AKUMS DRUGS & PHARMACEUTICALS LTD.

48, Sector-6A, I.I.E., SIDCUL,Ranipur
Haridwar-249403, Uttarakhand , INDIA

QUALITY CONTROL

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name :	DYDROSMART 10 mg		
Generic Name :	Dydrogesterone Tablets IP 10 mg		
Mfg. Lic. No. :	97/UA/SC/P-2009	**Market:**	DOMESTIC
Batch No. :	KWAC01	**A. R. No.:**	F20230922003
Mfg. Date :	Sep. 2023	**Pack Size:**	1x10 Tablets
Expiry date:	Aug. 2025	**Pack Type:**	Blister
Batch Size :	51500 Tablets	**Sampled On:**	22/09/23
Product Code :	40063882	**Sample Quantity:**	10 Tablets
Specification No,Ver No.:	STS/FP/40063882-00	**Sampled By:**	SAHIL KUMAR
Ref. STP No. , Ver No.:	STP/FP/0057-00	**Analyzed By:**	AMIT PUROHIT
Manufactured For :	Healing Pharma India Pvt. Ltd.	**Date of Analysis:**	22/09/23
Manufactured By :	AKUMS DRUGS (PLANT-4)	**Analysis Completion Date:**	22/09/23

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white, round, biconvex, film coated tablets, with break line on one side and plain on other side. Packed in a blister of clear PVC film and printed aluminium foil.	White, round, biconvex, film coated tablets, with break line on one side and plain on other side. Packed in a blister of clear PVC film and printed aluminium foil.
2	Identification		
A	By IR	Compare the spectrum with that obtained with Dydrogesterone IPRS or with the reference spectrum of Dydrogesterone.	The infrared absorption spectrum of sample is match with IR spectrum of standard.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	22/09/23	22/09/23	22/09/23
Name	AMIT PUROHIT	MANISH KUMAR	SUNIL M. JOSHI
Designation	EXECUTIVE	DY. MANAGER	A.G.M.

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QA REVIEWED
Name : AKSHAY KUMAR GAUTAM ; Date : 22/09/2023

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
B	By HPLC	In the assay, the principal peak in the chromatogram obtained with test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	In the assay, the principal peak in the chromatogram obtained with test solution is correspond to the peak in the chromatogram obtained with reference solution (a).
3	Average weight	144.00 mg ± 7.5% (133.20 mg – 154.80 mg)	142.94 mg
4	Uniformity of weight	± 7.5% of average weight.	-0.57% to +0.51%
5	Dimension		
A	Diameter	7.10 ± 0.20 mm (6.90 mm – 7.30 mm)	7.10 mm
B	Thickness	3.70 ± 0.30 mm (3.40 mm – 4.00 mm)	3.70 mm
6	Disintegration Time	Not more than 30 minutes.	12 min. 28 sec.

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
7	Dissolution	Not less than 75% (Q)	Min. = 99%, Max. = 103%, Mean = 102%
8	Related Substances		
A	Impurity A	Not more than 0.3%	0.069 %
B	Impurity B	Not more than 0.15%	Not detected
C	Impurity C	Not more than 0.3%	Below disregard limit
D	Single Maximum impurity	Not more than 0.1%	Below disregard limit
E	Total impurities	Not more than 0.5%	0.069 %

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
9	Uniformity of content	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 not more than [1+(0.01)(L2)] M where L1 is 15.0 and L2 is 25.0.	Min. = 97.1%, Max. = 102.1%, AV = 4.0
10	Water content	Not more than 7.0%	5.11 %

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
11	**Assay - Each film coated tablet contains:**	**Shelf Life Limit**	**Release Limit**	
	Dydrogesterone IP (Micronized) - 10 mg	NLT 9.00mg to NMT 11.00mg (NLT 90.0% to NMT110.0% of label claimed)	NLT 9.25mg to NMT 10.75mg (NLT 92.5% to NMT107.5% of label claimed)	10.17mg 101.7%

CONCLUSION : The Finished Product complies as per IP/IH Specifications.

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