

**AKUMS DRUGS & PHARMACEUTICALS LTD.**

2,3,4 and 5, Sector 6B I.I.E, SIDCUL, Ranipur

Haridwar-249403, Uttarakhand

QUALITY CONTROL**CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	AMERICAN BRUFOCAN IV		
Generic Name :	Ibuprofen Solution for Infusion 400mg/100ml		
Mfg. Lic. No. :	1/UA/SC/P(LVP)/2008	Market:	DOMESTIC
Batch No. :	GCZ01AAA	A. R. No.:	F20250727006
Mfg. Date :	07/2025	Pack Size:	100ml
Expiry date:	06/2027	Pack Type:	Infusion
Batch Size :	15073 Nos	Sampled On:	27/07/25
Product Code :	40075588	Sample Quantity:	30 Nos
Specification No, Ver No.:	STS/FP/40075588-00	Sampled By:	AMAN SHARMA
Ref. STP No. , Ver No.:	STP/FP/1125-01	Analyzed By:	ARCHANA RAWAT
Manufactured For :	American Remedies Healthcare Pvt. Ltd.	Date of Analysis:	28/07/25
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	Analysis Completion Date:	11/08/25

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Clear colourless to pale yellow colour solution filled in 100ml LDPE bottle.	Clear colourless solution filled in 100ml LDPE bottle.
2	Identification	As below	
	By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained by standard solution.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponded to the principal peak in the chromatogram obtained by standard solution.

	Prepared By	Reviewed By	Approved By
Sign	<i>NA</i>	<i>AT</i>	<i>AW</i>
Date	11/08/25	11/08/25	11/08/25
Name	NAUSHAD ALI	ATULYAGNI	AVINASH SINGH
Designation	ASST. EXECUTIVE	SR-EXECUTIVE	DY. MANAGER

FORMAT No. : CQC-422/F08-00

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
3	pH	Between 6.00 and 8.50	7.83
4	Extractable volume	Not less than 100ml	102 ml
5	Particulate Matter- Sub-visible particles	As below	
a.	Equal to or greater than 10 micron	Not more than 6000 particles per container.	155
b.	Equal to or greater than 25 micron	Not more than 600 particles per container.	Nil

	Prepared By	Reviewed By	Approved By
Sign	<i>NAUJHAD</i>	<i>ATUL</i>	<i>AVINASH</i>
Date	11/08/25	11/08/25	11/08/25
Name	NAUJHAD ALI	ATUL TYAGI	AVINASH SINGH
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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
6	Tonicity	Between 250 mOsmol/litre and 350 mOsmol/litre.	302 mOsmol/litre
7	Related Substances	As below	
a.	2-(4-Butylphenyl) Propionic Acid (Impurity B)	Not more than 0.3%	Not Detected
b.	Single Maximum impurity	Not more than 0.5%	0.06 %
c.	Total Impurities	Not more than 2.0%	0.07 %

	Prepared By	Reviewed By	Approved By
Sign	<i>Ali</i>	<i>HL</i>	<i>Am</i>
Date	11/08/25	11/08/25	11/08/25
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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
8	Bacterial endotoxins	Not more than 0.29 Endotoxin Units/mg of Ibuprofen.		Less than 0.29 Endotoxin Units/mg of Ibuprofen.
9	Sterility	No microbial growth should be observed.		No microbial growth observed.
10	Assay - Each 100ml contains:	Shelf Life Limit	Release Limit	

	Prepared By	Reviewed By	Approved By
Sign	<i>AH</i>	<i>AH</i>	<i>AH</i>
Date	11/08/25	11/08/25	11/08/25
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Designation	ASST. EXECUTIVE	JR. EXECUTIVE	DY. MANAGER





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	Ibuprofen IP - 400 mg/100ml	NLT 360.00mg/100ml to NMT 440.00mg/100ml (NLT 90.0% to NMT110.0% of label claimed)	NLT 380.00mg/100ml to NMT 420.00mg/100ml (NLT 95.0% to NMT105.0% of label claimed)	393.63mg 98.4%

CONCLUSION : The Finished Product complies as per IH Specifications.

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Sign	<i>AK</i>	<i>AL</i>	<i>AK</i>
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