

HJ

INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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**Technical specification for application and issuance of
pollutant permit Pharmacy industry -- Biological
pharmaceutical products manufacturing**

排污许可证申请与核发技术规范 制药工业-生物药品制品制造

(English Translation)

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Foreword

In order to implement the "Environmental Protection Law of the People's Republic of China" Water Pollution Control Law, Soil Pollution Control Law of the People's Republic of China, and other laws and regulations;

Notice on the Implementation Plan of the Emission Permit System (Guobanfa [2016] No. 81) and the Measures for the Administration of Emission Permits (Trial) (Environmental Protection (Ministry Decree No. 48), improve the technical support system for sewage permits, guide and standardize the pharmaceutical industry-biological product manufacturing sewage discharge units sewage permits Application for certification and issuance of this standard.

This standard specifies the basic requirements for reporting and issuing the pollution permit application for the pharmaceutical industry-biopharmaceutical manufacturing sewage discharge unit, Determination of permitted emission limits, methods of actual emissions accounting and compliance determination, as well as self-monitoring, environmental management ledger and pollution permit enforcement Environmental management requirements, such as bank reports, put forward feasible technical requirements for pharmaceutical industry-biological drug product manufacturing pollution prevention.

Appendices A to D of this standard are informative appendices.

This standard is issued for the first time.

This standard was formulated by the Department of Environmental Impact Assessment and Emission Management, and the Regulations and Standards Department of the Ministry of

Ecology and Environment.

1 Scope

This standard specifies the basic requirements for reporting and issuing the pollution permit application for the pharmaceutical industry-biopharmaceutical manufacturing sewage discharge unit, Determination of permitted emission limits, methods of actual emissions accounting and compliance determination, as well as self-monitoring, environmental management ledger and pollution permit enforcement Environmental management requirements, such as bank reports, put forward feasible technical requirements for pollution prevention.

This standard is applicable to guide the pharmaceutical industry-biopharmaceutical product manufacturing and discharge units in the national sewage permit management information platform (hereinafter abbreviated (Referred to as the sewage permit platform) to fill in relevant application information, which is applicable to guide the issuing authority to review and determine the permit requirements for sewage units' sewage permits.

This standard applies to the use of biotechnology to produce biochemical drugs, genetically engineered drugs and vaccines, etc.

Drainage permit management of pollutants and water pollutants. Pollution discharge permits for air pollutants and water pollutants discharged by veterinary biopharmaceutical manufacturing units Management also applies to this standard.

Pharmaceutical industry-Biopharmaceutical product manufacturing and sewage disposal units that implement the "Air Power Pollutant Emission Standards for Thermal Power Plants" (GB 13223) Production facilities and discharge outlets are applicable to the "Technical Specifications for the Application and Verification of Pollutant Discharge Permits in the Thermal Power Industry";

Standard (GB 13271) production facilities and discharge outlets are applicable to the "Boiler for the Application of Pollutant Discharge Permit and Technical Specifications" (HJ 953).

Other pollution-producing facilities and waste-discharging facilities that discharge industrial waste water, waste gas, or toxic and hazardous pollutants specified by the state the release shall be implemented in accordance with the General Rules for the Application and Issuance of Sewage Permits (HJ 942).

2 Normative references

The content of this standard refers to the following documents or clauses therein. For undated references, the valid version applies to this standard quasi.

GB 8978 Integrated Wastewater Discharge Standard GB 13223 Air Pollutant Emission Standard for Thermal Power Plants GB 13271 Boiler Air Pollutant Emission Standard GB

14554 Emission Standard for Odor Pollutants GB 15562.2 Environmental Protection Graphical Signs-Solid Waste Storage (Disposal) Site GB 18597 Pollution Control Standard for Hazardous Waste Storage GB 21907 Water Pollutant Discharge Standard for Bioengineering Pharmaceutical Industry GB 37823 Air Pollutant Emission Standards for the Pharmaceutical Industry GB/T 16157 Determination of particulate matter and sampling of gaseous pollutants in exhaust from stationary pollution sources HJ 75 Technical Specifications for Continuous Monitoring of Flue Gas (SO₂, NO_x, Particulate Matter) Emissions from Stationary Pollution Sources HJ 76 Technical requirements and detection methods of continuous monitoring system for the emission of flue gas (SO₂, NO_x, particulate matter) from stationary pollution sources HJ 493 Technical regulations for the storage and management of water samples HJ 494 Water Quality Sampling Technical Guide HJ 495 Water Quality Sampling Scheme Design Technical Regulations HJ 521 Wastewater Discharge Law Code (Trial) HJ 608 Sewage unit coding rules HJ 819 Technical Guidelines for Self-monitoring of Sewage Units HJ 942 General Rules for Application and Issuance of Sewage Permits HJ 944 General Regulations on Technical Specifications for Environmental Management Ledgers and Pollutant Permits of Pollutant Discharge Units HJ 953 Application for Sewage Permit and Issuance of Technical Specifications HJ 2025 Technical Specification for Collection, Storage and Transportation of Hazardous Waste HJ/T 55 Technical guidelines for fugitive emissions monitoring of air pollutants HJ/T 91 Technical specifications for surface water and sewage monitoring HJ/T 194 Technical Specifications for Manual Monitoring of Ambient Air Quality HJ/T 212 Data Transmission Standard for Online Automatic Monitoring (Monitoring) System of Pollution Sources HJ/T 353 Technical Specifications for Installation of Water Pollution Source Online Monitoring System (Trial) HJ/T 354 Technical Specification for Acceptance of Water Pollution Source Online Monitoring System (Trial) HJ/T 355 Water pollution source online monitoring system operation and assessment technical specifications (trial) HJ/T 356 Technical Specification for Judging Data Validity of Water Pollution Source Online Monitoring System (Trial) HJ/T 373 Technical Specifications for Monitoring Quality Assurance and Quality Control of Fixed Pollution Sources (Trial) HJ/T 397 Fixed source exhaust gas monitoring technical specifications Catalogue of Classified Management of Pollutant Discharge Permits for Fixed Pollution Sources "Technical Requirements for the Standardization of Sewage Outfalls (Trial)" (SEPA [1996] No. 470) "Administrative Measures for the Operation of Automatic Monitoring Facilities for Pollution Sources" (Huanfa [2008] No. 6) "Announcement on the Time for Implementing the Special Emission Limits of Water Pollutants for the National Discharge Standards in the Taihu Basin" 28th of the year) Announcement on the Scope of Administrative Regions for the Implementation of National Pollutant Discharge Standards for Water Pollutants in Taihu Basin (Announcement No. 30 of 2008) "Policy Policy for the Prevention and Control of Pollution in the Pharmaceutical Industry" (Announcement No. 18, 2012 of the Ministry of Environmental Protection) Announcement on the Implementation of Special Emission Limits of Air Pollutants (Ministry of Environmental Protection Announcement.2013 No. 14) National Hazardous Waste List (Order of the Ministry of

Environmental Protection No. 39) "Reply Letter on Issues Concerning the Implementation of Special Emission Limits of Air Pollutants" (Environment Office Atmospheric Letter [2016] No. 1087) Announcement on Beijing, Tianjin and Hebei air pollution transmission channels to implement special emission limits for air pollutants (Announcement of the Ministry of Environmental Protection (No. 9 of 2018)

3 Terms and definitions

The following terms and definitions apply to this standard.

Biological pharmaceutical products manufacturing pollutant emission unit Refers to the use of microorganisms, parasites, animal toxins, biological tissues, etc., using modern biotechnology methods (mainly genetic engineering technology, etc.) the process of producing peptides, protein drugs, and vaccines for therapeutic and diagnostic purposes, including genetically engineered drugs, Sewage discharge unit for pharmaceutical manufacturing and biopharmaceutical research and development due to engineering vaccines and cloning engineering.

Permitted emission limits Refers to the maximum discharge concentration (or rate) and amount of pollutants allowed by the pollutant discharge unit as specified in the pollutant discharge permit.

Special periods

Refers to the pollution discharge unit's pollution according to the environmental quality deadline compliance plan formulated by the local people's government and other relevant environmental management regulations.

Periods with special requirements for the discharge of dyes, including the period of response to severely polluted weather and the period of winter defense.

Volatile organic compounds (VOCs) Refers to organic compounds that participate in atmospheric photochemical reactions, or organic compounds determined in accordance with relevant regulations.

When characterizing the overall emissions of VOCs, according to industry characteristics and environmental management requirements, total volatile organic compounds (as TVOC (Represented), non-methane total hydrocarbons (represented by NMHC) as pollutant control projects.

4.1 Basic principles

Pharmaceutical industry-Biopharmaceutical product manufacturing and discharge units shall, in accordance with the requirements of this standard, fill in the corresponding information on the sewage permit platform. Sewage permit However, if the platform does not include the local ecological environment authority that requires reporting or the polluting