



# ALL INDIA INSTITUTE OF MEDICAL SCIENCES

ANSARI NAGAR, NEW DELHI-110029

(HOSPITAL STORES)

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Dated. 6<sup>th</sup> September, 2019

Ref. No-33/H/Proprietary/2019-20/EXONDYS51.

**Subject. Procurement of EXONDYS 51 (ETEPLIRSEN)-reg.**

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Hospital store has received a request letter from Division of Genetics (Department of Pediatrics, AIIMS for the purchase of **EXONDYS 51 (ETEPLIRSEN)**. Accordingly Proprietary Article Certificate (PAC) has been received from department that M/s Sarepta Therapeutics, Cambridge, MA is the only manufacturer of said drug/medicine. No other manufacturer is manufacturing similar /equivalent specification which can fulfil the vital requirements of end user. The detail is given below:-

Sr. No	Name of Molecule	Quantity Required.
1	<b>EXONDYS 51 (ETEPLIRSEN).</b>  Availability – Injection:- 100mg/2ml (50mg/ml) solution in a single dose vial & Injection: 500mg/10ml (50mg/ml) solution in a single dose vial	48 vials  (1000mg every week i.e 2 vials)

The above document is being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of M/s Sarepta Therapeutics, Cambridge, MA. within issue of 15 days giving reference no. 33/H/Proprietary/2019-20/ EXONDYS 51, Hospital store, 1<sup>st</sup> floor at AIIMS, New Delhi on or before 21.09.2019 upto 5.00pm, failure which it will be presumed that no other vender is having any comments of offer and the case will be decided to merits.

*9/6/19*

**STORES OFFICER  
(Hosp)**

Encl: Related documents enclosed.

1. Proprietary Certificate

## PROPRIETARY ARTICLE CERTIFICATE (PAC)

(for chemicals, spare parts, reagents, consumables etc.)

- (i) The indented goods are manufactured by **M/s. Sarepta Therapeutics.**
- (ii) Item Name : **Exondys 51**
- (iii) Model/Part/Catalogue No.....
- (iv) Reasons/Justification which makes the requirement proprietary##

..... Only M/s Sarepta Therapeutics is the  
..... company manufacturing this drug to the  
..... best of our knowledge.

1. It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user.
2. It is certified that the purchase is proposed to be made on proprietary usage basis because any other material / equipment / instrument chemical etc. if used will lead to deviation and affect the integrity/accuracy, validity or analysis of the assignment/ patient care.

Signature of TSEC

With name, Designation, Department, and Hospital/Institute/DGHS

*Madhulika*  
डॉ. मधुलिका काबरा / Dr. Madhulika Kabra  
आचार्य / Professor  
आनुवंशिकी एकक (बालरोग चिकित्सा विभाग)  
Division of Genetics (Deptt. of Pediatrics)  
अ.भा.आ.स., नई दिल्ली / A.I.I.M.S., New Delhi-29  
DMC Regn. No. 16800

*San*  
Dr. S.K. KABRA, MD  
Professor  
Department of Pediatrics  
All India Institute of Medical Sciences  
Ansari Nagar, New Delhi-110029

*Neerj*  
डॉ. नीरजा गुप्ता / Dr. Neerja Gupta  
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