AKUMS DRUGS & PHARMACEUTICALS LTD.

19,20,21, Sector-6A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand, INDIA

QUALITY CONTROL

CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Product Name :	NEW IVERMECTOL 12		
Generic Name :	Ivermectin Tablets IP		
Mfg. Lic. No. :	10/UA/2004	**Market:**	DOMESTIC
Batch No. :	BFC0174	**A. R. No.:**	F20251222003
Mfg. Date :	12/2025	**Pack Size:**	1x2 Tablets
Expiry date:	11/2027	**Pack Type:**	Blister
Batch Size :	1000000 Tablets	**Sampled On:**	22/12/25
Product Code :	40047763	**Sample Quantity:**	150 Tablets
Specification No,Ver No.:	STS/FP/40047763-01	**Sampled By:**	DHARMENDRA SINGH
Ref. STP No. , Ver No.:	STP/FP/40047763-01	**Analyzed By:**	VISHWAVEER KUMAR
Manufactured For :	Sun pharma laboratories ltd.	**Date of Analysis:**	29/12/25
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	**Analysis Completion Date:**	31/12/25

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white, round, flat, scored on one side, plain on other side & uncoated tablets. 2 tablets packed in a blister of clear PVDC film & printed aluminium foil.	White , round, flat, scored on one side, plain on other side & uncoated tablets. 2 tablets packed in a blister of clear PVDC film & printed aluminium foil.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	31/12/25 19:32:48	31/12/25 19:33:44	31/12/25 19:39:25
Name	PRASHANT KUMAR	SUMIT KUMAR	DHIRAJ KANDWAL
Designation	ASST.EXECUTIVE	ASST. MANAGER	SR. MANAGER

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
2	Identification (By HPLC)	In the Assay, the retention times of the H_2B_{1a} and H_2B_{1b} peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with reference solution (a).	In the Assay, the retention times of the H_2B_{1a} and H_2B_{1b} peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with reference solution (a).

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
3	Dimension	As below	As below
3.a	Diameter	9.1 mm ± 0.2 mm	9.01 mm
3.b	Thickness	3.2 mm ± 0.3 mm	3.19 mm
4	Average weight	260.0 mg ± 5.0%	260.71 mg
5	Uniformity of weight	Within ± 5.0% of Average Weight	-2.10% to +2.24%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
6	Disintegration Time	Not more than 15 minutes	Passes (01 Minutes 58 Seconds)
7	Hardness	Not less than 40 Newton.	55.9 Newton
8	Friability	Not more than 1.0 % w/w	0.17 %w/w
9	Water (By Karl Fischer)	For Information only	3.27%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
10	Dissolution	Not less than 80 % (Q) of the stated amount of sum of H_2B_{1a} ($C_{48}H_{74}O_{14}$) and H_2B_{1b} ($C_{47}H_{72}O_{14}$) in the medium in 45 minutes.	101.57%, 105.52%, 102.16%, 105.57%, 101.86%, 102.36%
11	Uniformity of content	85% to 115% of average value.	95.2% to 104.6%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
12	LIMIT OF 8a-oxo-H2B1a	Not more than 2.0%.	0.11 %
13	Microbial limit test	As Below	As Below
13.a	Total Aerobic Viable Count	Not more than 1000cfu/gm	Not applicable
13.b	Total fungal count	Not more than 100cfu/gm	Not applicable

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
13.c	Tests For Specified Microorganisms	As below		As below
13.c.1	E.coli	Should be absent/gm		Not applicable
14	Assay - Each uncoated tablet contains:	Shelf Life Limit	Release Limit	

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
	Ivermectin IP - 12 mg/Tab	NLT 10.80mg/Tab to NMT 13.20mg/Tab (NLT 90.0% to NMT110.0% of label claimed)	NLT 11.40mg/Tab to NMT 12.60mg/Tab (NLT 95.0% to NMT105.0% of	12.04mg 100.3%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		label claimed)	

CONCLUSION : The Finished Product complies as per IP 2022 & In-House Specifications.

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