

Discharge standard of water pollutants for pharmaceutical industry

(revised)

The discharge standard of pollutants for bio-pharmaceutical industry (DB31/ 373-2010) has worked for fourteen years. The regulation of air pollutants has been replaced by the emission standard of air pollutants from pharmaceutical industry (DB31/310005-2021). So the left part about discharge standard of water pollutants is revised here.

Abstract

1 This standard specifies the requirements for water pollutant discharge control, monitoring, and management in the pharmaceutical industry. The water pollutant discharge control requirements apply to enterprises that discharge water pollutants directly or indirectly beyond their legal boundaries.

2 This standard is applied to the management of water pollutant discharged from existing pharmaceutical industrial enterprises or production facilities, as well as to environmental impact assessment, design of environmental protection facilities, completion acceptance for environmental protection, issuance of pollutant discharge permits, and daily management of water pollutant discharges for pharmaceutical industrial construction projects.

3 This standard is also applied to water pollutant discharge management for pharmaceutical intermediate enterprises and their production facilities that supply pharmaceutical production, pharmaceutical research institutions and their laboratory facilities, as well as centralized wastewater treatment facilities in the pharmaceutical industry.

4 The water pollutant discharge control requirements stipulated in this standard apply to pharmaceutical intermediate enterprises and their production facilities that supply pharmaceutical production, pharmaceutical research institutions and their laboratory facilities, and concentrated wastewater treatment facilities for pharmaceutical industry that discharge water pollutants directly or indirectly beyond their legal boundaries.

5 The effluent limits for the first category of pollutants specified in this standard are as follows:

Table 1 the Effluent Limits of the first category pollutants

No.	Pollutant	Applicable Scope	Discharge Limit ^a , mg/L	Pollutant Discharge Monitoring Location
1	Total Cadmium	traditional Chinese medicine manufacturing and chemical drug formulation manufacturing are excluded	0.01	Outlet of the workshop or workshop treatment facility
2	Alkyl Mercury		Not detectable	
3	Total Chromium		0.15	
4	Hexavalent Chromium		0.05	
5	Total Selenium	chemical drug formulation manufacturing is excluded	0.05	
6	Total Arsenic		0.05	
7	Total Mercury		0.005	
8	Total Lead	Chemical synthesis-based pharmaceuticals, pharmaceutical intermediate manufacturing are excluded	0.1	
9	Total Nickel		0.1	

^a: If the wastewater of an enterprise contains any of the first category pollutants, the enterprise must implement classified collection, dedicated pipelines for transport, and centralized pre-treatment by pollutant type. If both water quality and quantity are monitored at the enterprise's discharge outlet and the inlet of the concentrated wastewater treatment facilities for pharmaceutical industry, indirect effluent limits can be negotiated. The effluent limits specified in this table apply to the outlet of centralized pre-treatment units at pharmaceutical industry wastewater treatment facilities.

6 The effluent limits of the second category of pollutants specified in this standard are as follows:

Table 2 Effluent limits for Basic Control Projects of Second Category Pollutants

No.	Pollutant	Applicable Scope	Discharge Limit, mg/L(excluding pH value and color)		Pollutant Discharge Monitoring Location
			Direct Discharge	Indirect Discharge ^a	
1	pH (Dimensionless)	All discharge units	6-9	6-9	Total Wastewater Discharge Outlet of the Enterprise
2	Color (Dilution factor)	All discharge units	30	60	
3	Suspended Solids (SS)	Traditional Chinese medicine manufacturing	15	120	
		Excluding traditional Chinese medicine manufacturing	10	120	
4	5-day Biochemical Oxygen Demand (BOD ₅)	All discharge units	10	300	
5	Chemical Oxygen Demand (COD _{Cr})	All discharge units	50	500	
6	Total Organic Carbon	Traditional Chinese medicine manufacturing	20	180	
		Excluding traditional Chinese medicine manufacturing	15	180	
7	Ammonia Nitrogen (NH ₃ -N)	All discharge units	5(8 ^b)	40	
8	Total Nitrogen (TN)	All discharge units	15(20 ^b)	60	
9	Total Phosphorus (TP)	All discharge units	0.5	8	
10	Volatile Phenols	All discharge units	0.2	1.0	
11	Animal and Vegetable Oils	Extraction-based pharmaceuticals, biological drug manufacturing, pharmaceutical research institutions	1	100	
12	Anionic Surfactants	Biological drug manufacturing, pharmaceutical research institutions	0.5	15	
13	Fecal Coliform (MPN/L) ^c	Fermentation-based pharmaceuticals, extraction-based pharmaceuticals, biological drug manufacturing, pharmaceutical research institutions	100	500	
14	Total Cyanides	Traditional Chinese medicine manufacturing	0.3	0.3	
		Excluding traditional Chinese medicine manufacturing	Not detectable	0.3	
15	Total Residual Chlorined	All discharge units	0.5	—	

^a: When the wastewater is discharged into urban concentrated wastewater treatment facilities, the indirect effluent limits should match the specified requirement in this table. When the wastewater is discharged into other concentrated wastewater treatment facilities, the indirect effluent limits of items 1-9 can be negotiated, or meet the requirement here if no agreement is reached; When the wastewater is discharge into the concentrated wastewater treatment facilities for pharmaceutical industry, the item 1-15 . can be negotiated, or meet the requirement here if no agreement is reached;

^b: From November to February of the following year, the effluent limits in parentheses shall be enforced.

^c: Indicator microorganism for disinfection.

^d: Applicable to processes using chlorine-based disinfection, and requires a disinfection contact time of ≥1 hour in the disinfection contact tank.

^e: Represented by either the minimum ineffective dilution factor or toxicity units. Compliance with either will be considered acceptable.

7 The characteristic control items for the second category of pollutants in this standard should be selected based on raw materials, auxiliary materials, production processes, products, by-products,

and intermediate products used. After being reviewed and confirmed by the ecological environment department, the specified effluent limits shall be implemented.

Table 3 Effluent limits for Characteristic Control Items of Second Category Pollutants

No.	Pollutant	Discharge Limit, mg/L		Pollutant Discharge Monitoring Location
		Direct Discharge	Indirect Discharge ^a	
1	Formaldehyde	0.5	3.0	Total Wastewater Discharge Outlet of the Enterprise
2	Methanol	3.0	15.0	
3	Benzene	0.02	0.5	
4	Toluene	0.02	0.5	
5	Total Xylenes ^b	0.01	1.0	
6	Adsorbable Organic Halides (AOX)	1.0	8.0	
7	Dichloromethane	0.2	0.2	
8	Trichloromethane	0.013	1.0	
9	1,2-Dichloroethane	Not detectable	1.0	
10	1,2-Dichlorobenzene	0.06	1.0	
11	Chlorobenzene	0.06	0.15	
12	Acetonitrile	2.0	5.0	
13	Anilines	1.0	1.0	
14	Nitrobenzenes	2.0	2.0	
15	Sulfides	1.0	1.0	
16	Total Copper	0.5	1.5	
17	Total Zinc	0.5	5.0	

^a: When the wastewater is discharged into urban concentrated wastewater treatment facilities, the indirect effluent limits should match the specified requirement in this table. When the wastewater is discharged into other concentrated wastewater treatment facilities, the indirect effluent limits should match the specified requirement in this table. When the wastewater is discharged into the concentrated wastewater treatment facilities for pharmaceutical industry, the item 1-15 can be negotiated, or meet the requirement here if no agreement is reached.

^b: Includes meta-xylene, ortho-xylene, and para-xylene.

8 From 2025, both new and existing pollutant discharge units shall monitor the comprehensive toxicity discharge in their wastewater in accordance with Table 4, with monitoring conducted no less than once a year. For direct discharges, except for the acute toxicity to zebrafish eggs, which must follow the monitoring values specified in Table 4, other indicators serve as guidance indicators. For indirect discharges, all monitoring items in Table 4 shall serve as guidance indicators, and the monitoring results shall be submitted to the local ecological and environmental authorities. Based on the monitoring results, enterprises should take appropriate control measures to reduce the comprehensive toxicity level of wastewater discharge and minimize the impact on the operation of centralized wastewater treatment facilities and the surrounding environmental quality.

Table 4 Monitoring Values for Comprehensive Toxicity in Wastewater Discharge

No.	Monitoring Item	Monitoring Value		Pollutant Discharge Monitoring Location
		LID value	TU value	
1	Acute Toxicity to Zebrafish Eggs ^a	≤6	≤2	Total Wastewater Discharge Outlet of the Enterprise
2	Luminescent Bacteria Toxicity ^a	≤8	≤8	
3	Daphnia Magna Toxicity ^a	≤6	≤8	
4	Algal Toxicity ^a	≤16	≤16	

^a: These toxicity indicators are represented either by the minimum ineffective dilution factor or toxicity units. If either meets the limit specified in this table, it is considered compliant.

8 From, 2025, both new and existing pollutant discharge units shall monitor pharmaceutical component discharge in their wastewater in accordance with Table5 , Based on the monitoring results, enterprises should take appropriate control measures to reduce the pharmaceuticals

discharged and minimize the impact on environmental quality.

Table 5 Monitoring value for pharmaceuticals in Wastewater Discharge

No.	Monitoring Item	Monitoring Value	Pollutant Discharge Monitoring Location
1	Antibiotics ^a	≤ 0.05 mg/L	Total Wastewater Discharge Outlet of the Enterprise
^a : Enterprises should select the types of antibiotics to monitor based on the raw materials, production processes, products, by-products, and intermediates used. Antibiotics for which monitoring methods have already been published should be included. Others will be incorporated into the analysis after national pollutant monitoring and analysis method standards are released.			