99005001005000

Manufacture of medicines permit

Heruntergeladen am 16.06.2025
https://fimportal.de/xzufi-services/S100002001000012000/S100002

Modul	Sachverhalt
Leistungsschlüssel	99005001005000
Leistungsbezeichnung I	Manufacture of medicines permit
Leistungsbezeichnung II	Permission to manufacture medicines
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Medicines manufacturing license , Medicines Permission to manufacture , Manufacturing authorisation for medicinal products
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	08.07.2022
Fachlich freigegen durch	
Handlungsgrundlage	• [§ 13 Medicines Act (AMG)](http://www.gesetze-im-internet.de/amg_1976/__13.html) • [Ordinance on the application of good manufacturing practice in the manufacture of medicinal products and active ingredients and on the application of good professional practice in the manufacture of products of human origin (drugs and active ingredient manufacturing ordinance - AMWHV)](https://www.gesetze-im-internet.de/amwhv/)
Teaser	You need a permit from the responsible authority if you want to manufacture medicinal products and are based in Hamburg.
Volltext	If you want to commercially or professionally manufacture medicinal products (human medicinal products, including clinical trial medicinal products), test sera or test antigens, active substances that are of human, animal or microbial origin or that are produced by genetic engineering or other substances of human origin intended for the manufacture of medicinal products, you require a permit to do so. The competent authority monitors the manufacture of human medicinal products and clinical trial medicinal products nationwide. Manufacturing activities that require a licence are usually applicable to the following categories of companies: • The classic pharmaceutical drug manufacturers • Manufacturer of blood products • Pharmaceutical entrepreneurs • Active ingredient manufacturer • Exporters • Importers • External testing laboratories for pharmaceuticals
Erforderliche Unterlagen	• Informal application with exact name of the applicant and information on the legal form, if applicable, extract

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	from the commercial register • Organizational chart of officials • Name of the establishment (name, street, place), • Site plans of the operational buildings and operating rooms for production, testing and storage including the flow of materials and personnel • if available, information on external warehouses (including addresses and site plans), • Proof of availability of the rooms (e.g. rental agreement) • Designation of a qualified person according to Section 14 of the Medicines Act, including telephone number • Proof of the required expertise of the persons according to Section 15 AMG • officially certified copy of the license certificate • Employment certificate to prove professional experience • CV • Proof of the reliability of the competent person and the reporting person from the management by means of a certificate of good conduct of document type O • Declarations of commitment for appointment as a qualified person or as a graduated plan representative or as an information representative • Declaration on the designation that no professional or public prosecutorial proceedings are pending against the competent person or graduated plan representative or information officer or managing director • Information on manufacturing activities (products, processes, volume per year) • Human medicinal products or clinical investigational medicinal products • Name of the medicinal product and dosage form, scope of manufacture and, where applicable, the process • if applicable, information on the companies commissioned to carry out tests under the Medicines Act • current "Site Master File" or description of the facility • Quality Assurance Manual • List of manufacturing activities including process overviews

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Voraussetzungen	• the presence of a person with the necessary expertise, reliability and availability (competent person) • the availability of suitable operating rooms and facilities • Proof that manufacturing and testing are carried out in accordance with the state of the art in science and technology and that the requirements of the EU Guide to Good Manufacturing Practice (GMP) are met. • As part of the procedure, an acceptance inspection is carried out by the competent authority
Kosten	Fees apply. The amount of the fees is calculated according to state law.
Verfahrensablauf	You can apply for permission informally to the responsible authority. Your application must contain the following information: • exact name of the applicant and information on the legal form • Organizational chart with functionaries • Name of the establishment (name, street, place) • Floor plan including planned material and personnel flows • Information on external warehouses (including address) • Name, telephone and fax number • a qualified person according to Section 15 of the Medicines Act, • a head of production and • a head of quality control, including telephone and fax number • Information on manufacturing activities (products, processes, volume per year) • Information on whether you are applying for authorisation for authorised human medicinal products or clinical investigational medicinal products • Name of medicinal products and dosage forms, scope of manufacture and process • Information on the companies commissioned to carry out tests under the Medicines Act, if applicable Please contact the relevant authority before submitting

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	your application to clarify the details. If the above-mentioned documents are available to the competent authority, further documents relating to the quality management system specific to your planned operation will be requested. Once all required documentation has been submitted, the responsible authority will carry out an acceptance inspection.
Bearbeitungsdauer	The processing time is at least 4 weeks. If all the necessary documents are submitted to the responsible authority, the processing takes a maximum of 3 months.
Frist	Submit your application in such a way that all required documents are available at least three months before the planned start of production operations.
weiterführende Informationen	https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/ https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/
Hinweise	No.
Rechtsbehelf	Contradiction
Kurztext	• Permission to manufacture medicinal products • Manufacture of medicinal products permit If you want to manufacture the following products, you need a permit: • Medicinal products (human medicinal products, including clinical trial medicinal products) • Test serum or test antigens • Active substances of human, animal or microbial origin or produced by genetic engineering • Other substances of human origin intended for use in the manufacture of medicinal products
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority

Modul	Sachverhalt
Formulare	
Ursprungsportal	Behördenfinder Hamburg, Authority finder Hamburg (Currently this link is only available in german)