



Zāļu valsts aģentūra

**Eudra GMDP datu bāzē attēlotā informācija:
zāļu lieltirgotavu jaunā licences forma,
labas ražošanas un izplatīšanas prakses sertifikāti**

Farmaceutiskās darbības licencēšanas nodaļas vadītāja **Signe Čudare**,
vecākā eksperte **Tatjana Valentīnasa**
Rīga, 23.01.2025.

EudraGMDP datubāzi uztur Eiropas Zāļu aģentūra

<https://eudragmdp.eudra.org>

EudraGMDP

Welcome to EudraGMDP

EudraGMDP is the name for the Union database referred to in article 111(6) of Directive 2001/83/EC as amended, and article 91 of Regulation (EU) 2019

- Manufacturing and import authorisations
- Good Manufacturing Practice (GMP) certificates.
- Statements of non-compliance with GMP
- GMP inspection planning in third countries

In addition the following new information is required in the database for the first time in 2013. As data transfer from national systems can be complex, it

- Wholesale Distribution Authorisations
- Good Distribution Certificates (GDP)
- Statements of non-compliance with GDP
- Registration of manufacturers, importers and distributors of active substances for human use located in the EEA.

Almost all information uploaded into the database is available to the general public. National Competent Authorities are able to exclude some information

Read-only access to EudraGMDP

Access to EudraGMDP application for registered users.

Users are advised that since inspections of manufacturers of active substances are based on risk, some active substance manufacturers may not be GMP.

EMA is not responsible for the contents of the database. Any questions on its content should be addressed to the relevant National Competent Authority

Ir divas iespējas
pieslēgties
EudraGMDP
datubāzei:

1) kā reģistrēts
lietotājs;

2) kā neregistrēts
– pieejama tikai
publiski ievietotā
informācija

Jaunas zāļu lieltirgotavas licenču formas

- EudraGMDP datubāzē informāciju par zāļu lieltirgotavām izsniegtajām licencēm var atrast, izvēloties sadaļu «WDA»
- No 01.11.2024.

The screenshot displays the EudraGMDP web application interface. At the top left, the 'EudraGMDP' logo is visible. Below it, a navigation bar contains links for MIA, GMP, API REG, WDA, GDP, Sites, and Alerts. The 'WDA' link is highlighted with a red box. On the left side, there is a 'WDA Menu' with options for 'New WDA', 'Draft WDA', and 'Search'. The 'WDA' link in this menu is also highlighted with a red box. The main content area is titled 'Search WDA' and contains several search criteria fields: 'Authorisation Number', 'Authorisation Holder OMS Organisation ID', 'Authorisation Holder', 'Additional Details on Units Inspected', 'Inspecting Authority Country', and 'Inspecting Authority'. Below these fields is the 'Site Details' section, which includes fields for 'Name', 'City', 'Country' (set to 'LATVIA'), 'Postcode', 'Additional Details on Units Inspected', 'OMS Location ID', and 'NCA Reference Key'. The 'Legal basis of authorisation' section has radio buttons for 'Art. 77(1) of Directive 2001/83/EC', 'Art. 99 of Regulation (EU) 2019/6', and 'Other'. At the bottom, there are checkboxes for 'Include Withdrawn WDA' and 'Include Suspended WDA'. A 'Search' button is located at the bottom right of the form.

Par jaunām zāļu lieltirgotavas licenču formām

- Ja zāļu lieltirgotavai ir vairāk nekā viena farmaceitiskās darbības vietas adrese, tad **EudraGMDP** datu bāzē tiek veidoti 2 pielikumi;
- Katrai farmaceitiskās darbības vietas adresei savs pielikums un katram pielikumam tiek atzīmēti atļautie darbības veidi;
- Katrai farmaceitiskās darbības vietas adresei jābūt reģistrētai OMS atsevišķi (**EudraGMDP** izvēlas atbilstoši katram pielikumam savu adresi).

Humāno zāļu lieltirgotavas pielikuma jaunā forma (ar sarkanu iezīmētas izmaiņas):

Annex 1 Annex 1 Remarks

Scope of Authorisation

Human medicinal products: Veterinary medicinal products:

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

1. MEDICINAL PRODUCTS

1.1. with a Marketing Authorisation or registration in EEA country(s)

1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market*

1.3. without a Marketing Authorisation or registration in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1. Procurement

2.2. Holding

2.3. Supply

2.4. Export

2.5. Other activities(s): (please specify)

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1. Narcotic or psychotropic products**

3.2. Products requiring low temperature handling

3.2.1. Temperatures between 2 to 8 °C

3.2.2. Other temperatures: (please specify)

3.3. Other products: (please specify here or make a reference to Annex 5)

Ja nepieciešams apskatīt **GMP** (Good Manufacturing Practices - **Labas** ražošanas prakses sertifikāti)

Certificate Number:	<input type="text"/>
Inspecting Authority Country:	<input type="text"/>
Inspecting Authority:	<input type="text"/>
From Date:	<input type="text"/> (YYYY-MM-DD)
To Date:	<input type="text"/> (YYYY-MM-DD)
DUNS Number:	<input type="text"/>
Name:	<input type="text"/>
City:	<input type="text"/>
Country:	<input type="text" value="LATVIA"/>
Postcode:	<input type="text"/>
OMS Organisation Identifier:	<input type="text"/>
OMS Location Identifier:	<input type="text"/>
EudraGMDP Site Reference Number:	<input type="text"/>
NCA Reference Key:	<input type="text"/>
Additional Details on Units Inspected:	<input type="text"/>
MIA Number:	<input type="text"/>
Enable Scope Search:	<input type="checkbox"/>
Enable Inspection Search:	<input type="checkbox"/>
Enable Operations Search:	<input type="checkbox"/>
Enable API Search:	<input type="checkbox"/>
Building Name:	<input type="text"/>
Room Name (or) Number:	<input type="text"/>
Line Equipment:	<input type="text"/>
QC Test:	<input type="text"/>
Product Name:	<input type="text"/>
Include Withdrawn documents:	<input type="checkbox"/>
Show only sites under Compliance Management:	<input type="checkbox"/>
Include Non-Compliance Report:	<input checked="" type="checkbox"/>
	<input type="button" value="Search"/>

GMP Compliance Menu	
Search	
Planned Inspections	
GMP Certificates	
Non-Compliance Report	
Withdrawn GMP Certificates	

Izvēlamies valsti: Piem., Latvija un meklēt

GMPC Search Results • 1 to 10 of 53

Certificate Number	EudraGMDP Document Reference Number	NCA Site Reference Number	EudraGMDP Site Reference Number	Document Type	MIA Number	OMS Organisation Identifier	OMS Location Identifier	Site Name	Site Address	City	Postcode	Country	Site under Compliance Management	Inspection End Date	Last Updated By
ZVA/LV/2025/001A	174850	54481205756485910	5448	GMPC		ORG-100002509	LOC-100000997	Olpha AS	Rupnicu Iela 5	Olaine	2114	LATVIA		2024-10-15	iumure (LV_SAM)
ZVA/LV/2024/017H	174025	80001260436539897	8000	GMPC	R00041	ORG-100003458	LOC-100002233	PHARMIDEA SIA	Rupnicu Iela 4	Olaine	LV-2114	LATVIA		2024-08-23	iumure (LV_SAM)
ZVA/LV/2024/013A	172374	54481205756485910	5448	GMPC		ORG-100002509	LOC-100000997	Olpha AS	Rupnicu Iela 5	Olaine	2114	LATVIA		2024-06-10	iliepa (LV_SAM)
ZVA/LV/2024/015H	172960	1688382607798	183308	GMPC		ORG-100013765	LOC-100079610	Jelgavfarm SIA	Zemgales Prospekts 3 A	Jelgava	3001	LATVIA		2024-04-12	iumure (LV_SAM)
ZVA/LV/2024/014H	172664	1674212537308	161763	GMPC	R00052	ORG-100000401	LOC-100071879	Elme Messer L SIA	Kattlakalna Iela 9f	Riga	1073	LATVIA		2024-04-10	iumure (LV_SAM)
ZVA/LV/2024/001H	167571	682	14835	GMPC	R00045	ORG-100004445	LOC-100000978	Ingen Pharma SIA	Karla Ulmana Gatve 119	Marupe	2167	LATVIA		2024-02-09	iliepa (LV_SAM)
ZVA/LV/2024/006H	170283	91941276523066065	9194	GMPC	R00042	ORG-100018789	LOC-100042733	Astra Logistic Ltd.	Ziemeļu Iela 4 Marupes Pagasts	Lidosta Riga	1053	LATVIA		2024-01-25	iliepa (LV_SAM)
ZVA/LV/2024/005A	171469	2164761718191179882	5440	GMPC		ORG-100001082	LOC-100001754	Grindeks AS	Krustpils Iela 53	Riga	1057	LATVIA		2023-12-20	ivilcane (LV_SAM)
ZVA/LV/2024/003HV	167575	54721205761776369	5472	GMPC	R00027	ORG-100005786	LOC-100005447	Elvim SIA	Kurzemes Prospekts 3g	Riga	1067	LATVIA		2023-12-06	iliepa (LV_SAM)
ZVA/LV/2024/002H	167574	195	10085	GMPC	R00014	ORG-100013036	LOC-100019394	Tamro SIA	Noliktavu 5, Drelini	Ropazi	2130	LATVIA		2023-11-16	iliepa (LV_SAM)

Atrod visus
Latvijā
izsniegtos
Labas
ražošanas
prakses
sertifikātus

GMPC Search Results • 1 to 10 of 53

Certificate Number	EudraGMDP Document Reference Number	NCA Site Reference Number	EudraGMDP Site Reference Number	Document Type	MIA Number	OMS Organisation Identifier	OMS Location Identifier	Site Name
ZVA/LV/2025/001A	174850	54481205756485910	5448	GMPC		ORG-100002509	LOC-100000997	Olpha AS
ZVA/LV/2024/017H	174025	80001260436539897	8000	GMPC	R00041	ORG-100003458	LOC-100002233	PHARMIDEA SIA
ZVA/LV/2024/013A	172374	54481205756485910	5448	GMPC		ORG-100002509	LOC-100000997	Olpha AS
ZVA/LV/2024/015H	172960	1688382607798	183308	GMPC		ORG-100013765	LOC-100079610	Jelgavfarm SIA
ZVA/LV/2024/014H	172664	1674212537308	161763	GMPC	R00052	ORG-100000401	LOC-100071879	Elme Messer L SIA
ZVA/LV/2024/001H	167571	682	14835	GMPC	R00045	ORG-100004445	LOC-100000978	Ingen Pharma SIA
ZVA/LV/2024/006H	170283	91941276523066065	9194	GMPC	R00042	ORG-100018789	LOC-100042733	Astra Logistic Ltd.
ZVA/LV/2024/005A	171469	2164761718191179882	5440	GMPC		ORG-100001082	LOC-100001754	Grindeks AS
ZVA/LV/2024/003HV	167575	54721205761776369	5472	GMPC	R00027	ORG-100005786	LOC-100005447	Elvim SIA
ZVA/LV/2024/002H	167574	195	10085	GMPC	R00014	ORG-100013036	LOC-100019394	Tamro SIA

Lai apskatītu kādu
konkrētu sertifikātu,
spiež uz Sertifikāta
numura

Ja nepieciešams apskatīt **GDP** (Good Distribution Practices - **Labas izplatīšanas prakses sertifikāti**):



Izvēlamies valsti: Piem., Latvija un meklēt:

GDP Certificates

Distribution Operation:

Certificate Number:

Inspection Authority Country:

Inspection Authority:

From Date: (YYYY-MM-DD)

To Date: (YYYY-MM-DD)

Site Details

DUNS Number:

Name:

City:

Country:

Postcode:

OMS Organisation Identifier:

OMS Location Identifier:

NCA Reference Key:

Additional Details on Units Inspected:

WDA No./ API Registration Number:

Include Non-Compliance Report:

Scope of certificate

Human Active Substances / Human medicinal products

Veterinary Active Substances / Veterinary medicinal products

Certificate Number ↕	EudraGMP Document Reference Number	OMS Location Identifier	WDA No./API Reg.No.	Document Type ↕	Site Name ↕	Site Address	City ↕	Postcode ↕	Country ↕	Site under Compliance Management ↕	Inspection End ↕
ZVA/LV/2025/001D	31911	LOC-100086990	L00142	GDPWDA	FuturaPharm SIA	Dambja iela 5	Riga	1005	LV (Latvia)	false	2024-09-25
ZVA/LV/2024/016D	31449	LOC-10000988	L00016	GDPWDA	Unifarma SIA	Vangazu iela 23	Riga	1024	LV (Latvia)	false	2024-05-23
ZVA/LV/2024/015D	31338	LOC-100005447	L00023	GDPWDA	Elvim SIA	Kurzemes Prospekts 3g	Riga	1067	LV (Latvia)	false	2024-04-18
ZVA/LV/2024/014D	30718	LOC-100079889	L00143	GDPWDA	Novo Nordisk Latvia SIA	Karla Ulmana Gatve 119	Marupe	LV-2167	LV (Latvia)	false	2024-03-27
ZVA/LV/2024/013D	30736	LOC-100026946	L00061	GDPWDA	Baltijas Dializes Serviss SIA	Slokas iela 84-1a	Riga	1007	LV (Latvia)	false	2024-03-22
ZVA/LV/2024/011D	30737	LOC-100057972	L00083	GDPWDA	Insbergs SIA	Dzirčiema iela 5a	Riga	1083	LV (Latvia)	false	2024-02-29
ZVA/LV/2024/006D	30034	LOC-100058201	L00115	GDPWDA	A.Medical SIA	Varkalu iela 13a	Riga	1067	LV (Latvia)	false	2024-02-23
ZVA/LV/2024/001D	29922	LOC-100076756	L00141	GDPWDA	Bizma SIA	Skolas iela 21	Riga	LV-1010	LV (Latvia)	false	2024-01-31
ZVA/LV/2024/005D	30036	LOC-100078484	L00010	GDPWDA	Farm Impeks SIA	Uriekstes iela 3k-3	Riga	1005	LV (Latvia)	false	2024-01-25
ZVA/LV/2024/008D	30035	LOC-100011823	L00114	GDPWDA	Novartis Baltics SIA	Gustava Zemgala Gatve 76	Riga	1039	LV (Latvia)	false	2024-01-18

Atrod visus Latvijā izsniegtos Labas izplatīšanas prakses sertifikātus

Certificate Number ↕	EudraGMP Document Reference Number	OMS Location Identifier	WDA No./API Reg.No.	Document Type ↕	Site Name ↕	Site Address	City ↕	Postcode ↕	Country ↕	Site under Compliance Management ↕	Inspection End ↕
ZVA/LV/2025/001D	31911	LOC-100086990	L00142	GDPWDA	FuturaPharm SIA	Dambja iela 5	Riga	1005	LV (Latvia)	false	2024-09-25
ZVA/LV/2024/016D	31449	LOC-10000988	L00016	GDPWDA	Unifarma SIA	Vangazu iela 23	Riga	1024	LV (Latvia)	false	2024-05-23
ZVA/LV/2024/015D	31338	LOC-100005447	L00023	GDPWDA	Elvim SIA	Kurzemes Prospekts 3g	Riga	1067	LV (Latvia)	false	2024-04-18
ZVA/LV/2024/014D	30718	LOC-100079889	L00143	GDPWDA	Novo Nordisk Latvia SIA	Karla Ulmana Gatve 119	Marupe	LV-2167	LV (Latvia)	false	2024-03-27
ZVA/LV/2024/013D	30736	LOC-100026946	L00061	GDPWDA	Baltijas Dializes Serviss SIA	Slokas iela 84-1a	Riga	1007	LV (Latvia)	false	2024-03-22

Lai apskatītu kādu konkrētu sertifikātu, spiež uz Sertifikāta numura



Zāļu valsts aģentūra

Paldies par uzmanību!

23.01.2025.