



DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES

VISHUTI KHANDE, GOMTI NAGAR, LUCKNOW-10 (U.P.)

Phone No: - 2622-4445552, 4445553, 4445554 E-mail id:hrf@rmlims.org

Ref No: ¹⁰⁵⁷/HNF/PAC/2025

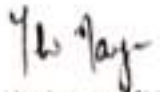
Date:-26.03.2025

To,
Computer Programmer,
Dr. RMLIMS, Lucknow

Subject: - To upload the Proprietary Product i.e Fos-Netupitant 235mg & Palonosetron 0.25mg Inj. (Akynzeo IV) Inj for Department of Urology on Proprietary/ single quotation basis on Dr. RMLIMS website.

Please find the product details to be purchased on Proprietary/ single quotation basis from) Fos-Netupitant 235mg & Palonosetron 0.25mg Inj. (Akynzeo IV) Inj for Department of Urology, Authorized Seller/ Company/Dealer: Wellness Neptune, Lucknow

The PROPRIETARY CERTIFICATE for above items(s) submitted by principal company or their authorized seller/ Company/Dealer is attached. The above documents are being uploaded for open information to all manufacturer/ suppliers to submit comments/objections/representation on the above proposal/ Proprietary nature of the medicine/ surgical items within 10 working days to the Chairman (HRF), Dr.RMLIMS, Lucknow on e-mail ID dr.rmlims.hrf2020@gmail.com, from the date mentioned above. Kindly instruct the concerned to do the needful.


Chairman (HRF)
Dr. RMLIMS, Lucknow



DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES

VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW-10 (U.P.)

Phone no: - 0522-4918502, 4918510 E-mail id:hrftendercell@gmail.com

105/
Ref No. /HRF/PAC/2025

Date:-26.03.2025

Notice

Sub:- Procurement of following item on Proprietary/single quotation basis for different departments.

The Dr.RMLIMS, Lucknow intends to procure following item(s) manufactured as per mentioned against item names for Fos-Netupitant 235mg & Palonosetron 0.25mg Inj. (Akynzeo IV) on Proprietary/single quotation basis from their authorized dealer/seller as per enclosed Technical Specifications.

Sl. No	Product Details	Principal Company (Manufacturer)	Subsidiary Company (Marketing)	Authorized Seller/Company/Dealer
1	Fos-Netupitant 235mg & Palonosetron 0.25mg Inj. (Akynzeo IV) Inj	Helsinn Healthcare S.A. Via Pian Scairolo 9 CH-6912 Lugano, Switzerland	Glenmark Pharmaceuticals Ltd., Glenmark house, B D Sawant Marg, Andheri (E), Mumbai - 400099, INDIA	Wellness Neptune Lucknow.

The PROPRIETARY CERTIFICATE for above items(s) submitted by principal company or their authorized seller/ Company/Dealer is attached. The above documents are being uploaded for open information to all manufacturer/ suppliers to submit comments/objections/representation on the above proposal/ Proprietary nature of the medicine/ surgical items within 10 working days to the Chairman (HRF), Dr.RMLIMS, Lucknow on e-mail ID dr.rmlims.hrf2020@gmail.com, from the date mentioned above, failing which it will be presumed that no other supplier is having any comment to offer and the case will be decided on merits. The comments/objections/representation to be submitted on the following:-

- Whether the above medicine/surgical item is manufactured by any other manufacturer other than as per mentioned principal company or their Authorized seller/company/Dealer.
- Fulfill all the parameter(s) as per technical specifications.

Encl: - Related documents enclosed.

- (1) HRF Requisition form.
- (2) PAC Certificate of Company letter.
- (3) Authorization from Company letter

Chairman (HRF)
Dr. RMLIMS, Lucknow

HRF Requisition Form

Request for new items/upgraded version (Drugs, Consumables & Disinfectants)

('X' if is not applicable)

1. Name of item (generic name only, no brand name).....
 FosNetupitant / Palonosetron I.V. (Injectable)
 (AKYNZEO I.V.)
 Please note that if another brand of the same item is already available in HRF, the request will not be entertained for another brand.
2. Quantity needed (Per month) 50
3. Probable Source (I)
 (II)
 (III)
 (If only one source please sign. The P-3 Form on back page)
4. Similar item available In HRF inventory? -Yes/No ☒ No
5. If yes then, why this item? X
6. Do you want this item to be made available on regular basis -Yes/No ☒ No
7. If yes, then what will be the monthly consumption of this item? 50
8. Is same item in single unit be used on many patients ? If yes then specify the Number of times/Number of patients, the unit will be used..... X
9. Will it be a part of any procedure (Dossier, please specify the name of procedure)..... X
10. If it is an upgraded version of an existing item in HRF inventory, do you want old version to continue? - X -Yes/No
11. Justification for new requisition.....

- Novel molecule to control persistent nausea & vomiting after chemo - CKD etc.

(Sign. of Consultant)
 Dr. Ishwar Ram Dhayal
 MBBS, MS, M.Ch. (AIIMS)
 Professor & Head
 (Signature of Head of Department)
 Dr. R.M.J.L.M. &

that new item will be processed for short-term rate contract- this may take months time.

105/03/2025

Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the items required should be purchased from M/s. Wellness.... Neptune..... Who are the sole manufacture/agents of the sole manufacturers M/s Glenmark Pharmaceuticals Ltd. (Helsinn Healthcare..)

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons: -

Novel molecule to Control persistent nausea, vomiting after chemo, CKD etc.


Signature of Indenter

Requisition No:

Department :

Dated :

Uro OT
16/12/24


Dr. Ishwar Ram Dhyal
MD, MS, MCh (UIMS)
Professor & Head
Dept. of Urology & Transplant
Lucknow
Designation &
Sign of Head of
Department/ Section

N.B. The Indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.



**INTELLECTUAL
PROPERTY INDIA**
PATENTS | DESIGNS | TRADE MARKS
GEOGRAPHICAL INDICATIONS



सत्यमेव जयते

भारत सरकार
GOVERNMENT OF INDIA
पेटेंट कार्यालय
THE PATENT OFFICE
पेटेंट प्रमाणपत्र
PATENT CERTIFICATE
(Rule 74 Of The Patents Rules)

क्रमांक : 044130545
SL No :



पेटेंट सं. / Patent No. : 368178
आवेदन सं. / Application No. : 201847049977
फाइल करने की तारीख / Date of Filing : 01/06/2017
पेटेंटी / Patentee : HELSINN HEALTHCARE SA

प्रमाणित किया जाता है कि पेटेंटी को उपरोक्त आवेदन में वथाप्रकटित **PHYSIOLOGICALLY BALANCED INJECTABLE FORMULATIONS OF FOSNETUPITANT** नामक आविष्कार के लिए, पेटेंट अधिनियम, 1970 के उपबंधों के अनुसार आज तारीख 1st day of June 2017 से बीस वर्ष की अवधि के लिए पेटेंट अनुदत्त किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled **PHYSIOLOGICALLY BALANCED INJECTABLE FORMULATIONS OF FOSNETUPITANT** as disclosed in the above mentioned application for the term of 20 years from the 1st day of June 2017 in accordance with the provisions of the Patents Act, 1970.



अनुदान की तारीख : 31/05/2021
Date of Grant :

पेटेंट नियंत्रक
Controller of Patent

टिप्पणी - इस पेटेंट के नवीकरण के लिए फीस, यदि इसे बनाए रखा जाना है, 1st day of June 2019 को और उसके पश्चात इसके वर्ष से उसी दिन देय होगी।
Note - The fees for renewal of this patent, if it is to be maintained will fall / has fallen due on 1st day of June 2019 and on the same day in every year thereafter.



**INTELLECTUAL
PROPERTY INDIA**
PATENTS | DESIGNS | TRADE MARKS
GEOGRAPHICAL INDICATIONS



सत्यमेव जयते

भारत सरकार
GOVERNMENT OF INDIA
पेटेंट कार्यालय
THE PATENT OFFICE
पेटेंट प्रमाणपत्र
PATENT CERTIFICATE
(Rule 74 Of The Patents Rules)

क्रमांक : 044114781
SL No :



पेटेंट सं. / Patent No. : 324179
आवेदन सं. / Application No. : 4907/CHENP/2014
फाइल करने की तारीख / Date of Filing : 28/11/2012
पेटेटी / Patentee : HELSINN HEALTHCARE SA

प्रमाणित किया जाता है कि पेटेटी को उपरोक्त आवेदन में विद्यमान SUBSTITUTED 4 - PHENYL -PYRIDINES FOR THE TREATMENT OF NK-1 RECEPTOR RELATED DISEASES नामक आविष्कार के लिए, पेटेंट अधिनियम, 1970 के उपबंधों के अनुसार आज तारीख 28th day of November 2012 से बीस वर्ष की अवधि के लिए पेटेंट अनुदान किया गया है।

It is hereby certified that a patent has been granted to the patentee for an invention entitled SUBSTITUTED 4 - PHENYL -PYRIDINES FOR THE TREATMENT OF NK-1 RECEPTOR RELATED DISEASES as disclosed in the above mentioned application for the term of 20 years from the 28th day of November 2012 In accordance with the provisions of the Patents Act, 1970.



अनुदान की तारीख : 31/10/2019
Date of Grant :

पेटेंट नियंत्रक
Controller of Patent

टिप्पणी - इस पेटेंट के नवीकरण के लिए बीस, यदि इसे बनाए रखा जाना है, 28th day of November 2014 से और उसके पश्चात प्रत्येक वर्ष में उसी दिन से होगी।
Note - The fees for renewal of this patent, if it is to be maintained will fall / has fallen due on 28th day of November 2014 and on the same day in every year thereafter.

23 Jan 2025

TO WHOMSOEVER IT MAY CONCERN

This is to inform that Glenmark Pharmaceuticals Ltd. has two granted patents issued by the Indian Patent Office bearing numbers IN324179 and IN368178 that claim Fosnetupitant and its injectable formulation. The Grant Certificates for both the patents are attached herewith. We confirm that the said patents cover Akynzeo Injection (IV) product marketed by Glenmark.

Authorised Signatory:



Laxmi Kant

Head Sales & Marketing – Oncology

Glenmark Pharmaceuticals Ltd.

Glenmark House, B D Sawant Marg, Andheri (E), Mumbai - 400 099, India

T: 91 22 4018 9999 F: 91 22 4018 9986 CIN No: L24299MH1977PLC019982 W: www.glenmarkpharma.com

Registered office: B/2, Mahalakshmi Chambers, 22 Bhulabhai Desai Road, Mumbai 400 026 E: complianceofficer@glenmarkpharma.com

I

TO WHOM SO EVER IT MAY CONCERN

This is to inform you that Fos-Netupitant 235mg & Palonosetron 0.25mg (Akynzeo IV) is a Proprietary product of Helsinn SA, Switzerland and is marketed and distributed in India exclusively by Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. is the only authorized entity to market Fos-Netupitant 235mg & Palonosetron 0.25mg (Akynzeo IV) and no other company or entity in India is authorized to market/sell Fos-Netupitant 235mg & Palonosetron 0.25mg (Akynzeo IV) in India.

For Glenmark Pharmaceuticals Ltd.

Rahul Sanap



Authorized Signatory

Rahul Sanap

General Manager - Sales & Marketing

Glenmark Pharmaceuticals Ltd.

Glenmark House, B D Sawant Marg, Andheri (E), Mumbai - 400 099, India

T: 91 22 4018 9999 F: 91 22 4018 9986 CIN No: L24299MH1977PLC019982 W: www.glenmarkpharma.com

Registered office: B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai 400 026 E: complianceoffice@glenmarkpharma.com

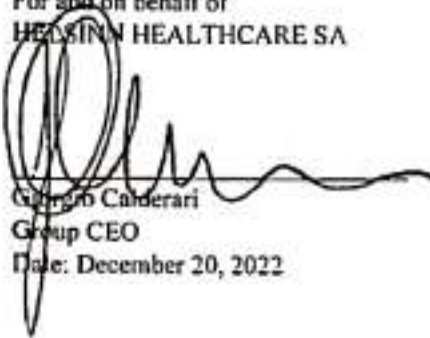
TO WHOM IT MAY CONCERN

The undersigned, **HELSINN HEALTHCARE SA**, a corporation organized and existing under the law of Switzerland, having registered offices at Via Pian Scaiolo 9, 6912 Lugano, Switzerland ("HHC"), as the License Holder of the medicinal product **Akynzeo® 235 mg/0.25 mg concentrate for solution for infusion** together with its affiliated company **Helsinn Birex Pharmaceuticals Ltd.**, with facility of manufacturing plant located at Damastown, Mulhuddart, Dublin 15, Ireland, hereby declares that:

1. **Helsinn Birex Pharmaceuticals Ltd.** is the sole batch release and secondary packaging site for **Akynzeo® 235 mg/0.25 mg concentrate for solution for infusion** and that the Manufacturing & Primary packaging is performed on behalf of **Helsinn Birex Pharmaceuticals Ltd.** at **Baxter Oncology GmbH**, Kantstrasse 2, Halle Westfalen, Nordrhein Westfalen 33790 Germany;
2. **Glenmark Pharmaceuticals Ltd** is the only company authorized to import and to market **Akynzeo® 235 mg/0.25 mg concentrate for solution for infusion** in India.

Yours faithfully,

For and on behalf of
HELSINN HEALTHCARE SA



Giorgio Calderari

Group CEO

Date: December 20, 2022

HELSINN HEALTHCARE S.A.

Via Pian Scaiolo 9
CH-6912 Lugano