99005001005000, 99005001005000

Applying for a permit to manufacture medicinal products

Modul	Sachverhalt
Leistungsschlüssel	99005001005000, 99005001005000
Leistungsbezeichnung I	Applying for a permit to manufacture medicinal products
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Sachsen-Anhalt
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

Modul	Sachverhalt
	Lizenz für die Vervielfältigung)
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200), Patente und geistiges Eigentum (2100500)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__13.html https://www.gesetze-im-internet.de/amg_1976/__13.html
Teaser	
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, excerpt 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, • Designation of a competent person in accordance with Section 15 of the German Medicines Act, stating telephone and fax number, • Proof of the required expertise of the persons according to 6. in the original or a certified copy, • Details of the manufacturing activities (products, processes, volume per year),

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	• 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 commissioned with 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 permit and the acceptance inspection.
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	
Ansprechpunkt	Please contact the State Administration Office.
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.

Modul	Sachverhalt
Ursprungsportal	Erlaubnis für die Arzneimittelherstellung beantragen, Applying for a permit to manufacture medicinal products