99005001005000

Manufacture of medicinal products - apply for a licence

Modul	Sachverhalt
Leistungsschlüssel	99005001005000
Leistungsbezeichnung I	Manufacture of medicinal products - apply for a licence
Leistungsbezeichnung II	Manufacture of medicinal products - apply for a licence
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher	

Modul	Sachverhalt
Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	
Teaser	If you want to manufacture medicinal products and are based in Baden-Württemberg, you need a licence from the Baden-Württemberg Medicines Monitoring Centre.
Volltext	If you want to manufacture medicinal products and are based in Baden-Württemberg, you need a licence from the Baden-Württemberg Medicines Monitoring Centre. The control centre monitors both human and veterinary medicinal products throughout the state • the classic pharmaceutical drug manufacturers, • Manufacturers of blood products, • pharmaceutical companies, • Exporters, • Importers and • external testing laboratories for medicinal products.
Erforderliche Unterlagen	• Site plans and floor plans of the company buildings and operating rooms for production, testing and storage • for external warehouses: site and floor plans • Proof of availability of the rooms, e.g: Copy of the rental agreement or Extract from the land register • Proof of the required expertise of the competent person(s) (for deeds: certified copy in paper form) • Proof of the required reliability of the competent person(s) and the applicant ("certificate of good conduct for submission to an authority") • current "Site Master File", description of the facility or quality assurance manual • List of manufacturing activities
Voraussetzungen	• In your company there are a competent person with the necessary reliability and suitable rooms and facilities for the intended manufacture, testing and storage of the medicinal products • You can guarantee that you Manufacture and test

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	medicinal products in accordance with the state of the art in science and technology and also comply with the provisions of the second section of the Transfusion Act when collecting blood and blood components.
Kosten	Fees are charged in accordance with the state fee schedule.
Verfahrensablauf	You can apply informally to the competent authority for authorisation. Your application must contain the following information: • exact name of the applicant and details of the legal form • Designation of the business premises (name, street, town) • Details of external warehouses (including address) • Name, telephone and fax number a qualified person in accordance with § 15 of the German Medicines Act, a production manager and a head of quality control • whether you are applying for authorisation for human or veterinary medicinal products • Designation of the medicinal product and pharmaceutical forms, process and planned manufacturing volume (quantity per year) • Details of the companies authorised to carry out tests in accordance with the Medicinal Products Act, if applicable Tip: Contact the competent body before submitting the application to clarify the detailsclarify the details. Once the complete documentation has been submitted, the competent body will carry out an acceptance inspection.
Bearbeitungsdauer	
Frist	Your complete application should be submitted at least three months before the planned start of production.
weiterführende Informationen	
Hinweise	Website of the Baden-Württemberg Drug Monitoring Centre

Modul	Sachverhalt
Rechtsbehelf	Action before the competent court
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	