ANMDMR - Nomenclatorul medicamentelor pentru uz uman

Lista medicamentelor din NOMENCLATOR

Actualizat în 06.06.2025

Căutare | Anulare filtru | Legendă | Descarcă Varianta Excel

1 2 3

	Denumire comercială	DCI	Forma farmaceutică	Cod ATC	Cod CIM	Firma / țara deținătoare APP	●	★	△	□	#
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950001	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950002	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950003	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950004	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950005	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950006	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL GEMAX PHARMA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W70950007	GEMAX PHARMA S.R.O. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL HEATON 0,50 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W65339001	HEATON K.S. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL HEATON 0,50 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W65339002	HEATON K.S. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL HEATON 0,50 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W65339003	HEATON K.S. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL HEATON 0,50 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W65339004	HEATON K.S. - REPUBLICA CEHA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665001	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665002	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665003	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665004	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665005	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,25 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69665006	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69666001	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69666002	STADA M&D SRL - ROMANIA					
Detalii	ALFACALCIDOL STADA 0,5 micrograme	ALFACALCIDOLUM	CAPS. MOI	A11CC03	W69666003	STADA M&D SRL - ROMANIA					

State Institute For Drug Control

CERTIFICATE NUMBER: ***sukls126967/2024***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of CZECHIA confirms the following:
The manufacturer: ***Heaton k.s.***
Site address: ***Podoli 78e, Podoli, 664 03, CZECHIA***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002884*** / ***LOC-100001478***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***sukls85302/2022*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-06-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

1.6.3 Chemical/Physical – only Physical 2.1.3 Chemical/Physical – only Physical

2024-08-26

Name and signature of the authorised person of the Competent Authority of CZECHIA

Confidential
State Institute For Drug Control
Tel:***Confidential***
Fax:***Confidential***

State Institute For Drug Control

CERTIFICATE NUMBER: ***sukls269232/2022***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***Heaton k.s.***
Site address: ***Podoli 78e, Podoli, 664 03, Czechia***
Additional details on units inspected: ***Areál společnosti Movianto Česká republika, s.r.o.***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002884*** / ***LOC-100001478***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***sukls85302/2022*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-01-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

1.6.3 Chemical/Physical - Physical only 2.1.3 Chemical/Physical - Physical only

2023-04-03

Name and signature of the authorised person of the Competent Authority of Czechia

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Tel:***Confidential***
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Landesamt Fuer Soziale Dienste Schleswig Holstein

CERTIFICATE NUMBER: ***DE_SH_01_GMP_2024_0045***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***Fairmed Healthcare GmbH***
Site address: ***Maria-Goeppert-Strasse 3, St. Juergen, Luebeck, Schleswig-Holstein, 23562***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002584*** / ***LOC-100050141***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_SH_01_MIA_2024_0022*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-10-01***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Batch certification for contract manufactured medicinal products and imported medicinal products(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products

Clarifying remarks (for public users)

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations To 1.6.3: Organoleptic tests only Any restrictions or clarifying remarks related to the scope of these Importation operations To 2.1.3: Organoleptic tests only The archiving of documents and the storage of retention samples is partly carried out in the rooms at the site Dorotheenstr. 48, D-22301 Hamburg. Property according to lease agreements dated 13/09/2024 and 04/10/2024P

2024-12-18

Name and signature of the authorised person of the Competent Authority of

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Confidential
Landesamt Fuer Soziale Dienste Schleswig Holstein
Tel:***Confidential***
Fax:***Confidential***

National Authority Of Medicines And Medical Devices

CERTIFICATE NUMBER: ***084/2024/RO***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Romania confirms the following:
The manufacturer: ***SANTA S.A.***
Site address: ***Strada Panselelor Nr 25, Brasov, 500419, Romania***
Additional details on units inspected: ***SANTA SA, complete address: Str. Panselelor, nr.25, nr.27 şi nr.29, Municipiul Braşov, Jude Braşov, cod po tal 500419, Romania***
OMS Organisation Id. / OMS Location Id.: ***ORG-100006043*** / ***LOC-100031043***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***47F*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-05-30***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: film-coated tablets(en) 1.2.1.13 Tablets Special Requirements 7 Other: corticosteroids(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: film-coated tablets(en) 1.5.1.13 Tablets Special Requirements 7 Other: corticosteroids(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

total manufacturing operations for non-sterile prod-tablets (including tab with corticosteroids,in campaign),film-coated tab,capsules,are carried out in Block 10;partial manufacturing operations-secondary packaging/collective packaging/collective packaging/labelling/re-labelling/serialization/batch certification for sterile prod and non-sterile prod with parallel import authorization in EU countries are carried out in Block 10;partial manufacturing op are carried out for human med prod-primary packing,secondary packing,serialization,batch testing and batch certification-non-sterile prod-tab,film-coated tab,capsules for third parties,under contract;(text missing);batch testing and batch certification are performed for imported human med prod mentioned in Annex no. 8 of Manufacturing Authorization;importation of intermediate prod from China (Metamizol Sodic DC 90 grade,Paracetamol DC 90,Paracetamol DC90-9),USA (Paracetamol Compap CPM).This GMP certificate is valid up to November 2025.

2024-11-29

Name and signature of the authorised person of the Competent Authority of Romania

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