99005001005000, 99005001005000

Pharmaceutical production - permission

Modul	Sachverhalt
Leistungsschlüssel	99005001005000, 99005001005000
Leistungsbezeichnung I	Pharmaceutical production - permission
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	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens, Rechte des geistigen Eigentums (Antrag auf Erteilung eines Patents,

Modul	Sachverhalt
	Anmeldung einer Marke, einer Zeichnung oder eines Gebrauchsmusters, Erwerb einer Lizenz für die Vervielfältigung)
Lagen Portalverbund	Patente und geistiges Eigentum (2100500), Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	http://www.gesetze-im-internet.de/amg_1976/index.html http://www.gesetze-im-internet.de/amg_1976/index.html
Teaser	For the commercial or professional manufacture of medicinal products, you need a permit from the competent authority.
Volltext	If you want to manufacture medicinal products (human or veterinary medicinal products, including investigational 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 on a commercial or professional basis, you need a permit to do so.
Erforderliche Unterlagen	• Informal application with exact designation of the applicant and information on the legal form • Excerpt from the commercial register, if applicable • Designation of the business premises (name, street, place) • Site plans of the company buildings and premises for production, testing and storage • if available, details of external storage facilities (addresses and site plans here too) • Proof of availability of the rooms • Nomination of a competent person according to § 15 German Medicines Act (AMG) including telephone and fax numbers

Modul	Sachverhalt
	• Proof of the required expertise of the persons in the original or certified copy • Details of manufacturing activities (products, processes, volume per year) • Medicinal products for human use/ veterinary medicinal products • Designation of the medicinal product and dosage forms, scope of manufacture and, if applicable, procedure • If applicable, details of the companies commissioned to carry out tests in accordance with the German Medicines Act • Current "Site Master File" or description of the facility, quality assurance manual • List of manufacturing activities
Voraussetzungen	
Kosten	Fees are charged for the issuance of the manufacturing permit and the acceptance inspection. In accordance with the Thuringian administrative cost regulations for the area of responsibility of the Ministry of Social Affairs, Family and Health of 14 March 2006 (BVBl. V. 30.03.2006 p. 73 ff.), fees of between 150.00 and 3,500.00 euros are incurred.
Verfahrensablauf	
Bearbeitungsdauer	
Frist	Applications should be complete at least three months prior to the planned start of manufacturing operations.
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 permit for the manufacture of medicinal products as part of normal pharmacy operations.
Rechtsbehelf	
Kurztext	• Permission is required for the commercial or

Modul	Sachverhalt
	professional manufacture of medicinal products • written application must be submitted with required documents • Fees are charged for the issuance of the manufacturing permit and the acceptance inspection. • Responsible: The authority responsible for drug monitoring. 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. 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.
Zuständige Stelle	
Formulare	The above list of application documents Nos. 1 to 13 contains only an overview of the documents to be submitted in principle. The drug regulatory authority responsible for you will be happy to provide you with a detailed information sheet tailored to your project.
Ursprungsportal	Arzneimittelherstellung - Erlaubnis, Pharmaceutical production - permission