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

HJ 611-2011

**Technical guidelines for environmental impact assessment.
Pharmaceutical constructional project
(English Translation)**

Issued on: February 11, 2011

Implemented on: June 1, 2011

Issued by: Ministry of Ecology and Environment

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Foreword

To implement the Environmental Protection Law of the People's Republic of China, the Environmental Impact Assessment Law of the People's Republic of China and the Environmental Protection of Construction Projects the Regulations governing and guiding the environmental impact assessment of pharmaceutical construction projects shall be formulated.

This standard specifies the general principles, contents, methods and technical requirements for environmental impact assessment of pharmaceutical construction projects.

This standard is the first release.

Appendix A of this standard is a normative appendix, and Appendix B and Appendix C are informative appendices.

This standard was formulated by the Science and Technology Standards Department of the Ministry of Environmental Protection.

This standard is mainly drafted by. Jilin Province Environmental Engineering Evaluation Center and PetroChina Northeast Refining & Chemical Engineering Co., Ltd.

This standard was approved by the Ministry of Environmental Protection on February 11, 2011.

This standard was implemented on June 1, 2011.

This standard is explained by the Ministry of Environmental Protection.

Technical Guidelines for Environmental Impact Assessment Pharmaceutical Construction Project

1 Scope of application

This standard specifies the general principles, contents, methods and technical requirements for environmental impact assessment of pharmaceutical construction projects.

This standard is applicable to the environmental impact assessment of pharmaceutical construction projects for new construction, reconstruction, expansion and enterprise relocation.

The environmental impact assessment of construction projects for the production of veterinary drugs and pharmaceutical intermediates can be carried out in accordance with this standard.

2 Normative references

The terms in the following documents become the terms of this standard by reference to this standard. Valid versions of undated references Applicable to this standard.

GB 5085 Hazardous Waste Identification Standard GB 18218 Identification of major hazard sources of hazardous chemicals GB 18484 Hazardous Waste Incineration Pollution Control Standard GB 18597 Hazardous Waste Storage Pollution Control Standard GB/T 14848 Groundwater Quality Standard GB/T 15190 Urban area environmental noise applicable area division technical specification HJ/T 2.1 Technical Guidelines for Environmental Impact Assessment HJ 2.2 Technical Guidelines for Environmental Impact Assessment Atmospheric Environment HJ/T 2.3 Technical Guidelines for Environmental Impact Assessment Surface Water Environment HJ 2.4 Environmental Impact Assessment Technical Guidelines Acoustic Environment HJ/T 14 Environmental Air Quality Functional Area Division Principles and Technical Methods HJ/T 25 Industrial Enterprise Soil Environmental Quality Risk Assessment Benchmark HJ/T 164 Groundwater Monitoring Technical Specification HJ/T 166 Technical Specifications for Soil Environmental Monitoring HJ/T 169 Technical Guidelines for Environmental Risk Assessment of Construction Projects HJ/T 176 Technical Specifications for Construction of Hazardous Waste Centralized Incineration Disposal Project HJ/T 338 Technical specification for division of drinking water source protection zones National Directory of Hazardous Wastes (Order No. 1 of the Ministry of Environmental Protection) "Catalogue of Classified Management of Environmental Impact Assessment of Construction Projects" (Order No. 2 of the Ministry of Environmental Protection) Interim Measures for Public Participation in Environmental Impact Assessment (Huanfa [2006] No. 28)

3 Terms and definitions

The following terms and definitions apply to this standard.

Drugs pharmaceuticals Refers to the production approved by the drug regulatory authority of the State Council for the prevention, diagnosis and treatment of human diseases, and the purposeful regulation of human physiology Functional and prescribed substances with adaptive or functional indications, usage and dosage.

Pharmaceutical intermediate Refers to chemical raw materials or chemical products used in the process of drug synthesis.

Veterinary drug

Refers to substances used to prevent, treat, diagnose, or purposefully regulate the physiology of animals.

Active pharmaceutical ingredient, API Refers to the production of the active ingredients and active ingredients approved by the drug regulatory department of the State Council, which

constitutes a part of the raw materials of the drug.

Chemical synthesis

The production process of chemical or chemical raw materials by chemical reaction of organic or inorganic substances.

Biochemical products manufacturing biological pharmacy the use of organisms and biological life activities to manufacture pharmaceutical products, including fermenting pharmaceuticals, extracting pharmaceuticals, and biotechnology pharmaceuticals.

Fermentation pharmacy refers to the production of medicines through the process of fermentation, filtration and purification of organic raw materials through the life activities of microorganisms.

Cheng.

Extraction of pharmaceuticals refers to the use of physical, chemical, and biochemical methods to extract active substances that play an important physiological role in living organisms.

Separation, purification and other means to produce a pharmaceutical production process.

Biotechnology pharmacy refers to the use of microorganisms, parasites, animal toxins, biological tissues, etc., using modern biotechnology (mainly genes) Engineering technology, etc.) The production process of peptides and protein drugs, vaccines, etc.

Simple drug dispensing and compounding pharmaceuticals subpackage and compounding by mixing, processing and formulating, the pharmaceutically active ingredients and excipients are made into a process for the production of a dosage form.

Chinese medicine decoction pieces processing and Chinese patent medicine manufacturing pharmacy of traditional Chinese medicine decoction pieces and Traditional Chinese patent medicine Taking medicinal plants and medicinal animals as the main raw materials, according to the Chinese Pharmacopoeia, the pharmaceutical process of Chinese herbal medicine pieces and Chinese patent medicines is produced.

Pharmaceutical construction project Refers to the manufacture of chemical drugs, the manufacture of biochemical products, the dispensing and compounding of simple drugs, the processing of Chinese herbal medicines and the manufacture and matching of proprietary Chinese medicines.

Set of construction projects.

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Pharmacy manufacturing enterprise Pharmaceutical and API manufacturing companies.

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