

Plot No.:13, Sector-6A, IIE., SIDCUL, Ranipur, Haridwar-249403, Uttrakhand, INDIA Phone No.: +91-1334-239220, 239221, 239222, E-mail: works@maxcure.in QUALITY CONTROL

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name :	SCITRON MULTI WOMEN TAB LS1X60		
Generic Name :	NA		
Mfg. Lic. No. :	10016012000340	Market:	Domestic
Batch No.:	JSAF01	A. R. No. :	MF2020122211
Mfg. Date :	11/2020	Pack Size : ,	1X60 TABLET
Exp. Date / Best Before:	04/2022	Pack Type:	HDPE BOTTLE
Batch Size :	200000 NOS	Sampled On:	22/12/20
Product Code:	40044638	Sample Quantity	: 120 TABLETS
Specification No., Ver. No.:	STS/FP/40044638-00	Sampled By:	QA
Ref. STP No., Ver. No.:	STP/FP/40044638-00	Analyzed By:	ANSAR
Manufactured For:	SCITRON NUTRITION (INDIA) PVT.LTD	Date of Analysis :	22/12/20
Manufactured By:	Maxcure Nutravedics Limited (Plant-I)	Analysis Complet	ion Date: 01/01/21

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Pink coloured, oval, biconvex both side plain, Film Coated Tablets	Pink coloured, oval, biconvex both side plain, Film Coated Tablets
2	Average weight	2420 mg ± 5%	2373.71 mg
3	Uniformity of weight	± 5.0 % of Average Weight	-2.7%' to +1.4%
4	Disintegration Time	Not more than 30 mintues	Passes (19 min.55 sec.)
5	Identification		
5.1	Vitamin A (By UV)	The test solution exhibit absorption maxima at same wavelength as that of the standard solution	The test solution exhibit absorption maxima at same wavelength as that of the standard solution
5.2	Vitamin E (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution
5.3	Vitamin B3 (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.

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

Checked By Operating Manager QC (Sign & Date)

Approved By Head QC (Sign & Date)

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
5.4	Vitamin B1 (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.5	Vitamin B2 (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.6	Vitamin B6 (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.7	Biotin (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
5.8	Pantothenic Acid (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.9	Folic Acid(By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.10	Vitamin B12(By Micro)	Positive for Cynocobalamin	Positive for Cynocobalamin
5.11	Vitamin C (By Titrimetric)	Should be positive	positive
5.12	Vitamin D3(By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.13	Zinc (By ICP-OES)	Should be Positive	Positive
5.14	Copper (By ICP-OES)	Should be Positive	Positive

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
5.15	Calcium (By ICP-OES)	Should be Positive	Positive
5.16	Iodine (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.
5.17	Boron (By ICP-OES)	Should be Positive	Positive .
5.18	Molybdenum (By ICP-OES)	Should be Positive	Positive
5.19	Magnesium (By ICP- OES)	Should be Positive	Positive
5.20	Manganese (By ICP-OES)	Should be Positive	Positive
5.21	Potassium (By ICP- OES)	Should be Positive	Positive
5.22	Chromium (By ICP- OES)	Should be Positive	Positive
5.23	Selenium (By ICP- OES)	Should be Positive	Positive

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
5.24	Elemental Iron (By ICP-OES)	Should be Positive	Positive
5.25	Phosphorus (By Chemically)	Should be Positive	Positive
5.26	Lutein (By HPTLC)	Should be Positive	Positive
5.27	Vitamin K (By HPTLC)	Should be Positive	Positive
5.28	Zeaxanthin (By HPTLC)	Should be Positive	Positive
5.29	Grape Seed Extract (By HPTLC)	Should be Positive	Positive
5.30	Collagen Hydrolyzed (By HPTLC)	Should be Positive	Positive
5.31	Choline (By HPTLC)	Should be Positive	Positive
5.32	Inositol (By HPLC)	Should be Positive	Positive
5.33	Vitamin K2-7 (By HPLC)	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the standard solution.

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S.No.	TEST	ACCEPTANC	E CRITERIA	RESULTS
6	Microbial Limit			
(A)	Total plate count	Not more than 1000	cfu/gm	65 cfu/gm
(B)	Yeast & mould count	Not more than 100	cfu/gm	<10 cfu/gm
(C)	E.coli	Should be Absent/g	m	Absent/gm
	Assay - Each Film coated Tablet contains	Shelf Life Limit	Release Limit	
7.1	Vitamin E 10mg	NLT 9.00mg NLT 90.00% of label claimed	NLT 9.50 mg NLT 95.00% of label claimed	9.82mg 98.20%
7.2	Vitamin B6 2mg	NLT 1.80mg NLT 90.00% of label claimed	NLT 1.90 mg NLT 95.00% of label claimed	2.37mg 118.50%
7.3	Pantothenic Acid 5mg	NLT 4.50mg NLT 90.00% of label claimed	NLT 4.75 mg NLT 95.00% of label claimed	6.01mg 120.20%

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S.No.	TEST Vitamin B12 1mcg	ACCEPTANCE CRITERIA		RESULTS	
7.4		NLT 0.90mcg	NLT 0.95 mcg	1.18mcg 118.00%	
		NLT 90.00% of label claimed	NLT 95.00% of label claimed		
7.5	Vitamin-C (Ascorbic Acid) 40mg	NLT 36.00mg	NLT 38.00 mg	48.48mg 121.20%	
		NLT 90.00% of label claimed	NLT 95.00% of label claimed		
7.6	Vitamin B1 (Thiamine Mononitrate) 1.4mg	NLT 1.26mg	NLT 1.33 mg	1.58mg 112.86%	
		NLT 90.00% of label claimed	NLT 95.00% of label claimed		
7.7	Vitamin B2 (Riboflavin) 1.7mg	NLT 1.53mg	NLT 1.62 mg	2.21mg 130.00%	
		NLT 90.00% of label claimed	NLT 95.00% of label claimed		
7.8	Vitamin B3 (Nicotinamide) 16mg	NLT 14.40mg	NLT 15.20 mg	17.98mg 112.38%	
		NLT 90.00% of label claimed	NLT 95.00% of label claimed		

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S.No.	TEST*	ACCEPTANC	E CRITERIA	RESULTS
7.9	Iron (As Ferrous Fumarate) 21mg	NLT 18.90mg NLT 90.00% of label claimed	NLT 19.95 mg NLT 95.00% of label claimed	20.54mg 97.81%
7.10	Magnesium (As Magnesium Oxide) 100mg	NLT 90.00mg NLT 90.00% of label claimed	NLT 95.00 mg NLT 95.00% of label claimed	105.02mg 105.02%
7.11	Copper (As Copper Sulfate Pentahydrate) 1mg	NLT 0.90mg NLT 90.00% of label claimed	NLT 0.95 mg NLT 95.00% of label claimed	1.00mg 100.00%
7.12	Manganese (As Manganese sulfate) 2mg	NLT 1.80mg NLT 90.00% of label claimed	NLT 1.90 mg NLT 95.00% of label claimed	1.94mg 97.00%
7.13	Chromium (as chromium chloride hexahydrate) 50mcg	NLT 45.00mcg NLT 90.00% of label claimed	NLT 47.50 mcg NLT 95.00% of label claimed	50.25mcg 100.50%

CONCLUSION: The Finished Product complies as per IH Specification.

Prepared By Jan Voltage Officer/Executive-QC (Sign & Date)

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