HEILSA LIFE SCIENCES PVT. LTD.
KH No. 940, 941, 942, Vill. - Kishanpur, Jamalpur, Bhagwanpur,
Roorkee-247668. Distt. - Haridwar, (Uttarakhand) INDIA.

Quality control Department
Certificate of analysis of Finished Product

A.R. No: - HLS/FP/26/CH07

NAME OF PRODUCT	**Sugammadex Injection 100mg/ml (SUGRIVERSE)**		
BATCH NO.	**VCH07**	**SAMPLED ON**	**18/08/2026**
MFG. DATE	**08/2026**	**QTY. SAMPLED**	**80 X 2ml**
EXP. DATE	**07/2028**	**TESTED BY**	**Haripriya**
BATCH SIZE	**35 Ltr.**	**TESTING ON**	**19/08/2026**
REFERENCE	**As per IH**	**COMPLETION ON**	**03/09/2026**

S. No.	Test	Specification	Observation
1.	**Description**	Clear, colorless to slightly yellowish-brown solution	A Clear colourless solution.
2.	**Identification** **A. By HPLC** **B. By UV spectrophotometer**	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay. The absorbance of standard and sample solution at 195 nm shall be concordant to each other.	Complies Complies
3.	**Extractable Volume**	NLT 2.0 ml	2.11 ml
4.	**Particulate Matter** **a) ≥10µm** **b) ≥25 µm**	 NMT 6000 Particles/container NMT 600 Particles/container	 1.07 Particles/container 0.13 Particles/container
5.	**Sterility**	Complies with the test for sterility	Complies
6.	**Bacterial endotoxins**	Not more than 0.16 Endotoxin Unit per mg of Sugammadex.	Less than 0.16 Endotoxin Unit per mg of Sugammadex.
7.	**pH**	7.0 to 8.0	7.499
8.	**Monohydroxy Sugammadex sodium content**	Not more than 4.0%	1.36 %
9.	**Osmolality**	280 to 500 mOsmol/kg	456 mOsmol/kg
10.	**Weight/mL**	Approximately 1.0 g/ml	1.038 g/ml
11.	**Viscosity**	For data generation	1.460

	Prepared By	Reviewed By	Approved By
Name	Haripriya	Kamal Kishor	
Designation	Jr. Officer	QC- Executive	manager
Sign.			
Date	10/10/26	10/10/26	10/10/26

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12.	**% Transmittance at 650 nm**	Not Less Than 95 %	99.91 %
13.	**Assay** **Sugammadex Sodium eq. to Sugammadex (By HPLC)**	Not less than 93.0% and not more than 107.0% of the label claim.	101.49 %
14.	**Related substance (By HPLC)**		
	Formic acid	NMT 0.2%	Not detected
	SUGA-Mono-Sulfoxide Isomer-I	NMT 0.3%	0.043 %
	SUGA-Mono-Sulfoxide Isomer-2	NMT 0.3%	Not detected
	SUGA-Mono-Thio Dimer	NMT 0.3%	0.007 %
	SUGA-Mono-Thio	NMT 0.3%	0.019 %
	SUGA-Mono-Chloro	NMT 0.3%	Not detected
	SUGA-Mono-Methyl Ester	NMT 0.3%	Not detected
	Any unspecified Impurity	NMT 0.5%	0.208 %
	Total Impurities	NMT 4.0%	0.729 %

Conclusion: The sample Complies / doesn't comply as per prescribed standards of In - house specification No: HLS/FPS/076, Rev. 02.

	Prepared By	**Reviewed By**	**Approved By**
Name	Haripriya	Kamal Kishor	
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Date	10/10/26	10/10/26	10/10/26