AKUMS DRUGS & PHARMACEUTICALS LTD

19,20,21, Sector-6A, I.I.E., SIDCUL
Haridwar-249403, Uttrakhand, INDIA
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name :	NEW IVERMECTOL 12		
Generic Name :	Ivermectin Tablets USP		
Mfg. Lic. No. :	10/UA/2004	**Market :**	Domestic
Batch No. :	BFY0023	**A. R. No. :**	F2021052002
Mfg. Date :	May. 2021	**Pack Size :**	1x2 Tablets
Exp. Date / Best Before:	Apr. 2023	**Pack Type :**	Blister
Batch Size :	500000 Tablets	**Sampled On :**	19/05/21
Product Code :	40044513	**Sample Quantity :**	116 Tablets
Specification No., Ver. No.:	STS/FP/40044513-00	**Sampled By :**	MOHIT
Ref. STP No., Ver. No.:	STP/FP/40044513-00	**Analyzed By :**	CHANDRA MANI
Manufactured For :	Sun pharma Laboratories Ltd.	**Date of Analysis :**	19/05/21
Manufactured By :	Akums Drugs & Pharmaceuticals Ltd.	**Analysis Completion Date :**	22/05/21

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 tablet 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 tablet packed in a blister of clear PVDC film & printed aluminium foil.
2	Identification (By HPLC)	The retention times of the H2B1a and H2B1b peaks in the chromatogram of the Assay preparation correspond to those in the chromatogram of the Standard preparation, as obtained in the Assay.	The retention times of the H2B1a and H2B1b peaks in the chromatogram of the Assay preparation correspond to those in the chromatogram of the Standard preparation, as obtained in the Assay.
3	Dimension	As below	As below
3.a	Diameter	9.1 mm ± 0.2 mm	9.18 mm
3.b	Thickness	3.2 mm ± 0.3 mm	3.30 mm
4	Average weight	260.0 mg ± 7.5%	260.17 mg
5	Uniformity of weight	Within ± 7.5% of Average Weight	-1.5% to +3.2%
6	Disintegration Time	Not more than 15 minutes	Passes (4 min.10 sec.)
7	Hardness	Not less than 40 Newton.	81.41 Newton
8	Friability	Not more than 1.0 % w/w	0.10 % w/w

Prepared By 27/05/21
Officer/Executive-QC
(Sign & Date)

Checked By 27/05/21
Operating Manager QC
(Sign & Date)

Approved By 27/05/21
Head QC
(Sign & Date)

Q.A. APPROVED
SIGN. DATE. 27/05/21

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
9	Water (By Karl Fischer)	For Information only	3.86%
10	Dissolution	Not less than 80 % (Q) of the labeled amount of C48H74O14 (H2B1a) plus C47H72O14 (H2B1b) dissolved in 45 minutes.	103.82%, 102.19%, 102.22%, 105.14%, 102.20%, 102.32%
11	Uniformity of dosage units (By content uniformity)	The acceptance value of the first 10 dosage units shall be less than or equal to L1%. If the acceptance value is greater than L1%, test the next 20 units, and calculate the acceptance value. The requirements shall met if the final acceptance value of the 30 dosage units less than or equal to L1%, and no individual content of any dosage unit shall be less than [1-(0.01)(L2)] M nor more than [1 + (0.01)(L2)] M Where, L1 is 15.0 and L2 is 25.0.	11.30
12	LIMIT OF 8a-oxo-H2B1a	Not more than 2.0%.	Not detected

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
13	Assay - Each uncoated tablet contains:	Shelf Life Limit	Release Limit	
	Ivermectin IP 12.00mg	NLT 10.80mg/Tab and NMT 13.20 mg/Tab NLT 90.0% and NMT110.0% of label claimed	NLT 11.40 mg/Tab and NMT 12.60 mg/Tab NLT 95.0% and NMT105.0% of label claimed	12.26mg 102.2%

CONCLUSION : The Finished Product complies as per USP Specification.

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27/05/21

FORMAT No. : AQC-229/F05-00

Q.A. APPROVED
SIGN. DATE 27/05/21