



HEALTH BIOTECH LTD.

Village: Sandoli, Nalagarh Road Baddi (H.P)-173205, India

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS-FINISHED PRODUCT

Name of Product		MESNA INJECTION 100 MG/ ML	
Generic Name		MESNA INJECTION 4 ML	
Manufactured By	Health Biotech Ltd. Nalagarh Road Baddi Distt. Solan (H.P)-173205	Mfg. Date	10/2022
		Exp. Date	09/2024
Batch No.	HIME22007	Date of Sample	14/10/2023
		Qty. sampled	50 UNITS
Sampled By	VIKASH	Release Date	28/10/2023
Specifications	IH	A.R. No.	HIME 22007/10/22/FP
S.NO.	TEST	SPECIFICATION	RESULT
1	Description	Clear colorless solution, filled in colorless glass ampoules.	Clear colorless solution, filled in colorless glass ampoules.
2	IDENTIFICATION (BY HPLC)	Should be positive for Mesna	Complies
3	Extractable Volume	Not Less than 4.0 ml	4.1ml
4	PARTICULATE MATTER A. (Visible Particles)	Should be free from particulate matter, when examined visually.	Free from particles
	B. (Sub Visible Particles) ≥1 ^μ m ≥25 ^μ m	Not more than 6000 particles/Container Not more than 600 particles/Container	Less than 6000 Particles/Container Less than 600 particles/Container
5	Bacterial Endotoxins	Not more than 16.1 EU/ml	Less than 16.1 EU/ml
6	Sterility Test	Should be sterile	Sterile
7	ASSAY: Each ml contains MESNA BP—100 mg	90 mg to 110.0 mg (90.0-110.0%)	99.82 mg 99.82%

Conclusion: The above Sample Complies as per ~~IP/BP/USP~~ IH Specification

	Analyzed by	Checked by	Approved by
Designation	QC Chemist	QC Executive	QC Head
Name	Amit Kumar	Keshav	
Sign/Date	At 28/10/2023	28/10/2023	