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 Finish Product

A.R. No: - HLS/FP/26/CH14

NAME OF PRODUCT	**Hyoscine butylbromide injection IP 20mg/ml (Spasmocan)**		
BATCH NO.	**ACH14**	**SAMPLED ON**	**27/08/2026**
MFG. DATE	**08/2026**	**QTY. SAMPLED**	**115 Nos**
EXP. DATE	**07/2028**	**TESTED BY**	**Haripriya**
BATCH SIZE	**100 Ltr**	**TESTING ON**	**28/08/2026**
REFERENCE	**As per IP**	**COMPLETION ON**	**20/09/2026**

S. No.	Test	Specification	Observation
1.	**Description**	A clear colourless solution.	A clear colourless solution.
2.	**Identification**		
	A) By IR:	Compare the spectrum with that obtained with hyoscine butylbromide WS or with the reference spectrum of hyoscine butylbromide.	Complies
	B)* By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	**pH**	3.7 to 5.5	4.806
4.	**Extractable volume**	Not less than nominal volume	1.1 ml
5.	**Bacterial Endotoxins Test**	Not more than 8.75 Endotoxin Units per mg of hyoscine butylbromide.	Less than 8.75 Endotoxin Units per mg of hyoscine butylbromide.
6.	**Sterility**	Comply with the test for sterility.	Complies
7.	**Particulate Matter** **Visible Particle** **Sub Visible Particle** **a) ≥10µm** **b) ≥25 µm**	Should be free from any visible particles Not more than 6000 Particles/container Not more than 600 Particles/container	Free from any visible particles 37.47 Particles/container 0.40 Particles/container

	Prepared By	Reviewed By	Approved By
Name	Bajrangbali gupta	Kamal Kishor	Jagmal C. Rewasi
Designation	Jr. officer-QC	QC- Executive	Manager QC
Sign.		Kamal	
Date	08/10/26	08/10/26	08/10/26

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BATCH SIZE	100 Ltr	TESTING ON	28/08/2026
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8*	Assay: Each ml contains: Hyoscine Butylbromide IP 20 mg	NLT 18.50 mg/ml to NMT 21.50 mg /ml (NLT 92.5 % to NMT 107.5 % of the stated amount of Hyoscine butylbromide.)	19.87 mg/ml. 99.34 %
9.	%Transmittance at 650 nm	Not Less Than 95 %	99.92 %
10*	Hyoscine	NMT 0.1%	Not detected
11.	Related Substances		
	Hyoscine Impurity G	NMT 1.0 %	Not detected
	Tropic acid	NMT 1.2 %	0.04 %
	The area of any other secondary peak	NMT 0.2 %	0.01 %
	The sum of the areas of all secondary peaks	NMT 2.5 %	0.01 %

Conclusion: The sample Complies / doesn't comply as per prescribed standards of IP and specification No: HLS/FPS/134

***This test is analysed by ayush laboratories ltd.**

	Prepared By	Reviewed By	Approved By
Name	Banjraghali gupta	Kamal Kishor	Ganesh C. Tewari
Designation	Jr. officer-QC	QC- Executive	Manager QC
Sign.	[signature]	[signature]	[signature]
Date	08/10/26	08/10/26	08/10/26

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