99005001005000, 99005001005000

Apply for permission to manufacture medicinal products

Modul	Sachverhalt
Leistungsschlüssel	99005001005000, 99005001005000
Leistungsbezeichnung I	Apply for permission to manufacture medicinal products
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Schleswig-Holstein
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

Modul	Sachverhalt
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
Teaser	Anyone wishing to manufacture medicinal products requires a permit to do so.
Volltext	If you • 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 produced by genetic engineering or • other substances of human origin intended for the manufacture of medicinal products for the manufacture of medicinal products, you require a license. Prerequisites include proof of the required expertise of a competent person to be appointed, the existence of suitable premises and proof that production 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.
Erforderliche Unterlagen	As different documents may be required, it is recommended that you contact the responsible office in advance.

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Voraussetzungen	
Kosten	Fees are charged for the issue of the manufacturing permit and the acceptance inspection in accordance with the state ordinance on administrative fees (general fee schedule). Detailed information on this can be obtained from the responsible office.
Verfahrensablauf	
Bearbeitungsdauer	
Frist	3 Monat(e) Applications should be submitted in full at least three months before the planned start of production.
weiterführende Informationen	
Hinweise	The owner of a pharmacy does not require a license to manufacture medicines as part of normal pharmacy operations. Information on the subject of drug monitoring can be found on the website of the State Office for Social Services. https://www.schleswig-holstein.de/DE/Landesregierung/LASD/Aufgaben/Arzneimittelueberwachung/ArzneimittelueberwachungSubmenue_kachelnTable.html https://www.schleswig-holstein.de/DE/Landesregierung/LASD/Aufgaben/Arzneimittelueberwachung/ArzneimittelueberwachungSubmenue_kachelnTable.html
Rechtsbehelf	
Kurztext	
Ansprechpunkt	To the State Office for Social Services (LAsD).
Zuständige Stelle	
Formulare	
Ursprungsportal	Apply for permission to manufacture medicinal products, Erlaubnis zu Arzneimittelherstellung beantragen