Nomenclatorul medicamentelor de uz uman

Lista medicamentelor din NOMENCLATOR

Actualizat în 14.11.2023

Căutare | Anulare filtru (medicamente) | Legendă | Descarcă Varianta Excel (/files/nomenclator.xlsx)

	Denumire comercială denCom=E
Detalii	ENTECAVIR

Detalii medicament

Denumire comercială	ENTECAVIR ACCORD 1 mg
DCI	ENTECAVIRUM
Forma farmaceutică	COMPR. FILM.
Concentrația	1mg
Cod ATC	J05AF10
Acțiune terapeutică	ANTIVIRALE CU ACTIUNE DIRECTA INHIB. NUCLEOZIDICI SI NUCLEOTIDICI AI REVERSTRANSCRIPTAZEI
Prescripție	PR
Ambalaj	Cutie cu 30 x 1 compr. film.
Volum ambalaj	
Valabilitate ambalaj	3 ani
Cod CIM	W65672001
Firma / țara producătoare APP	PHARMADOX HEALTHCARE LTD. - MALTA
Firma / țara deținătoare APP	ACCORD HEALTHCARE S.L.U. - SPANIA
Nr. / data ambalaj APP	1211/2017/05
Rezumat caracteristici produs	vizualizare în pagină nouă (https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human)
Prospect	vizualizare în pagină nouă (https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human)
Ambalaj	vizualizare în pagină nouă (https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human)

Închide

Digitally signed by Moraru Grigore
Date: 2024.01.25 08:54:34 EET
Reason: MoldSign Signature
Location: Moldova

PHARMADOX

BATCH RELEASE CERTIFICATE

Product & Dose:	Entecavir Accord 1 mg tabletki powlekane / comprimate filmate / filmsko obložene tablete
Importing Country:	Poland, Romania, Slovenia
Marketing Authorization number:	EU/1/17/1211/005
Strength / Potency:	1 mg
Dosage form:	Film-coated Tablets
Package size and type:	3 blisters x 10 tablets = 1 pack (30 tablets)
Batch number:	ENT23022A
Date of Manufacture:	Mar-2022
Expiry date:	Feb-2026
Batch quantity:	1917 packs
Name and address of all manufacturing sites and quality control sites:	Hetero Drugs Limited, Unit I Survey Nos. 213, 214 and 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana, India Hetero Labs Limited, Unit-V Sy.No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District 509301, Telangana, India Pharmadox Healthcare Ltd (ML 013) KW20A Kordin Industrial Park, Paola PLA3000, Malta
Reference to CoA:	X23G0283/00
Comments:	• Certificates of GMP Compliance of above sites available • The following deviations were reported and properly investigated and closed: IR-FDPD-23-0002

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country or product specification file for Investigational Medicinal Products as outlined in the Technical Quality Agreement. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The batch is released for sale by the undersigned Qualified Person in accordance with EC directive 2001/83.

Prepared by & Date:

10.10.2023

QA Manager (Batch Documentation)
Suraj Mettu

Approved by & Date:

10 OCT 2023

Qualified person

SALVATORE LEONE VENUTO
QUALIFIED PERSON

PHARMADOX	PHARMADOX HEALTHCARE LTD. KW20A Corradino Industrial Estate Paola PLA3000, Malta

CERTIFICATE OF ANALYSIS

Product Name:	Entecavir Film-coated tablets 1mg by 30 Tablets		
Generic Name:	Entecavir Film-coated tablets 1mg		
Product QC Lab No:	FP23-6715	CoA No / Rev.:	X23G0283/00
Client Batch No:	ENT23022A	Mfg. Date:	As per Manufacturer's CoC
Client Name:	Accord	Exp. Date:	02/2026
Manufacturer's Name:	As per Manufacturer's CoC	Batch Qty.:	As per Manufacturer's CoC
Specification Ref No:	CF-335 : Sec 5 Ver 08	Analytical Method Ref No:	CF-335 : Sec 6 Ver 08

S. NO	TEST DESCRIPTION	SPECIFICATION	RESULT	
01.	**Description**	Pink, triangle shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '111' on the other side.	Complies	
02.	**Identification**			
	A) By HPLC	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the Assay.	Complies	
	B) By UV	The UV absorption spectrum of the sample solution should exhibit maxima only at the same wavelengths as that of a standard solution.	Complies	
03.	**Average Weight (mass)**	412.0mg ± 3% (399.64mg-424.36mg)	413.33 mg	
04.	**Water Content (By KF)**	NMT 5.0%m/m.	1.8 %m/m	
05.	**Dissolution (By HPLC)**	Not less than 85% (Q) of the labeled amount of Entecavir ($C_{12}H_{15}N_5O_3$) is dissolved in 15 minutes.	Min.	92 %
			Max.	94 %
			Avg.	93 %
06.	**Uniformity of Dosage units (Content uniformity, by HPLC) Acceptance value Entecavir ($C_{12}H_{15}N_5O_3$)**	L1=15.0 on the first 10 dosage units or if greater than L1 then the value is less than or equal to L1 for 30 dosage units in total and no individual content of the dosage unit is less than (1-L2 x 0.01)M not more than (1+L2 x 0.01)M in the calculation of acceptance value under the content uniformity.	0.7	
07.	**Related compounds (By HPLC)**			
	Impurity at RRT 1.4	Not more than 0.2%m/m.	0.18%	
	H-ETVRC01	NMT 0.50%m/m.	<LOQ [LOQ=0.034%]	
	H-ETVRC02	NMT 0.50%m/m.	Not Detected	
	Maximum single unspecified impurity	NMT 0.20%m/m.	0.08%	

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Generic Name:	Entecavir Film-coated tablets 1mg		
Product QC Lab No:	FP23-6715	CoA No / Rev.:	X23G0283/00
Client Batch No:	ENT23022A	Mfg. Date:	As per Manufacturer's CoC
Client Name:	Accord	Exp. Date:	02/2026
Manufacturer's Name:	As per Manufacturer's CoC	Batch Qty.:	As per Manufacturer's CoC
Specification Ref No:	CF-335 : Sec 5 Ver 08	Analytical Method Ref No:	CF-335 : Sec 6 Ver 08

	Total impurities	NMT 1.5%m/m.	0.31%
08.	**Assay (By HPLC)** **Each film coated tablet contains:**		
	Entecavir ($C_{12}H_{15}N_5O_3$), in mg	NLT 0.950 and NMT 1.050.	0.997 mg
	(%) Labeled amount	NLT 95.0 and NMT 105.0.	99.7 %
09.	**Microbiological examination***		
	Microbial enumeration tests		
	Total Aerobic Microbial Count	Not more than 1000 cfu per g.	N/A
	Total Combined Yeast and Molds Count	Not more than 100 cfu per g.	N/A
	Tests for Specified Microorganisms		
	Bile – Tolerant Gram Negative Bacteria @	Should be absent.	N/A
	Escherichia coli	Should be absent.	N/A
	Salmonella @	Should be absent.	N/A
	Staphylococcus aureus @	Should be absent.	N/A
	Pseudomonas aeruginosa @	Should be absent.	N/A
10.	**Identification of colourant** @		
	Titanium dioxide	A pale yellow color to yellow color should develop Immediately.	N/A
	Iron oxide	A orange color to red color should develop which does not disappear upon addition of dilute hydrochloric acid.	N/A
11.	**Dimensions #**		

PHARMADOX HEALTHCARE	PHARMADOX HEALTHCARE LTD. KW20A Corradino Industrial Estate Paola PLA3000, Malta

CERTIFICATE OF ANALYSIS

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Client Name:	Accord	Exp. Date:	02/2026
Manufacturer's Name:	As per Manufacturer's CoC	Batch Qty.:	As per Manufacturer's CoC
Specification Ref No:	CF-335 : Sec 5 Ver 08	Analytical Method Ref No:	CF-335 : Sec 6 Ver 08

	Shape	Triangular	Complies
	Length	11.00 ± 0.20 mm	Min: 10.91 mm Max: 10.99 mm Mean: 10.95 mm
	Width	10.60 ± 0.20 mm	Min: 10.74 mm Max: 10.78 mm Mean: 10.77 mm
	Thickness	4.20 ± 0.30 mm	Min: 4.12 mm Max: 4.18 mm Mean: 4.15 mm

* Microbiological examination: Test for Microbiological examination is a non-routine test and will be carried out for the first three commercial batches and thereafter on every 10th batch or one batch per year, whichever is earlier.
@ These tests will be performed by the EU release site upon special request only.
# Please note that the dimensions of the tablet is static, there will not be any change in the tablet once it is compressed and coated. Hence the dimensions of the tablet are not included as a part of routine testing. However, if tested, the product will comply with the above specifications.

Chemical names of related compounds:
H-ETVRC01
2 -Amino-9-((1S,3R,4S)-3-(benzyloxymethyl)-4-hydroxy-2-methylenecyclopentyl)-9H-purin-6-ol
H-ETVRC02
2-Amino-9-((1S,3R,4S)-4-(benzyloxy)-3[(benzyloxy)methyl]-2-methylenecyclopentyl)-9H-6-purinol

Definitions: <LOQ – Below Limit of Quantification, <LOD – Below Limit of Detection, <DL – Below Disregard Limit, <RT – Below Reporting Treshold, N/A – Not Applicable.

Remarks:	**APPROVED (Sample conforms to above Specification)**
Comment(s):	N/A

	Prepared By:	Approved By:
Name:	Ridhhi Joshi	Larisa Danilin
Title:	Quality Control Reviewer	Quality Control Officer
Sign. & Date:	17 AUG 2023	17 AUG 2023

Malta Medicines Authority

CERTIFICATE NUMBER: ***MT/012HM/2022***

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

Part 1

Issued following an inspection in accordance with
Art. 15 of Directive 2001/20/EC
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Malta confirms the following:
The manufacturer: ***Pharmadox Healthcare Limited***
Site address: ***Kw20a Kordin Industrial Park, Paola, PLA 3000, Malta***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012142*** / ***LOC-100018944***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***ML013 (4th variation)*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-21 00:00:00.0***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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. 15 of Directive 2001/20/EC and 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 Investigational Medicinal Products 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
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *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**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *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
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

Re 1.5.2: Secondary packaging refers to the over labelling of the primary and secondary packaging, replacement of secondary packaging (outer carton) as well as the removal and insertion of Patient information leaflets. It does not include overprinting of the unique identifier and data matrix.

2022-03-07 00:00:00.0

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

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Confidential
Medicines Authority
Tel:***Confidential***
Fax:***Confidential***

Norwegian Medicines Agency

CERTIFICATE NUMBER: ***22/21534-18***

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 Norway confirms the following:
The manufacturer: ***Hetero Labs Limited***
Site address: ***Unit 5, Survey No 439 440 441 And 458, Polepally Tsiic Formulation Sez, Mahabubnagar, 509301, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011681*** / ***LOC-100021677***
DUNS Number: ***65-045-2530***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-10-20***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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 Special Requirements 7 Other: Antineoplastic agents(en) 1.2.1.13 Tablets Special Requirements 7 Other: Antineoplastic agents(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Antineoplastic agents(en) 1.5.1.13 Tablets Special Requirements 7 Other: Antineoplastic agents(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

This certificate applies only to building Block-VB.

2023-04-14

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

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Confidential
Norwegian Medicines Agency
Tel:***Confidential***
Fax:***Confidential***