

HJ

INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Self-monitoring technology guidelines for pollution sources - Pharmaceutical industry Chinese traditional medicine category, biological pharmaceutical products category, chemical pharmaceuticals preparations category

排污单位自行监测技术指南 中药、生物药品制品、化学药品制剂制造业

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1 Scope of application

This standard specifies the general requirements and monitoring plans for the self-monitoring of pollutant discharge units in the manufacturing industries of traditional Chinese medicine, biological pharmaceutical products, and chemical pharmaceutical preparations.

Basic content and requirements for formulation, information recording and reporting.

This standard is applicable to the water, water, water, etc. discharged by the pollutant-discharging units of the manufacturing industries of traditional Chinese medicine, biological pharmaceutical products, and chemical pharmaceutical preparations during the production and operation stage.

Self-monitoring of air pollutants, noise and the impact on the quality of the surrounding environment.

This standard is also applicable to Tibetan medicine, Mongolian medicine and other ethnic traditional medicine manufacturing sewage units, as well as traditional Chinese medicine, biological drug products, chemical drugs Sewage units such as veterinary drug manufacturers with similar preparations and drugs.

Self-monitoring of sewage discharge units of pharmaceutical manufacturing industry that use traditional microbial fermentation technology to prepare antibiotics, vitamins, amino acids and other drugs Execute in accordance with HJ 882. The pollution discharge unit of the traditional Chinese medicine manufacturing industry extracts a specific pharmaceutical ingredient production facility, and the self-monitoring of its pollution discharge shall be carried out in accordance with the HJ 881 executes.

Among the pollutant discharge units in the manufacturing of traditional Chinese medicine,

biological pharmaceutical products, and chemical pharmaceutical preparations, self-provided thermal power generating units (factories) and supporting power boilers the self-monitoring requirements are implemented in accordance with HJ 820.

2 Normative references

This standard refers to the following documents or clauses thereof. For dated references, only the dated version applies to this standard.

For undated references, the latest edition (including all amendments) applies to this standard.

GB 14554 Emission Standard of Odor Pollutants GB 21906 Discharge Standard of Water Pollutants in Traditional Chinese Medicine Pharmaceutical Industry GB 21907 Water Pollutant Discharge Standard for Bioengineering Pharmaceutical Industry GB 21908 Discharge Standard of Water Pollutants in Pharmaceutical Industry of Mixed Preparations GB 37823 Air Pollutant Emission Standard for Pharmaceutical Industry HJ 2.3 Technical Guidelines for Environmental Impact Assessment Surface Water Environment HJ 91.2 Technical Specification for Surface Water Environmental Quality Monitoring HJ 164 Technical Specification for Groundwater Environmental Monitoring HJ/T 166 Technical Specification for Soil Environment Monitoring HJ 442.8 Technical Specifications for Environmental Monitoring in Offshore Sea Areas Part VIII Direct Sea Pollution Sources and Impact on the Water Environment in Offshore Sea Areas monitor HJ 610 Environmental Impact Assessment Technical Guidelines Groundwater Environment HJ 819 General Principles of Technical Guidelines for Self-Monitoring of Pollutants HJ 820 Technical Guide for Self-Monitoring of Pollutant Emission Units Thermal Power Generation and Boiler HJ 881 Technical Guidelines for Self-Monitoring of Pollutant Discharge Units Extraction Pharmaceutical Industry HJ 882 Technical Guidelines for Self-Monitoring of Pollutant Discharge Units Fermentation Pharmaceutical Industry HJ 964 Environmental Impact Assessment Technical Guidelines Soil Environment (Trial) HJ 1200 Technical Specification for Pollution Discharge Permit Application and Issuance Industrial Solid Waste (Trial) "National Hazardous Waste List"

3 Terms and Definitions

The terms and definitions defined in GB 14554, GB 21906, GB 21907, GB 21908, and GB 37823 and the following terms and definitions apply to this standard.

Chinese traditional medicine manufacturing Using medicinal plants and medicinal animals as the main raw materials, guided by the theory of traditional Chinese medicine, according to the national pharmacopoeia or the approval document of the drug administration department Pieces, etc., production activities of various dosage forms of Chinese herbal medicines and Chinese patent medicines.

processing of traditional Chinese medicines decoction pieces Process and concoct the parts of medicinal materials collected from natural or artificially planted or cultivated animals, plants and minerals to make them meet the requirements of the Department of Traditional Chinese Medicine.

Activities for the production and use of prescription preparations or proprietary Chinese medicines.

Chinese patent medicines manufacturing Taking traditional Chinese medicinal materials as raw materials, under the guidance of traditional Chinese medicine theory, in order to prevent and treat diseases, according to the prescribed prescription and preparation process the production activities of traditional Chinese medicine products processed into certain dosage forms.

biological pharmaceutical products manufacturing Formulation production activities using biotechnology to produce biochemicals, genetically engineered drugs and vaccines.

chemical pharmaceuticals preparations manufacturing the active ingredients and excipients of chemical drugs are mixed, processed and formulated to form various dosage forms directly used for the prevention and diagnosis of human diseases.

Manufacture of drugs.

solvent recovery equipment A device that collects and purifies the solvents used in the production process of various pharmaceutical manufacturing industries for reuse or disposal.

direct discharge

The act of discharging water pollutants directly into environmental water bodies.

indirect discharge

The act of discharging water pollutants into the public sewage treatment system by a sewage unit.

rainwater outlet

A discharge outlet that specifically discharges natural precipitation outside the plant boundary, either directly or through ditch, canal, or pipeline.

3.10

volatile organic compounds (VOCs) Organic compounds participating in atmospheric photochemical reactions, or organic compounds determined according to relevant regulations.

When characterizing the overall emission of VOCs, according to industry characteristics and environmental management requirements, total volatile organic compounds (with

TVOCs) can be used.

expressed), non-methane total hydrocarbons (expressed as NMHC) as pollutant control items.

6.1.2.1 General provisions

The pollutant discharging unit shall record in detail the operation status of its production and pollution control facilities, and shall refer to 6.1.2.2 ~ 6.1.2.6 for content records in daily production Relevant information and organize it into a ledger for future reference.

6.1.2.2 Production Health Record

According to the various types of pharmaceutical products in the manufacturing of traditional Chinese medicine, biological pharmaceutical products, and chemical pharmaceutical preparations, record each production batch or cycle below Related Information.

- a) The dosage of raw and auxiliary materials, mainly including the dosage of raw materials, the dosage of various solvents, the dosage of adsorbents, the dosage of other auxiliary materials, etc.;
- b) Product output, rate and material balance;
- c) Fresh water intake, water consumption, electricity consumption, etc.;
- d) The main production equipment used, the operation and use records of the facilities, etc.

6.1.2.3 Records of the operation status of wastewater pollution control facilities

Record sewage treatment volume, return water consumption, reuse rate, sewage discharge volume, sludge production volume (record moisture content by day or batch), Name and dosage of chemicals used in sewage treatment, power of blower, etc.; record the operation, failure and maintenance of sewage treatment facilities.

6.1.2.4 Records of operating status of waste gas pollution control facilities

Record the names and quantities of consumables such as adsorbents and filter materials used in waste gas treatment according to the replacement batch; record the operating parameters of waste gas treatment facilities number, faults and maintenance.

6.1.2.5 Records of solvent use and operation status of recovery equipment

Record the solvent name, usage, recovery, replenishment, as well as the energy and consumables of solvent recovery equipment according to the production batch or cycle of each product usage, etc.