

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Ansari Nagar, New Delhi-110029

(HOSPITAL STORES)

e-mail: storesofficer.aiims@gmail.com

Fax no.: 011-26588739

Ref. No. 04/Hosp. Store/Proprietary/2017-18/Surgical

Dated: 05.10.2017

Subject: Purchase of "Immunoabsorption column for ABO incompatible renal transplant patients" on proprietary basis-Inviting comments thereon.

Hospital Stores has received a request from Prof. & Head, Deptt. of Urology, AIIMS for the purchase of "Immunoabsorption column for ABO incompatible renal transplant patients" on proprietary basis. The proposal submitted by M/s Wayinia Lifesciences OPC Private Ltd. (Authorised distributors of M/s Glycorex Transplantation AB, proprietary product of this item) and PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the **M/s Wayinia Lifesciences OPC Private Ltd. (Authorised distributors of M/s Glycorex Transplantation AB, proprietary product of this item)** within issue of 15 days giving reference No. 04/Hosp. Store/ Proprietary/2017-18, Hospital Stores, 1st Floor at AIIMS, New Delhi on or before 20.10.2017 up to 12.30 P.M., failing with it will be presumed that any other vendor is having no comments to offer and case will be decided on merits.

Yours faithfully,


STORE OFFICER (H)

Encl: Related documents enclosed.



PROPRIETARY ARTICLE CERTIFICATE

This is to certify that the following products manufactured by Glycorex Transplantation AB has been manufactured in an ISO 14644-1 class 8 (class 100,000) clean room according to GMP principles, operating within an quality system (CE-mark) according to the certificate, Certificate number 41313750, which states 'FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE' (Annex II of the Directive 93/42/EEC on Medical Devices),

Glycorex Transplantation AB is the only manufacturer of Anti A, Anti B and Anti AB immunoabsorption columns in the world, that have the safety effectiveness and capacity to reduce the anti-A/B titres of a transplant recipient to acceptable levels in a treatment without being saturated and without any intermediate washing steps required.

Product name: Glycosorb® ABO, A-column, Immunoabsorption column
Product number: 7601-1
Single use only

Product name: Glycosorb® ABO, B-column, Immunoabsorption column
Product number: 7602-1
Single use only

Product name: Glycosorb® ABO, AB-column, Immunoabsorption column
Product number: 7621-1
Single use only

Glycorex Transplantation AB

Henrik Johansson
QA



VISAED 2016 -12- 08
MALMÖ
CHAMBER OF COMMERCE AND INDUSTRY
OF SOUTHERN SWEDEN

Monica Svensson



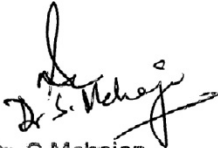
**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
DEPARTMENT OF NEPHROLOGY**


Subject: Immunoabsorption Column for specific removal of anti- A and/or anti-B antibodies for ABOi transplant.


Technical Specifications

1. Immunoabsorption Column for specific removal of anti- A and/or anti-B, IgG and IgM antibodies
2. Immunoabsorption Column should be free from toxic chemicals and preservatives
3. Immunoabsorption Column should not require any replacement fluids in the treatment, such as Albumin or FFP
4. Immunoabsorption Column should ensure that antibodies other than specific anti-A/B antibodies and other plasma components such as coagulation factors are not affected
5. Immunoabsorption Column should allow treatment of wide range of patients from paediatric patients to adult patients weighing above 100 kg
6. Immunoabsorption Column must be CE/FDA Approved.
7. Immunoabsorption Column should not have need of the plasma flow rate above 40-50mL per minute
8. Immunoabsorption Column should be compatible with both centrifugation and membrane filtration equipment
9. Immunoabsorption Column should be non-saturable and be able to treat plasma upto 10-12 litre in a single treatment session
10. Immunoabsorption column should have been used widely across the world and its results scientifically reported.


Dr. SK Agarwal
Prof. & Head


Dr. S Mahajan
Professor


Dr. S Bagchi
Assoc. Professor


Dr. RK Yadav
Asst. Prof.