99005001005000, 99005001005000

Pharmaceutical production - authorization

Modul	Sachverhalt
Leistungsschlüssel	99005001005000, 99005001005000
Leistungsbezeichnung I	Pharmaceutical production - authorization
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Erlaubnis (005)
SDG-Informationsbereich	Rechte des geistigen Eigentums (Antrag auf Erteilung eines Patents, Anmeldung einer Marke, einer Zeichnung oder eines Gebrauchsmusters, Erwerb einer Lizenz für die Vervielfältigung), Erlangung von Lizenzen,

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	Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Patente und geistiges Eigentum (2100500), Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/index.html https://www.gesetze-im-internet.de/amg_1976/index.html
Teaser	You require a license from the competent authority for the commercial or professional manufacture of medicinal products.
Volltext	If you wish to manufacture medicinal products (human or veterinary medicinal products, including clinical investigational medicinal products), test sera or test antigens, active substances of human, animal or microbial origin or which are manufactured by genetic engineering or other substances of human origin intended for the manufacture of medicinal products on a commercial or professional basis, you require a license to do so.
Erforderliche Unterlagen	• Informal application with exact name of the applicant and details of the legal form • Extract from the commercial register, if applicable • Designation of the business premises (name, street, town) • Site plans of the company buildings and premises for production, testing and storage • If available, details of external warehouses (also addresses and site plans) • Proof of availability of the rooms • Appointment of a competent person in accordance with Section 15 of the German Medicines Act (AMG), stating telephone and fax number • Proof of the required expertise of the persons in the

Modul	Sachverhalt
	original or a certified copy • Details of manufacturing activities (products, processes, volume per year) • Medicinal products for human use/veterinary medicinal products • Designation of the medicinal products and pharmaceutical forms, scope of manufacture and, where applicable, procedures • If applicable, details of the companies responsible for testing in accordance with the Medicinal Products Act • Current "Site Master File" or description of the facility, quality assurance manual • List of manufacturing activities
Voraussetzungen	
Kosten	Fees are charged for the issue of the manufacturing authorization and the acceptance inspection. In accordance with the Thuringian Administrative Cost Regulations for the Ministry of Social Affairs, Family and Health of March 14, 2006 (BVBl. V. 30.03.2006 p. 73 ff.), fees of 150.00 to 3,500.00 euros are charged.
Verfahrensablauf	
Bearbeitungsdauer	
Frist	Applications should be submitted in full at least three months before the planned start of production.
weiterführende Informationen	
Hinweise	As part of the procedure, an acceptance inspection is carried out by the competent authority. The owner of a pharmacy does not require a license for the manufacture of medicinal products as part of normal pharmacy operations.
Rechtsbehelf	
Kurztext	• A license is required for the commercial or professional manufacture of medicinal products • Written application must be submitted with the required documents • Fees are charged for the issue of the manufacturing authorization and the acceptance inspection

Modul	Sachverhalt
	• Responsible: The authority responsible for the supervision of medicinal products. This can be found on the website of the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) under Medicinal Products/ Directory of Authorities and Institutions.
Ansprechpunkt	Contact the authority responsible for drug monitoring. You can find these on the website of the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) under Medicinal Products/ Directory of Authorities and Institutions.
Zuständige Stelle	
Formulare	The above list of application documents no. 1 to 13 only provides an overview of the documents that generally need to be submitted. The competent regulatory authority for medicinal products will be happy to provide you with a detailed information sheet tailored to your project.
Ursprungsportal	Arzneimittelherstellung - Erlaubnis, Pharmaceutical production - authorization