

**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 :	CONCIVON 100 INJECTION		
Generic Name :	Progesterone Injection IP 100 mg / 2 ml		
Mfg. Lic. No. :	97/UA/SC/P-2009	Market:	DOMESTIC
Batch No. :	IXD01AAB	A. R. No.:	F20260911008
Mfg. Date :	Aug. 2026	Pack Size:	5x2 ml
Expiry date:	Jul. 2028	Pack Type:	Ampoule
Batch Size :	30000 Ampoules	Sampled On:	11/09/26
Product Code :	40084432	Sample Quantity:	10 Ampoules
Specification No, Ver No.:	STS/FP/40084432-00	Sampled By:	PRAMOD CHAUHAN
Ref. STP No. , Ver No.:	STP/FP/0045-02	Analyzed By:	AMIT PUROHIT
Manufactured For :	American Remedies Healthcare Pvt. Ltd.	Date of Analysis:	12/09/26
Manufactured By :	Akums Drugs (Plant-4)	Analysis Completion Date:	19/09/26

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Clear colourless to pale yellow solution filled in 2 ml ampoules, Packed in 5x2 ml transparent plastic tray.	Clear colourless solution filled in 2 ml ampoules, Packed in 5x2 ml transparent plastic tray.
2	Identification		
A	By IR	The infra-red absorption spectrum of the residue, is concordant with the reference spectrum of Progesterone.	The infra-red absorption spectrum of the residue, is concordant with the reference spectrum of Progesterone.
3	Particulate Contamination : visible particles		

	Prepared By QC	Reviewed By QC	Approved By QC
Date	19/09/26 15:01:20	19/09/26 15:52:42	19/09/26 17:03:00
Name	AMIT PUROHIT	PANKAJ RAJPUT	Dr. KAMLAINDERA RAI
Designation	SR. EXECUTIVE	ASST. MANAGER	Sr. GENERAL MANAGER

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QA REVIEWED

Name : AKSHAY GAUTAM ; Date : 19/09/2026 17:53:11

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
A	Equal to or greater than 10 μ m	Not more than 6000 per container	483.87 per container
B	Equal to or greater than 25 μ m	Not more than 600 per container	18.00 per container
4	Extractable volume	Between 2.00 ml and 2.30 ml	2.10 ml

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
5	Uniformity of dosage units	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.	AV = 3.6

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
6	Related substance (By HPLC)			
A	Single Impurity	Not more than 0.500%		Below disregard limit
B	Total impurity	Not more than 1.000%		Below disregard limit
7	Bacterial Endotoxin Test	NMT 3.5 EU/mg		Less than 3.5 EU/mg
8	Sterility	No microbial growth should be observed after 14 days of incubation.		No microbial growth is observed during 14 days of Incubation period.
9	Assay - Each ml contains :	Shelf Life Limit	Release Limit	

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
	Progesterone IP - 50 mg	NLT 46.25mg to NMT 53.75mg (NLT 92.5% to NMT 107.5% of label claimed)	NLT 46.25mg to NMT 53.75mg (NLT 92.5% to NMT 107.5% of label claimed)	49.73 mg (99.5%)

CONCLUSION : The Finished Product complies as per IP & IH Specifications.**REMARKS :** All test results except description referred from semi finished, Batch No: 0005204314.

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