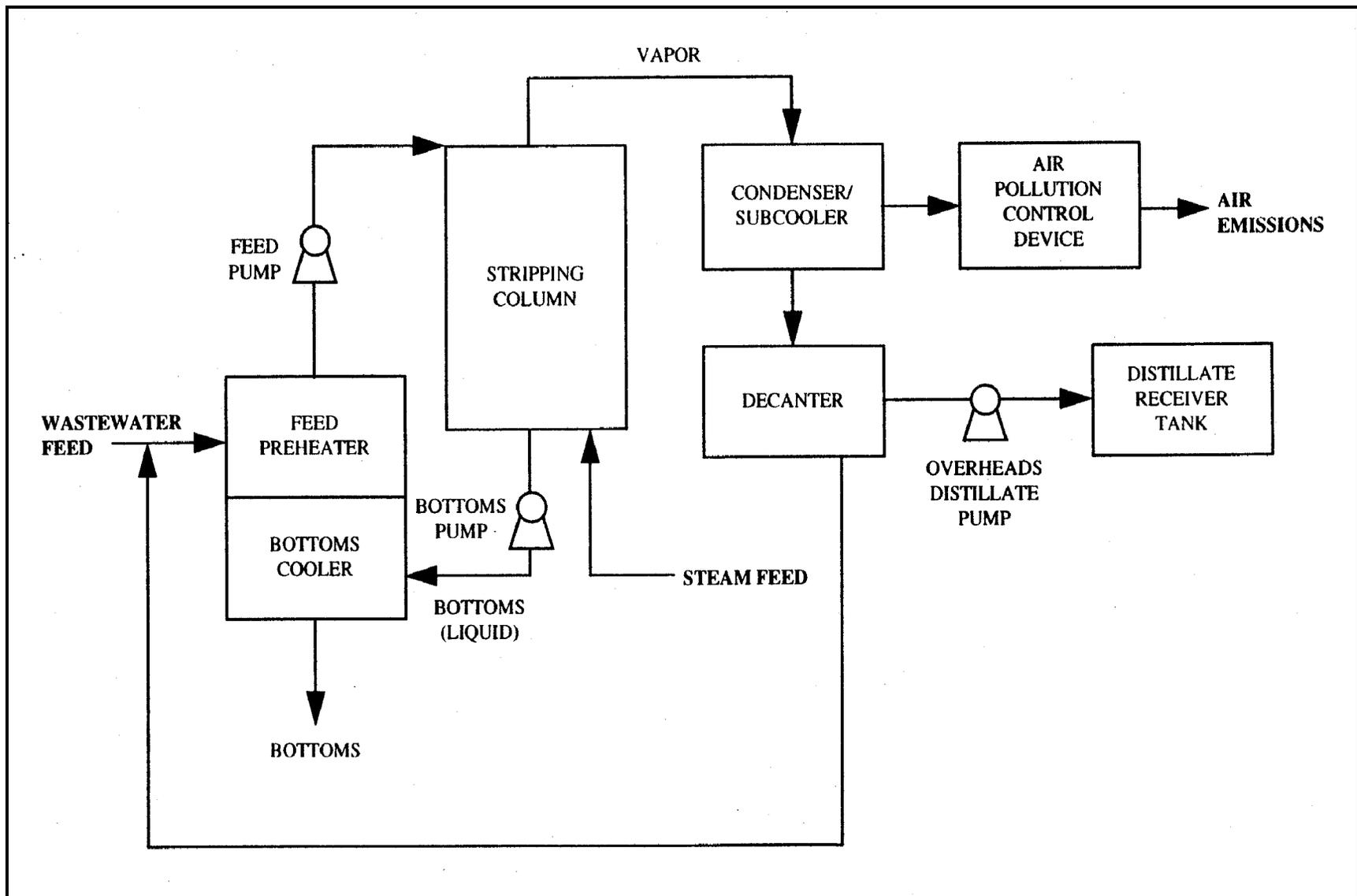


Figure 7-3. Steam Stripping Column Diagram

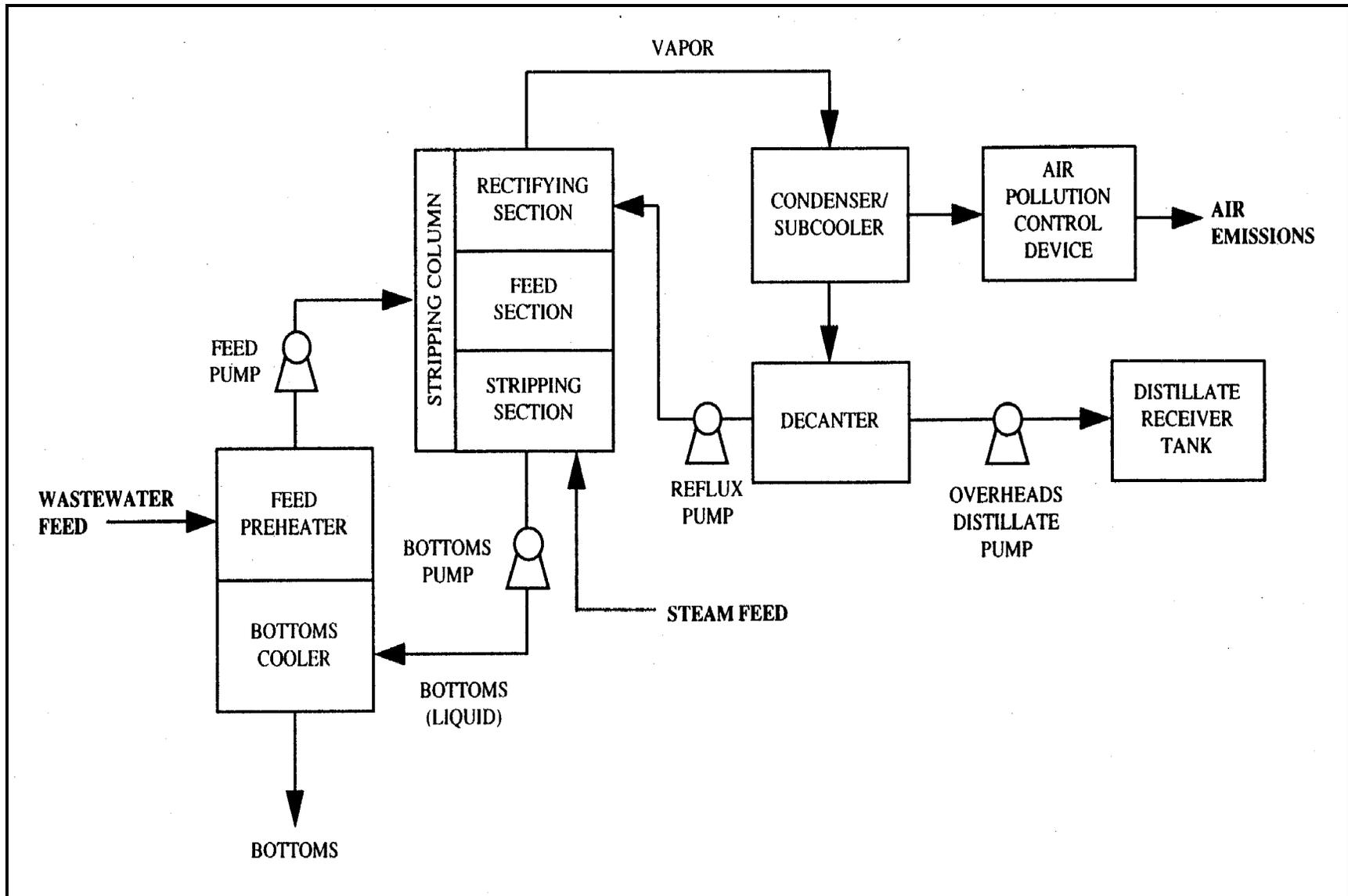


Figure 7-4. Steam Stripping and Rectification Column Diagram

equilibrium ratio of the least strippable contaminant in the wastewater stream and the removal efficiency required to treat the contaminant to the desired concentration. Typical ranges for steam-to-feed ratios vary from 1:3 to 1:35, and the typical number of trays or equilibrium stages vary from 2 to 20. Generally, columns with smaller diameters are packed while columns with larger diameters have trays. Typical column packings are Pall rings, Rashing rings, Berl saddles, and Intalox saddles.

7.2.6.2 Industry Application

In responses to the Detailed Questionnaire, 61 of 244 responding facilities in the pharmaceutical manufacturing industry reported using steam stripping with rectification for solvent recovery operations. Fourteen facilities reported using steam strippers for wastewater treatment. However, a review of these 14 facilities resulted in a determination by the Agency that only four were actually using the technology for wastewater treatment, while the other ten facilities were using the strippers for solvent recovery purposes. Steam stripping and steam stripping with rectification columns are currently used in this industry as stand-alone treatment or as pretreatment before biological treatment. They are also used to recover specific constituents from waste streams. Direct dischargers tend to use steam stripping or steam stripping with rectification as a pretreatment before biological treatment more frequently than as a stand-alone treatment, whereas indirect dischargers tend to use steam stripping or steam stripping with rectification more as a stand-alone treatment or to recover a specific constituent from the waste stream.

7.2.7 Granular Activated Carbon Adsorption

7.2.7.1 General Description

Granular activated carbon (GAC) adsorption is used in the pharmaceutical manufacturing industry to treat BOD₅, COD, or organic constituents in wastewater. Adsorption is a process in which soluble or suspended materials in water are bonded onto the surface of a solid medium. Activated carbon is an excellent medium for this process because of its high internal surface area, high

attraction to most adsorbates (the constituents to be treated), and the fact that it is hydrophobic (water will not occupy bonding sites and interfere with the adsorption process). Constituents in the wastewater bond onto the GAC grains until all surface bonding sites are occupied. At this point, the carbon is considered to be "spent", and requires regeneration, cleaning, or disposal.

Activated carbon is normally produced in two standard grain sizes: powdered activated carbon (PAC) with diameters less than a 200 mesh, and GAC with diameters greater than 0.1 mm. PAC is generally added to the wastewater, whereas GAC is normally used in flow-through fixed bed units.

For treatment units, GAC is packed into one or more beds or columns. Multiple beds are more common, and are normally operated in series because this design allows for monitoring between beds, and therefore minimizes the risk of discharging wastewater from the system with concentrations above acceptable levels. Wastewater flows through a bed and is allowed to come in contact with all portions of the GAC. The GAC in the upper layers of the bed is spent first as bonding sites are occupied, and the GAC in progressively lower regions is spent over time as the adsorption zone moves down through the unit. When contaminant concentrations begin to increase at the bottom of the bed above acceptable levels, the bed is considered to be spent and must be removed. The above description assumes that beds are operated in downflow mode; however, it is also possible to use an upflow design for GAC systems.

Once a bed is spent, the carbon can be treated in three ways: regeneration, backwash, or disposal. Normally, it is possible to use high heat (1,500 to 1,700° F), steam, or chemical treatment to regenerate the spent carbon. These processes remove contaminants from the carbon without significantly affecting the carbon itself; however, some carbon is lost each time this procedure is performed, and carbon performance decreases slightly with each regeneration. Because the bonds formed between the GAC and the adsorbate are not generally strong, it may also be possible to backwash the carbon bed as described in 7.2.3. If the carbon cannot be regenerated or backwashed, it must be disposed of as a solid waste.

The performance of GAC treatment units can be affected by several factors. Three important design criteria are saturation loading, wastewater TSS concentration, and hydraulic loading. Saturation loading is a treatment performance coefficient relating mass of contaminant adsorbed versus mass of carbon used. If this coefficient is very low (as is the case for highly soluble constituents), a GAC system will not perform efficiently. Parameters that effect solubility (i.e., pH and temperature) must also be considered when calculating a design saturation loading for a system. High TSS concentrations in wastewater will foul the GAC system. Solids will occupy bonding sites on the carbon and will get plugged in the pore spaces between GAC grains. If this happens, head loss may occur and a portion of the carbon bed will not be used for treatment. Flushing to remove solids can upset the mass flux zone in the GAC system. In some cases, it may be necessary to install some type of filtration prior to GAC treatment to keep TSS concentrations within acceptable limits. The effectiveness of GAC can only improve with lower TSS, and ideally, TSS levels in the influent should be as close to zero as possible. The amount of time the wastewater spends in contact with the GAC is directly related to hydraulic loading rate. If this time is not long enough, effluent contaminant concentrations will be higher than expected.(3)(4)

7.2.7.2 Industry Application

Based on responses to the Detailed Questionnaire, 10 of 244 responding pharmaceutical manufacturing facilities use GAC treatment to reduce concentrations of organic constituents (and BOD₅ and COD) in wastewater. This treatment is generally used to treat wastewater directly from a production area or somewhere prior to the facility treatment plant. GAC treatment can also be used to remove organics following biological treatment.

7.2.8 pH Adjustment/Neutralization

7.2.8.1 General Description

Because many treatment technologies used in the pharmaceutical manufacturing industry are sensitive to pH fluctuations, pH adjustment, or neutralization, may be required as part of an

effective treatment system. A pH adjustment system normally consists of a small tank (10 to 30 minutes retention time) with mixing and a chemical addition system. To adjust pH to a desired value, either acids or caustics can be added in the mixing tank. Some treatment technologies require a high or low pH to effectively perform treatment (e.g., air stripping of ammonia requires a pH of 10 to 11). pH is generally adjusted to between 6 and 9 prior to final discharge.

7.2.8.2 Industry Application

Based on responses to the Detailed Questionnaire, 126 of 244 responding facilities in the pharmaceutical manufacturing industry use pH adjustment or neutralization treatment of wastes. Retention times for these treatment units average approximately one hour.

7.2.9 Equalization

7.2.9.1 General Description

Because many of the treatment technologies listed in this are performed continuously and some are sensitive to spikes of high flow or high contaminant concentrations, it is necessary to include equalization as a part of most treatment systems. Equalization is normally performed in large tanks or basins designed to hold a certain percentage of a facility's daily wastewater flow. Equalization will equalize high- and low-flow portions of a typical production day by allowing wastewater to be discharged to downstream treatment operations at a constant flow rate. Equalization can also provide a continuous wastewater feed to operations such as biological treatment that perform more effectively under continuous load conditions.

The mixing that occurs in an equalization basin minimizes spikes of various contaminants in the discharged wastewater. This equalization will prevent loss of treatment effectiveness or treatment system failures associated with these spikes.

7.2.9.2 Industry Application

Based on responses to the Detailed Questionnaire, 70 of 244 responding facilities in the pharmaceutical manufacturing industry use equalization. Retention times for these treatment units average approximately 20 hours.

7.2.10 Air Stripping

7.2.10.1 General Description

Air stripping is used in the pharmaceutical manufacturing industry to remove volatile organic constituents from wastewater. Air stripping can also be used to remove ammonia from wastewater. Air stripping is normally performed in a countercurrent, packed tower or tray tower column. In these systems, the wastewater is introduced at the top of the column and allowed to flow downward through the packing material or trays. Air is simultaneously delivered at the bottom of the column and blows upward through the water stream. Volatile organics are stripped from the water stream, transferred to the air stream, and carried out of the system at the top of the column. Treated water discharges from the bottom of the column. If ammonia treatment is desired, the pH of the waste stream would be adjusted to between 10 and 11 prior to introduction to the column.

7.2.10.2 Industry Application

Based on responses to the Detailed Questionnaire, 2 of 244 responding pharmaceutical manufacturing facilities use air strippers to treat wastewater. This technology is not common in the industry, and its use has decreased due to increasingly strict air emission regulations. Because the standard air stripper design simply transfers pollutants from water to air, the Agency does not regard it as an acceptable treatment technology and is not including air stripping as part of the technology base of any of the regulatory options.

7.2.11 Incineration

7.2.11.1 General Description

Incineration is used in the pharmaceutical manufacturing industry to treat organic and inorganic constituents in wastewater. This treatment is typically performed in a fixed bed or multiple hearth incinerator equipped with an acid gas scrubber for control of generated hydrochloric acid. Contaminants in the wastewater are destroyed by combustion and the remaining water vapor is discharged to the atmosphere.

7.2.11.2 Industry Application

Based on responses to the Detailed Questionnaire, 12 of 244 responding pharmaceutical manufacturing facilities use incinerators to treat wastewater. Because incineration is costly and energy-intensive when used to treat high-water content streams and does not allow for direct recycle or reuse of constituents contained in wastewater, the Agency is not including incineration as part of the technology basis for any of the regulatory options.

7.3 Development of Control and Treatment Options

7.3.1 Introduction

This describes the combinations of treatment technologies that the Agency evaluated as technology options for the basis of the promulgated regulations:

- Best practicable control technology currently available (BPT);
- Best conventional pollutant control technology (BCT);
- Best available technology economically achievable (BAT);
- New source performance standards (NSPS);
- Pretreatment standards for existing sources (PSES); and
- Pretreatment standards for new sources (PSNS).

Treatment technologies for each option are selected from the list of technologies presented in 7.2, and include advanced biological treatment, advanced biological treatment with nitrification, cyanide destruction, and steam stripping. In addition, BCT was also evaluated for additional TSS removal using multimedia filtration and polishing pond treatment.

These promulgated regulations establish limits on the discharge of pollutants from industrial point sources. The regulations are based upon the performance of specific technologies, but do not require the use of any specific technology. The regulations applicable to direct dischargers (BPT, BCT, BAT, NSPS) are effluent limitations guidelines and standards that are applied to individual facilities through NPDES permits issued by EPA or authorized states under 402 of the CWA. The regulations applicable to indirect dischargers (PSES, PSNS) are standards, and are administered by local permitting authorities (i.e., the government entity controlling the POTW to which the industrial wastewater is discharged). The final pretreatment standards are designed to control pollutants that pass through or interfere with POTWs.

The treatment technologies that form the basis of the BPT options were selected to provide reduction of BOD₅, COD, and TSS, in pharmaceutical manufacturing wastewater. The treatment technologies that form the basis of the BCT options were selected to provide reduction of BOD₅ and TSS beyond the removals of these pollutants achieved by BPT effluent limitations guidelines. The treatment technologies that form the basis of BAT, PSES, NSPS, and PSNS options were selected to provide reduction of organic constituents, COD, ammonia, and cyanide. 6 identifies the list of organic constituents regulated by these options.

Sections 7.3.2 through 7.3.7 provide discussions of each of the regulatory options described above, including the treatment technologies that form the basis of each option, and the rationale for the development of each of the options. Technologies included under each regulatory option may vary by subcategory and are therefore presented in separate subsections for Subcategories A and C and Subcategories B and D, respectively. Table 7-3 summarizes the regulatory options, identifying the treatment technologies included under each one.

7.3.2 Best Practicable Control Technology Currently Available (BPT)

Effluent limitations guidelines based on the best practicable control technology currently available establish quantitative limits on the direct discharge of pollutants from existing industrial point sources. BPT effluent limitations guidelines are based upon the average of the best existing performance, generally in terms of treated effluent discharged by facilities of various sizes, ages, and unit processes within an industry or subcategory. BPT effluent limitations guidelines are most commonly developed for the control of conventional and nonconventional pollutants, but also may be used for the control of priority pollutants.

In developing BPT, the Agency considers the total cost of applying the technology in relation to the effluent reduction benefits to be achieved from the technologies; the size and age of equipment and facilities; the processes used; the engineering aspects of applying various types of control techniques; process changes; and nonwater quality environmental impacts, including energy requirements.

7.3.2.1 Subcategories A and C

EPA considered five regulatory options as BPT for Subcategories A and C as part of the development of the proposed effluent limitations guidelines for the pharmaceutical manufacturing industry. These options are discussed in detail in the technical development document supporting the proposed rule, and are not discussed further in this section. In the May 2, 1995 proposal, the selected options were based on the application of advanced biological treatment. After gathering additional data after proposal and reviewing comments on the proposed rule and the supplemental Notice of Availability to the proposed rule, the Agency considered four options for the final BPT limitations for Subcategories A and C. Under the first option, EPA would not revise the existing BPT limitations for BOD₅, TSS, COD and cyanide. Under the second option, EPA would revise the BPT limitations based on advanced biological treatment only for COD, and revise the monitoring requirements for the existing cyanide limitations. Under option three, EPA would revise BPT limitations for BOD₅ and TSS based on advanced biological treatment and revise the monitoring requirements for the existing cyanide limitations. Under the fourth option, EPA

would revise BPT limitations for BOD₅, TSS, and COD based on advanced biological treatment, and revise the monitoring requirements for the existing cyanide limitations. The three options with advanced biological treatment are based on a system installed immediately prior to the off-site wastewater discharge point (end-of-pipe). As discussed in 8, advanced biological treatment provides significant removal of BOD₅, COD, and TSS and is widely used in the pharmaceutical manufacturing industry.

7.3.2.2 Subcategories B and D

EPA considered three regulatory options as BPT for Subcategories B and D as part of the development of the proposed effluent limitations guidelines for the pharmaceutical manufacturing industry. These options are discussed in detail in the technical development document supporting the proposed rule, and are not discussed further in this section. In the May 2, 1995 proposal, the selected options were based on the application of advanced biological treatment. After gathering additional data after proposal and reviewing comments on the proposed rule and the supplemental Notice of Availability to the proposed rule, the Agency considered four options for the final BPT limitations for Subcategories B and D. Under the first option, EPA would not revise the existing BPT limitations for BOD₅, TSS, COD and withdraw the existing cyanide limitations. Under the second option, EPA would revise the BPT limitations based on advanced biological treatment only for COD, and withdraw the existing cyanide limitations. Under option three, EPA would revise BPT limitations for BOD₅ and TSS based on advanced biological treatment and withdraw the existing cyanide limitations. Under the fourth option, EPA would revise BPT limitations for BOD₅, TSS, and COD based on advanced biological treatment, and withdraw the existing cyanide limitations.

7.3.2.3 Rationale

Advanced biological treatment is the basic treatment in each of the technology options described above. Biological treatment is a well-established method for treating BOD₅ and COD in wastewater and is the most common method in the pharmaceutical manufacturing industry for treating BOD₅. Of the facilities in the industry that reported using biological treatment, 74% use

the activated sludge process. The secondary clarifier, which is a standard component of the biological treatment system, provides TSS treatment of the wastewater prior to discharge from the system.

The treatment performance of these regulatory options considered for promulgation is discussed in 8.

7.3.3 Best Conventional Pollutant Control Technology (BCT)

Effluent limitations guidelines based on the best conventional pollutant control technology establish quantitative limits on the direct discharge of conventional pollutants from existing industrial point sources. In contrast to BPT guidelines that are devised as the average of the best existing performance by a group of like facilities, BCT guidelines are developed by identifying candidate technologies and evaluating their cost-reasonableness. Effluent limitations guidelines based upon BCT may not be less stringent than BPT effluent limitations guidelines. As such, BPT effluent limitations are a "floor" below which BCT effluent limitations guidelines cannot be established. EPA uses a BCT cost test methodology in determining whether it is "cost-reasonable" for industry to control conventional pollutants at a level more stringent than would be required by BPT effluent limitations. This methodology is fully described in 14.

In performing the BCT cost test, a BPT baseline must be developed to serve as the starting point against which more stringent technologies are analyzed. In each subcategory at proposal, EPA conducted the BCT analysis assuming the baseline was the proposed BPT level of advanced biological treatment. EPA received comments that this was not an appropriate choice for the BPT baseline, and that instead the level of control associated with the existing BPT effluent limitations guidelines should be used as the BPT baseline in the cost test. In consideration of these comments, EPA has modified the BPT baseline in the cost test to be equal to the level of control associated with the existing BPT effluent limitations guidelines.

7.3.3.1 Subcategories A and C

The BCT treatment options for Subcategories A and C are the same as the BCT options considered at proposal: a no revision option; revision of BOD₅, TSS and COD based on advanced biological treatment; revision of BOD₅ and TSS based on advanced biological treatment and effluent filtration; revision of BOD₅ and TSS based on advanced biological treatment and polishing ponds; and revision of BOD₅ and TSS based on advanced biological treatment and effluent filtration and polishing ponds.

7.3.3.2 Subcategories B and D

The BCT treatment options for Subcategories B and D are the same as the BCT options considered at proposal: a no revision option; revision of BOD₅ and TSS based on advanced biological treatment; and revision of BOD₅ and TSS based on advanced biological treatment and effluent filtration.

7.3.3.3 Rationale

The rationale for the use of advanced biological treatment under BCT is the same as that presented for BPT. EPA also evaluated whether additional TSS control using effluent filtration and/or polishing ponds was cost reasonable under the BCT cost test. TSS is a conventional pollutant present at significant levels and effluent filtration and polishing ponds provide a greater degree of control of TSS than advanced biological treatment.

7.3.4 Best Available Technology Economically Achievable (BAT)

Effluent limitations guidelines based on the best available technology economically achievable establish quantitative limits on the direct discharge of priority and nonconventional pollutants to waters of the United States. These limits are based upon the performance of specific technologies, but they do not require the use of any specific technology. BAT effluent limitations guidelines are applied to individual facilities through NPDES permits issued by EPA or authorized

states under 402 of the CWA. The facility then chooses its own approach to complying with its permit limitations.

The technology selected by the Agency to define the BAT performance may include end-of-pipe treatment, process changes, and internal controls, even when these technologies are not common industry practice. BAT performance is established for groups of facilities with shared characteristics. Where a group of facilities demonstrates uniformly inadequate performance in controlling pollutants of concern, BAT may be transferred from a different subcategory or industrial category.

A primary consideration in selecting BAT is the effluent pollutant reduction capability of the available technologies. Implementation of the best available technology must be economically achievable by the industry, so the cost of applying the technology is also considered. Other factors considered in establishing BAT include:

- The processes used;
- Engineering aspects of the application of various types of control techniques;
- Potential process changes;
- Age and size of equipment and facilities; and
- Nonwater quality environmental impacts, including energy requirements.

7.3.4.1 Subcategories A and C

EPA considered four regulatory options as BAT for Subcategories A and C as part of the development of the proposed effluent limitations guidelines for the pharmaceutical manufacturing industry. These options are discussed in detail in the technical development document supporting the proposed rule, and are not discussed further in this section. In the May 2, 1995 proposal, the selected options were based on the application of in-plant steam stripping and hydrogen peroxide

oxidation followed by end-of-pipe advanced biological treatment for Subcategories A and C, and application of end-of-pipe advanced biological treatment for Subcategories B and D.

After proposal, the Agency gathered additional data and reviewed comments on the proposed rule and the Supplemental Notice of Availability to the proposed rule. The Agency also considered the regulatory effects of the Maximum Achievable Control Technology (MACT) standards for the Pharmaceutical Manufacturing Industry, which were proposed on April 2, 1997, to control emissions of Hazardous Air Pollutants (HAPs) from storage tanks, process vents, equipment leaks, and wastewater. The MACT standards, for releases from wastewater, provide for in-plant control, or equivalent control of the wastestreams that contain sufficient quantities of volatile organic pollutants. Since the wastestreams that require control by in-plant steam stripping will receive that control under MACT, the Agency has decided to change its model BAT technology basis for VOCs to avoid duplicative regulations. As a result of this additional data and associated analyses, EPA considered three options as the basis of promulgated regulations. All three options modify the existing BAT regulations to parallel the BPT regulations and to clarify the compliance monitoring point for the existing cyanide limitations. The first option is a no cost revision which includes revised limitations for COD equal to the final BPT limitations and clarifies the monitoring requirements for cyanide. The second option adds limitations for 30 organic pollutants based on advanced biological treatment, revised limitations for COD equal to the final BPT limitations and clarifies the monitoring requirements for cyanide. The third option adds limitations for 30 organic pollutants based on advanced biological treatment, ammonia limitations based on one or two stage biological nitrification technology, incorporates the revised COD limitations and clarifies the monitoring requirements for cyanide.

7.3.4.2 Subcategories B and D

EPA considered two final BAT regulatory options. The first option is a no cost option consisting of the withdrawal of the existing cyanide limitations and the addition of the BPT revised COD limitations. The second option includes the withdrawal of the existing cyanide limitations and the addition of the BPT revised COD limitations and limitations based only on advanced biological

treatment for the same organic pollutants selected for regulation at the Subcategory A and C facilities.

7.3.4.3 Rationale

Advanced biological treatment is the basic treatment operation in the technology options described above. Advanced biological treatment is a proven method for treating COD and organic constituents in pharmaceutical manufacturing industry wastewater. Treatment performance data for advanced biological treatment and the other technologies included in the BAT options are provided in 8. Of the facilities in the industry that reported using biological treatment, 74% use the activated sludge process. Biological treatment systems, including activated sludge systems, can achieve significant ammonia removal through nitrification. Nitrification can be achieved through adjusting the operating parameters of a single stage system or by using a two stage system.

In-plant steam stripping, which was considered as a treatment technology in the effluent guidelines proposal, was not included in the list of BAT regulatory options for promulgation. Steam stripping was originally included to control highly volatile components that would not be treated, but would be air stripped. EPA has determined that MACT standards will provide this control, and these standards have been promulgated concurrently. The inclusion of steam stripping treatment beyond what is currently provided under the MACT standards for BAT would be unnecessary and duplicative.

Because cyanide and ammonia are not present at concentrations of concern in Subcategory B and D wastewaters, cyanide destruction and ammonia treatment are not included under the Subcategory B and D options.

7.3.5 New Source Performance Standards (NSPS)

The basis for new source performance standards under 306 of the CWA is the best available demonstrated technology. Industry has the opportunity to design and install the best and most

efficient processes and wastewater treatment facilities at new facilities. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible. In response to that directive, and as with the development of options for the BAT effluent limitations guidelines, EPA considered effluent reductions attainable by the most advanced and demonstrated process and treatment technologies at pharmaceutical manufacturing facilities.

7.3.5.1 Subcategories A and C

EPA considered two regulatory options as the basis of NSPS for Subcategories A and C as part of the development of the proposed effluent limitations guidelines for the pharmaceutical manufacturing industry. These options are discussed in detail in the technical development document supporting the proposed rule. In the May 2, 1995 proposal, the selected option was based on the application of in-plant steam stripping with rectification and hydrogen peroxide oxidation followed by end-of-pipe biological treatment to a treatment level achieved by the best performing facility for Subcategories A and C. After proposal, the Agency gathered additional data, reviewed comments on the proposed rule and the Supplemental Notice of Availability to the proposed rule, and considered the regulatory effects of the MACT standards for the industry. The MACT standards for releases from wastewater provide for in-plant control (or equivalent) of the wastestreams that contain sufficient quantities of volatile organic pollutants. Since the wastestreams that require control by in-plant steam stripping will receive this control under MACT, the Agency has decided to remove this component of its NSPS technology basis for VOCs to avoid duplicative regulations.

EPA evaluated technology options capable of achieving greater pollutant removal of conventional pollutants (BOD₅ and TSS), COD, organics, cyanide, and ammonia than those selected as the basis for existing source limitations (BPT, BCT, and BAT). The only option potentially capable of achieving additional removals involves the use of granular activated carbon (GAC) absorption technology. This technology is capable of reducing the COD from some direct discharging A and C Subcategory facilities. However, there is only limited GAC performance data available, from

one pilot study. EPA ultimately concluded that this study did not provide a sufficient basis to develop NSPS limitations.

Therefore, EPA considered a single NSPS option based on the best available demonstrated control technologies, which include advanced biological treatment with nitrification and cyanide destruction. NSPS under this option are the same as BAT effluent limitations for 30 organic pollutants, cyanide, and ammonia. EPA is also promulgating revised NSPS for BOD₅, COD, and TSS at a level equal to the discharge characteristics of the best performing BPT plants. For COD this is equivalent to the BAT/BPT level of control.

7.3.5.2 Subcategories B and D

Similar to Subcategories A and C, for Subcategories B and D EPA considered a single NSPS option based on the best available demonstrated control technology, which is advanced biological treatment. The revised NSPS for BOD₅, COD, and TSS associated with this option is at a level equal to the discharge characteristics of the best performing BPT plants. For COD this is equivalent to the BAT/BPT level of control.

7.3.5.3 Rationale

Because new plants have the opportunity to install the best and most efficient wastewater treatment technologies, NSPS should be based on the most stringent control technology demonstrated for all pollutants of concern (conventional, nonconventional, and priority pollutants). The NSPS options include the most advanced wastewater treatment technologies demonstrated to effectively treat pharmaceutical manufacturing industry wastewater. The NSPS options address the treatment of conventional, nonconventional, and priority pollutants in Subcategory A and/or C and Subcategory B and/or D wastewaters. Because cyanide and ammonia are not present in wastewaters at concentrations of concern at existing Subcategory B and D facilities, cyanide destruction and ammonia treatments are not included under the NSPS option for Subcategories B and D.

7.3.6 Pretreatment Standards for Existing Sources (PSES)

Pretreatment standards for existing sources establish quantitative limits on industrial discharges to POTWs. PSES are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The CWA requires pretreatment for pollutants that pass through POTWs in amounts that would exceed direct discharge effluent limitations or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands. The transfer of a pollutant to another media (air) through volatilization does not constitute treatment. Pretreatment standards are to be technology-based and analogous to BAT for removal of priority and nonconventional pollutants. Like effluent guidelines limitations and standards based on BPT, BCT, BAT, and NSPS, PSES do not require the use of any specific technology.

7.3.6.1 Subcategories A and C

In developing the final PSES for Subcategories A and C, EPA considered three options. The first option was not to develop pretreatment standards for ammonia or any of the VOC pollutants, and to modify the monitoring requirements for the existing cyanide standards. The second option builds on compliance with the MACT standard with additional pretreatment standards for VOC's based on steam stripping technology and ammonia based on steam stripping or nitrification. The second option also includes modification of the existing cyanide monitoring requirements. The third option is the same as the second option, with the addition of revised pretreatment standards for cyanide based on an in-plant technology unit consisting of either hydrogen peroxide oxidation technology or alkaline chlorination technology, depending on individual facility conditions.

7.3.6.2 Subcategories B and D

For Subcategories B and D, EPA considered two options. The first option was not to add regulated pollutants to the existing PSES and, since cyanide is not present in wastewaters for these subcategory facilities, to withdraw the existing cyanide standards. Thus, compliance with the MACT standard would be the only requirement for controlling VOC pollutants. The second

option was to add pretreatment standards for VOCs based on steam stripping in addition to withdrawing the existing cyanide standards. No ammonia standards were considered since facilities in these subcategories do not generate significant levels of ammonia in their wastewaters.

7.3.6.3 Rationale

Steam stripping is an effective technique for the removal of priority and nonconventional pollutants of concern in pharmaceutical manufacturing wastewater. Steam stripping provides effective pretreatment of wastewater that is further treated off-site by biological treatment at a POTW. The regulatory options beyond no revision use steam stripping to control the additional discharge of VOCs not controlled by the MACT standards.

Cyanide and ammonia are not present at concentrations of concern in Subcategory B and D wastewaters; therefore, cyanide destruction and ammonia treatment are not included under the Subcategory B and D options. It was also determined that biological treatment beyond what is currently provided at the POTW would not be appropriate treatment of wastewater from all pharmaceutical facilities. Therefore, the PSES regulatory options for Subcategories A, B, C, and D include in-plant steam stripping without any end-of-pipe biological treatment.

7.3.7 Pretreatment Standards for New Sources (PSNS)

Pretreatment standards for new sources establish quantitative limits on the indirect discharge of priority and nonconventional pollutants to waters of the United States. 307(c) of the CWA requires EPA to promulgate PSNS at the same time it promulgates NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies, including process changes, in-plant controls, and end-of-pipe treatment technologies.

As discussed in 17, EPA determined that a range of priority and nonconventional organic pollutants, ammonia, and cyanide pass through POTWs. PSNS are applicable to these pollutants.

7.3.7.1 Subcategories A, B, C, and D

For all subcategories, EPA considered the same technology options under PSNS as under PSES. For the final rule, EPA was not able to identify a technology option that would achieve greater removal of pollutants than the PSES technology options.

7.3.7.2 Rationale

New indirect dischargers, like new direct dischargers, have the opportunity to incorporate into their plants the best available wastewater treatment technologies. Therefore, the treatment technologies included in the PSNS options are the most advanced wastewater treatment technologies demonstrated to effectively treat pharmaceutical manufacturing industry wastewater. The PSNS technology options address the treatment of organics, ammonia, and cyanide in Subcategory A and C wastewater and organics in Subcategory B and D wastewater in a manner similar to the PSES technology options. Since cyanide and ammonia are not present in wastewater at concentrations of concern at Subcategory B and D facilities, cyanide destruction and ammonia treatment are not included under the Subcategory B and D options. EPA did not consider a technology option employing advanced biological treatment for the same reasons EPA rejected end-of-pipe advanced biological treatment as part of the PSES technology options.

Table 7-1

Summary of Major Treatment Technologies Used in the Pharmaceutical Manufacturing Industry

Technology	Number of Facilities Using the Technology ^(a)	
	Subcategories A and C	Subcategories B and D
pH Adjustment/Neutralization	81	45
Equalization	44	26
Biological Treatment		
Single-Stage Activated Sludge	31	21
Two-Stage Activated Sludge	2	2
Oxygen Activated Sludge	1	1
Aerated Lagoons	7	5
Trickling Filters	4	1
Rotating Biological Contactors	2	1
Multimedia Filtration	3	3
Cyanide Destruction		
Alkaline Chlorination	6	0
H ₂ O ₂ Oxidation	3	0
Hydrolysis	1	0
Distillation Technologies		
Solvent Recovery		
Distillation	12	3
Distillation with reflux	28	5
Rectification	12	1
Wastewater treatment		
Steam stripping	4 ^(b)	0
Carbon Adsorption	6	4
Polishing Pond	2	6
Air Stripping	2	0
Incineration	10	1

(a)Data based on responses from the Detailed Questionnaire (244 responding facilities).

(b)In their Detailed Questionnaire responses, 14 facilities reported using steam stripping for wastewater treatment; however, based on a review of each of these facilities, EPA determined that only four facilities were actually using the technology for wastewater treatment.

Table 7-2

**Pharmaceutical Manufacturing Facilities Quantity of Chemicals
Recycled/Reused (1990)**

Chemical Name	Number of Facilities Reporting	Total Quantity Recycled/Reused (lbs)
Acetone	2	17,107,958
Acetonitrile	2	10,518,000
n-Butyl acetate	1	37,302,726
1,2-Dichloroethane	2	187,020
Ethyl acetate	1	10,243,000
Ethyl alcohol	1	122,304,000
Heptane	1	5,680,400
Hexane	1	248,082
Isopropanol	1	27,441
Methanol	7	19,027,784
Methylene chloride	7	92,599,587
Pyridine	1	451,000
Tetrahydrofuran	1	76,666
Toluene	6	19,185,893
Triethylamine	1	29,534
TOTAL		334,989,091

Table 7-3

Summary of Regulatory Options

Regulation	Option Name	Technology Basis	
		Subcategory A and C Facilities	Subcategory B and D Facilities
BPT	No Revision (MACT Only)	Current Treatment Technology	Current Treatment Technology and Withdraw Cyanide
	Clarify Cyanide, Revise COD Only	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Clarify Cyanide, Revise BOD ₅ and TSS Only	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Clarify Cyanide and Revise BOD ₅ , TSS, & COD	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
BCT	No Revision	Current BPT	Current BPT
	Revise BOD ₅ & TSS	Advanced Biological Treatment	Advanced Biological Treatment
	Revise BOD ₅ & TSS	Advanced Biological Treatment and Effluent Filtration	Advanced Biological Treatment and Effluent Filtration
	Revise BOD ₅ & TSS	Advanced Biological Treatment and Polishing Pond	--
	Revise BOD ₅ & TSS	Advanced Biological Treatment and Effluent Filtration and Polishing Pond	--
BAT	Revise COD to BPT Limits and Clarify Cyanide	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Add Organics Only, Revise COD to BPT Limits, and Clarify Cyanide	Advanced Biological Treatment and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
	Add Organics and Ammonia, Revise COD to BPT Limits, and Clarify Cyanide	Advanced Biological Treatment with Nitrification, and Revised Monitoring Requirements for Cyanide	<i>Ammonia and cyanide limits do not apply for B/D facilities</i>

Table 7-3 (Continued)

Regulation	Option Name	Technology Basis	
		Subcategory A and C Facilities	Subcategory B and D Facilities
NSPS	Revise Equal to Promulgated Level of BPT/BAT Control	Advanced Biological Treatment with Nitrification, and Revised Monitoring Requirements for Cyanide	Advanced Biological Treatment and Withdraw Cyanide
PSES	No Revision (MACT Only) and Clarify Cyanide	Current Treatment Technology and Revised Monitoring Requirements for Cyanide	Current Treatment Technology and Withdraw Cyanide
	Organics Only and Withdraw Cyanide	<i>This option was not considered for A/C Facilities</i>	In-Plant Steam Stripping for Organic Compounds and Withdraw Cyanide
	Organics and Ammonia, and Clarify Cyanide	In-Plant Steam Stripping for Organic Compounds and Ammonia, and Revised Monitoring Requirements for Cyanide (Nitrification may be used for Ammonia)	<i>Ammonia and Cyanide limits do not apply for B/D Facilities</i>
	Organics and Ammonia, and Revise Cyanide	In-Plant Steam Stripping for Organic Compounds and Ammonia, and In-Plant Cyanide Destruction (Nitrification may be used for Ammonia)	<i>Ammonia and Cyanide limits do not apply for B/D Facilities</i>
PSNS	Revise Equal to Promulgated PSES Limits	PSES Treatment Technology	PSES Treatment Technology

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