

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

ANSARI NAGAR, NEW DELHI-110029 (HOSPITAL STORES)

E-mail:storeofficerhospital2021@gmail.com

Dated: 26th July, 2021

Ref. No-10/H/Glycosorb Column/2021-2022/ Prop.

Subject: Procurement of "Glycosorb Column" -reg.

Hospital store has received demand from Department of Nephrology, AIIMS for the purchase of "Glycosorb Column". Accordingly Proprietary Article Certificate (PAC) has been received from department that M/s GLYCOREX TRANSPLANTATION is the only manufacturer of aforesaid item. No other manufacturer is manufacturing similar /equivalent specification which can fulfil the vital requirements of end user. The detail is given below:-

Sr. No	Product Name	Description	Quantity Required (Approx)
1.	Glycosorb®-ABO Column-A	Immunoadsorption Column (Column biospecifically binds Anti-Aantibodies)	50-100 Per Year
2.	Glycosorb®-ABO Column-B	Immunoadsorption Column (Column biospecifically binds Anti-Bantibodies)	50-100 Per Year
3.	Glycosorb®-ABO Column-A/B	Immunoadsorption Column (Column biospecifically binds Anti-A/B antibodies)	50-100 Per Year

The above document is being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the product "Glycosorb Column". Within issue of 15 days giving reference no.10/H/Glycosorb Column/2021-2022/Prop. to Hospital store, 1st floor at AIIMS, New Delhi on or before 10.08.2021 upto 03.00pm, failure which it will be presumed that no other vender is having any comments of offer and the case will be decided to merits.

ASSTT.STORES OFFICER (Hospital Store)

Encl: Related documents enclosed.

1. Proprietary Certificate





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 immunoadsorption columns in the world.

Product name: Glycosorb® ABO, A-column, Immunoadsorption column

Product number: 7601-1

Product name: Glycosorb® ABO, B-column, Immunoadsorption column

Product number: 7602-1

Product name: Glycosorb® ABO, AB-column, Immunoadsorption column

Product number: 7621-1

Glycorex Transplantation AB

Kurt Nilsson PhD Director www.glycorex.com

Dr. Sanjay Klandr Agarwal MD, FRCP, FAMS, DNB, FISH, FICP, MNAMS Professor & Head

Department of Nephrology Atims, New Delhi-110029



ALL INDIA INSTITUTE OF MEDICAL SCIENCES DEPARTMENT OF NEPHROLOGY

Subject:

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

Technical Specifications

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

10. Immunoadsorption column should have been used widely across the world and its results scientifically reported.

Dr. SK Agarwal Prof. & Head

Dr. Sanjay Kumar Agarwal MD, FRCP, FAMS, DNB, FISN, FICP, MNAMS

डी. भोगेक/Dr D Bnowrest अमिता बमाची/Dr. SOUNT (Assistant Professor Wireld Professor) अपनिता बमाची/Dr. SOUNT (Assistant Professor) अपने अपने अपने अपने अपने (Assistant Professor) अपने अपने अपने (Additional Land Assistant Professor) अपनाम बमार्चा / Dr. SOUMER 3 अपनाम / Dr. AKUN Professor अपन असार्च / Additional Professor अस्ताम / Deptt. of Nephrology अरुक विज्ञान विभाग / Deptt of Haman Agent / Deptt. of Nephrology MS आवाय/Prefessor व्यानमा बानाया / Dr. SOUME 6 अपि | Assistant Profesor व्यानमा बानाया / Additional निर्माय / Assistant Profesor व्यानमा / Additional निर्माय / Deptt. of New Delhi-इसक विज्ञान विभाग / Deptt. of New Delhi-प्रिया / Deptt. of New Delhi-प्रिया / ALLIM.S., New Delhi-प्रिया / Red (ALLIM.S., New Delhi-प्रिया) / ALLIM.S., New Delhi-प्रिया / ALLIM.S., New Delhi-U. Professor & Head द्वा विभाग विभाग/Deptt. of Nephrology विभाग विभाग/Deptt. of Nephrology अ.भा.आ.चं., नई दिल्ली/A.L.M.S., New Delhi-110029