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CERTIFICATE OF ANALYSIS

Page 1 of 1

NAME OF THE PRODUCT/ IMPURITY (IUPAC Name)		SUGAMMADEX MONOHYDROXY IMPURITY IUPAC NAME: Heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin
CAS. No.	: 2376607-98-4	STRUCTURE
BATCH No.	: SRD054/SUG-IMP3-II/019/0622	
MFG. DATE	: JUN-2022	
AR No.	: SRD054/SUG-IMP3-II/019/0622/AR23-3851	
DATE OF ANALYSIS	: 20 JUN 2023	
RETEST DATE	: 19 JUN 2024	
GRADE	: IN-HOUSE	
BATCH QUANTITY	: 100 mg	

S. No.	TESTS	SPECIFICATIONS	RESULTS
1	Description	Report the result	White solid
2	Identification by MS	The exact mass of Sugammadex Mono Hydroxy impurity should be confirmed as 1912Da	Mass spectral data confirms the exact mass of Sugammadex Mono Hydroxy impurity as 1912Da
3	Identification by ^1H & ^{13}C NMR	The molecular structure of Sugammadex Mono Hydroxy impurity should be confirmed by ^1H & ^{13}C NMR spectra	^1H & ^{13}C NMR spectra confirms the molecular structure of Sugammadex Mono Hydroxy impurity
4	Purity by HPLC	For Informative	90.09% Area
5	Volatile loss by TGA	For Informative	0.47% w/w
6	Potency	For Informative	89.62% w/w

Storage condition: (i) For long term: Storage at 2 to 8°C.
(ii) For transport: Ambient temperature.

Remarks: The product **conforms** / **does not conform** to the above specification.

Prepared By (Sign& Date)	A. Sanish 03 Jul 2023	Reviewed By (Sign& Date)		Approved By (Sign& Date)	 03 Jul 23
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