

National Center For Public Health And Pharmacy

CERTIFICATE NUMBER: **OGYÉI/8227-6/2023**

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 Hungary confirms the following:

The manufacturer: ***Zydus Lifesciences Limited***

Site address: ***Plot No 203-213, Kundaim Industrial Estate, Kundaim, Kundaim, 403115, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100005979 / LOC-100010357***

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 **2023-04-04**, 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.

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

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

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

Remarks for information: *The inspection covered the manufacturing in Oral Solid Dosage plant. The following products were inspected: Pregabalin 75 mg capsules, Donepezil 5 & 10 mg orodispersible tablets, Tramadol HCl & Paracetamol filmcoated tablets (37.5/325 mg).*

2023-06-19

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

Confidential
National Institute of Pharmacy and Nutrition
Tel: **Confidential**
Fax: **Confidential**

National Center For Public Health And Pharmacy

CERTIFICATE NUMBER: **OGYÉI/20221-6/2023**

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 Hungary confirms the following:

The manufacturer: ***Zydus Lifesciences Limited***

Site address: ***Plot No 1 A 1 And 2 Pharmez Special Economic Zone, Matoda Sarkhej Bavla N H No 8 A, Tal Sanand Dist, Ahmedabad, 382213, India***

OMS Organisation Id. / OMS Location Id.: **ORG-100005979 / LOC-100056649**

DUNS Number: **65-034-8852**

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 **2023-06-20**, 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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	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

Oncology OSD Facility was inspected Clarifying remarks: The following products were in scope of inspection Imatinib Mesilate tablets 100 mg, 400 mg & Dasatinib tablets 50 mg, 70 mg, 100 mg, 140 mg.

2023-10-13

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

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National Center For Public Health And Pharmacy
Tel: **Confidential**
Fax: **Confidential**

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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

RX OTC DISCN

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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/ML		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	UPTRAVI	N214275	POWDER	INTRAVENOUS	1.8MG/ML		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
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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
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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

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
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Showing 1 to 23 of 23 entries