Ministry of Food and Drug Safety

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Certificate of DMF Registration

No. of Certificate : 2024-A1-0156
Exporting (certifying) country : Republic of Korea
Importing (requesting) country : India

The Ministry of Food and Drug Safety certifies that following drug substance has been registered to be imported under the Pharmaceutical Affairs Act. Attached is the registration license that has been issued to the applicant of the drug substance.

o **Applicant**
- Name : [redacted]

o **Manufacturer**
- Name : ASOLUTION PHARMACEUTICALS PVT LTD
- Address : K-3/8, ANAND NAGAR MIDC, AMBERNATH EAST, THANE, 421506, MAHARASHTRA STATE, INDIA

o **The Generic Name of Drug Substance** : SUGAMMADEX SODIUM

Attachment
Attached form #17 of the Regulation on Safety of Pharmaceuticals, etc. (Ordinance of the Prime Minister)

Issued date :JAN. 19, 2024 (Certificate No.2024-A1-0156)
Certified by **Kim Eunju**

Kim Eunju

Director
Director for Approval Management
Ministry of Food and Drug Safety

Drug Substance Registration License

DMF Registration No.수794-2-ND

Applicant	Name of Representative [redacted]	Date of Birth 20TH APRIL 1960
	Name [redacted]	Registered No. 794
	Address [redacted]	
Manufacturer	Name ASOLUTION PHARMACEUTICALS PVT LTD	Manufacturing Country INDIA Tel No. 91-9028098510
	Address K-3/8, ANAND NAGAR MIDC, AMBERNATH EAST, THANE, 421506, MAHARASHTRA STATE, INDIA	
	Manufacturer's Representative (e-mail) Nandkumar Chodankar(nandkumar@asolution.in)	

Route of administration(Final Product) INJECTION | [ ] Manufacture [o] Import

Name	Generic Name SUGAMMADEX SODIUM
	Chemical Name Octakis-S-(2-Carboxyethyl)-octathio-γ-cyclodextrin sodium salt CAS No. 343306-79-6
Appearance	Physical Properties White to off-white granules or Powder Chemical Properties Freely Soluble in water. Freely Soluble in DMSO(1) : Water(30). Very Slightly to slightly soluble in polar solvents. Practically insoluble in Acetonitrile, Methanol and Ethanol.

Data Requirements	Items	page number
	1. Data for each of the following items on the manufacturing site of the drug substance	
	a. Data on the facilities pursuant to Article 31 (1) of the Pharmaceutical Affairs Act	
	b. Data demonstrating that implementation status of each product meets or exceeds Good Manufacturing Practice for Drug Substances in Annex 1-2 of the Regulation on Safety of Pharmaceuticals, etc., or a certificate of manufacture pursuant to Article 4 (1) 4 A	
	2. Data for each of the following items on the ingredients, name and manufacturing method of the drug substance	
	a. Data on physicochemical properties and stability	
	b. Data on the manufacturing methods, packaging, containers, cautions in handling, etc.	
	c. Data on certificate of analysis of drug substances, analytical procedures, the solvents used, etc.	
	d. Drug substances for investigational use (as applicable only when deemed necessary for quality test by the Minister of Food and Drug Safety)	

Storage Condition and Shelf Life Store in a well-closed container at room temperature(1-30°C) / 24 months from the date of manufacture

Other Remarks General, Synthesis

This certifies that the drug substance is registered or the registration is updated as above pursuant to the provisions of Article 31-2 (2) and (3) and Article 42 (4) of the Pharmaceutical Affairs Act and Article 16 (1) and 17 (3) of the Regulation on Safety of Pharmaceuticals, etc.

07th Dec. 2023

The Minister of Food and Drug Safety