Landesverwaltungsamt Sachsen-Anhalt

CERTIFICATE NUMBER: ***DE_ST_01_GMP_2024_0005***

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: ***Alembic Pharmaceuticals Limited***
Site address: ***Village Panelav, Post Office Tajpura Near Baska, Taluka Halol, Panchmahal, 389350***
OMS Organisation Id. / OMS Location Id.: ***ORG-100006039*** / ***LOC-100002984***

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 transposed in the following national legislation:
The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-01-23***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The GMP-Certificate is only valid for Formulation-1 Unit.

2024-02-14

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

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Landesverwaltungsamt Sachsen-Anhalt
Tel:***Confidential***
Fax:***Confidential***

Finnish Medicines Agency

CERTIFICATE NUMBER: ***FIMEA/2023/004861***

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 Finland confirms the following:
The manufacturer: ***Alembic Pharmaceuticals Limited***
Site address: ***Halol Road Jarod, Waghodia, Vadodara, 391510***
OMS Organisation Id. / OMS Location Id.: ***ORG-100006039*** / ***LOC-100070435***
DUNS Number: ***67-546-9976***

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 ***2023-11-09***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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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Part 2

Human Medicinal Products

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	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Production restricted to Block 1 building, Formulation IV site. The inspection was done by checking the following products as an example: etoricoxib tablets and venlafaxine hydrochloride extended release capsules

2023-12-13

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

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home | Modify Search

Search Results for Proprietary Name, Active Ingredient or Application Number: *selexipag*

RX OTC DISCN

CSV Excel Print

Display 50 records per page

Showing 1 to 23 of 23 entries

Search for text in the table

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	SELEXIPAG	UPTRAVI	N214275	POWDER	INTRAVENOUS	1.8MG/VIAL		RLD	RS	ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	0.2MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	0.4MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	0.6MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	0.8MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	1.4MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	1.6MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.2MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.4MG	AB	RLD	RS	ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.6MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.8MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	1MG		RLD		ACTELION PHARMACEUTICALS US INC

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RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	0.8MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	1.4MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	SELEXIPAG	A214414	TABLET	ORAL	1.6MG	AB			ALEMBIC PHARMACEUTICALS LTD
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.2MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.4MG	AB	RLD	RS	ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.6MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	0.8MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	1MG		RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	1.2MG		RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	1.4MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
RX	SELEXIPAG	UPTRAVI	N207947	TABLET	ORAL	1.6MG	AB	RLD		ACTELION PHARMACEUTICALS US INC
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	0.2MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	0.4MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	0.6MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	0.8MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	1MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	1.2MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	1.4MG				ZYDUS LIFESCIENCES GLOBAL FZE
DISCN	SELEXIPAG	SELEXIPAG	A214302	TABLET	ORAL	1.6MG				ZYDUS LIFESCIENCES GLOBAL FZE
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