

**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

HJ 858.1-2017

**Technical Specification for Application and Issuance of
Pollutant Permit Pharmacy Industry - Active Pharmaceutical
Ingredient Manufacturing**

排污许可证申请与核发技术规范 制药工业—原料药制造
(English Translation)

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Foreword

In order to implement the "Law of the People's Republic of China on Environmental Protection" "Law of the People's Republic of China on Prevention and Control of Air Pollution" "China Law of the People's Republic of China on Prevention and Control of Water Pollution" and other laws and regulations and the "General Office of the State Council on Printing and Distributing the Control of Emission Permit System Implementation Plan Notice (State Office issued (2016) 81), improve the technical support system for sewage permits, guidance and standardization of pharmaceutical Industrial - API manufacturing sewage disposal units permit application and the issuance of work to develop this standard.

This standard specifies the pharmaceutical industry - raw materials manufacturing sewage treatment units to apply for the sewage permit and the basic conditions Fill Requirements, the determination of allowable emission limits, actual emissions accounting, compliance assessment methods and self-monitoring, environmental management accounts and the implementation of emission permits and other environmental management requirements, put forward the pharmaceutical industry - raw materials manufacturing pollution prevention and control technology to be begging.

When the issuance of a permit for discharge of pollutants is issued by an issuing authority, if it is located in a place prohibited by the laws and regulations from establishing the area, where the pharmaceutical industry has been clearly stipulated to be eliminated or banned - raw material drug manufacturing sewage disposal units or production facilities, should not be nuclear Pharmaceutical industry - API manufacturing sewage permits.

This standard Appendix A ~ Appendix G is an informative annex.

This standard is released for the first time.

This standard is formulated by the Ministry of Environmental Protection Planning and Finance Department, Ministry of Environmental Protection Science and Technology Standards Division.

This standard is mainly drafted by. Hebei University of Science and Technology, Beijing Institute of Environmental Protection, Environmental Protection Department Environmental Engineering Cheng assessment center, Hebei Huayuan Environmental Protection Institute Co., Ltd., Henglian HNA (Beijing) Management Consulting Co., Ltd.

National Chemical Pharmaceutical Industry Association, Hebei Province Environmental Science Society.

This standard was approved by the Ministry of Environmental Protection on September 29, 2017.

This standard since September 29, 2017 come into operation.

This standard is interpreted by the MEP.

1 Sewage permit application and issuance of technical specifications

Pharmaceutical Industry - Manufacture of APIs 1 scope of application this standard specifies the pharmaceutical industry - raw materials manufacturing sewage treatment units to apply for the sewage permit and the basic conditions Fill Requirements, the determination of allowable emission limits, actual emissions accounting, technical methods of compliance determination and self-monitoring, environmental management Taiwan account and sewage permit implementation of the report and other environmental management requirements, put forward the pharmaceutical industry - raw materials manufacturing pollution control feasible Surgery requirements.

This standard applies to the guidance of the pharmaceutical industry - raw materials manufacturing sewage units to fill in the "sewage permit application form" and in the national row Filing license management information platform Fill the declaration system to fill in the relevant application information, at the same time apply to guide the verification and determination of the issuing authority Pharmaceutical Industry - Permits for the manufacture of APIs for pollutant discharge permits.

This standard applies to the further processing of pharmaceutical preparations required for the production of bulk drugs, mainly for the production of pharmaceutical drugs Production of intermediates and manufacture of veterinary drugs (APIs) Discharge of air pollutants and water pollutants discharged by pollutant discharge units License management.

Pharmaceutical industry - raw materials manufacturing sewage units, the implementation of

GB 13223 of the production facilities and emissions for "thermal power industry Sewage permit application and the issuance of technical specifications "; the implementation of GB 13271 of the production facilities and emissions with reference to the implementation of this standard, Pending the issuance of the boiler's sewage permit application and issuance of technical specifications from its provisions.

This standard does not make provisions but the discharge of industrial waste water, waste gas or toxic and harmful air pollutants state pharmaceutical workers Industry - raw materials manufacturing sewage treatment units other pollutant discharge facilities and emissions, with reference to "sewage permit application and the issuance of technical specifications total Then "execute.

2 Normative references

The contents of this standard reference the following documents or terms. Any undated reference documents, the effective version Applicable to this standard.

GB 13223 Thermal Power Plant Air Pollutant Emission Standard GB 13271 Boiler air pollutant emission standards GB 14554 Odor pollutant emission standards GB 16297 Integrated Air Pollutants Emission Standard GB 18484 hazardous waste incineration pollution control standards GB 21903 fermentation pharmaceutical industry water pollutant emission standards GB 21904 chemical synthesis pharmaceutical industry water pollutant emission standards GB 21905 extraction of pharmaceutical industry water pollutant discharge standards Determination of Particulate Matter and Gaseous Pollutants in Exhaust of Fixed Pollution Sources GB/T 16157 2GB/T 31962 sewage into the town sewer water quality standards HJ/T 55 Guidelines for Unorganized Emissions Monitoring of Air Pollutants HJ/T 75 Stationary Pollutant Source Discharge Continuous Monitoring Technical Specifications (Trial Implementation) HJ/T 76 Fixed Pollutant Source Discharge Continuous Monitoring System Technical Requirements and Testing Methods (Trial) HJ/T 91 Technical Specifications for Surface Water and Sewerage Monitoring HJ/T 212 pollution source online automatic monitoring (monitoring) system data transmission standards HJ/T 353 water pollution source on-line monitoring system installation technical specifications (Trial) HJ/T 354 water pollution source on-line monitoring system acceptance Technical Specifications (Trial) HJ/T 355 water pollution source on-line monitoring system operation and evaluation of technical specifications (Trial) HJ/T 356 Water Pollution Source Online Monitoring System Data Validation Technical Specifications (Trial) HJ/T 373 fixed pollution source monitoring quality assurance and quality control technical specifications (Trial) HJ/T 397 fixed source exhaust gas monitoring technical specifications HJ 493 sample preservation and management of technical regulations HJ 494 water sampling technical guidance HJ 495 water quality sampling program design specifications HJ 732 Fixed polluting sources - Volatile organic compounds - Sampling airbag method HJ 819 Technical Guidelines for Self-Monitoring of Sewage Disposal Units General HJ 820 Self-Monitoring Technical

Guidelines for Sewage Disposal Units Thermal Power Generation and Boilers GB -- -20 --
 Volatile organic matter emission control standards GB -- -20 - - Pharmaceutical Industry Air
 Pollutant Emission Standards HJ -- -20 -- Discharge Permit Application and Issuance
 Technical Specifications General HJ -- -20 -- Self-Monitoring Technical Guide of Sewage
 Disposal Unit Fermentation Pharmaceutical Industry HJ -- -20 -- Self-monitoring technical
 guide for sewage disposal units Chemical synthesis Pharmaceutical industry HJ -- -20 --
 sewage unit self-monitoring technology guide extraction class pharmaceutical industry HJ --
 -20 -- Environmental Management Ledger and Drainage Permit Implementation Report
 Technical Specification (Trial Implementation) "Fixed pollution sources permit classification
 management directory" "Technical requirements for the standardization of sewage outfall
 (Trial)" (GAC [1996] 470) Measures for the Administration of Automatic Monitoring Facilities
 for Pollution Sources (Huanfa [2008] No. 6) "Notice on Implementation of Special Emission
 Limit of Water Pollutants for National Emission Standards in Taihu Lake Basin" (MEP Notice
 No. 28 of 2008) "On the implementation of the Taihu Lake Basin national pollutant
 discharge standards of water pollutants discharge limits the administrative area of the
 public Notice "(Ministry of Environmental Protection Notice No. 30 of 2008) 3
 "Pharmaceutical Industry Pollution Prevention and Control Technology Policy" (Ministry of
 Environmental Protection Announcement No. 18 of 2012) Notice on Implementing Special
 Emission Limits for Air Pollutants (MEP Announcement No. 14 of 2013) "Volatile Organic
 Compounds (VOCs) Pollution Prevention and Control Technology Policy" (Ministry of
 Environmental Protection Notice No. 31 of 2013) Circular on Printing and Distributing the
 Interim Provisions on the Management of Sewage Discharge Permits (Huishui [2016] No.
 186) Circular on the Management of License for Permitting Pollution Caused by Elevated
 Sources in Thermal Power, Papermaking Industry and Beijing, Tianjin and Hebei Pilot Cities
 Water [2016] No. 189) Reply on Issues Related to the Implementation of Special Emission
 Limits for Air Pollutants (Circular Letter No. [2016] 1087) Circular on Issues Concerning the
 Automatic Monitoring of Elevated Source Contaminants in Beijing-Tianjin-Hebei Region
 (Circular on Harmonious Environment Circular [2016] 1488 number)

3 Terms and definitions

The following terms and definitions apply to this standard.

3.1

Raw material manufacturing sewage unit active pharmaceutical ingredient manufacturing
 pollutant emission unit Refers to the further processing of pharmaceutical preparations
 required for the manufacture of APIs sewage units.

3.2 Permitted emission limits permitted emission limits

Refers to the maximum allowable concentration of pollutants (or rate) and the amount of
 discharge of pollutants permitted by the pollutant discharging units stipulated in the