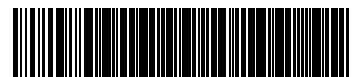




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QA.15.0.0.3

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FORM 39

[RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC

TEST REPORT

ISSUED TO :	REPORT NO	: EFRAC/2019/PRJ/1128/00001
Central Medical Services Society	ISSUE DATE	: 10/12/2019
Ministry of Health & Family Welfare, Govt. of India 2nd Floor,	CUSTOMER REFERENCE	: TRF sent by CMSS Ahmedabad
Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Road, Teen Murti		
Marg, New Delhi	DATE	: 28/11/2019
Chankayapuri - 110021	PAGE NO	: 1 of 3
MFG. LICENCE No : N/A		

SAMPLE DETAILS

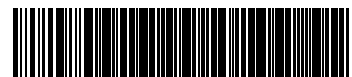
SAMPLE REGISTRATION DETAILS			
Sample Name	: O.C Pills-Asha (HDC)/Cycles [66]	Sample Quantity Received	: 10 Strips
		Sample Registration Date	: 28/11/2019
		Sample Submitted/Drawn by	: Ahmedabad Ware House; 380028
Sample Receipt Date	: 28/11/2019	Batch Size	: N/A
Registration No	: EFRAC/2019/PRJ/1128/00001	Date of Expiry	: 08-2022
Name of Manufacturer	: N/A		
Batch No.	: MN1920002; 020153		
Date of Mfg.	: 09-2019		
SAMPLE ANALYSIS DETAILS			
Analysis Starting Date	: 29/11/2019	Analysis Completion Date	: 05/12/2019

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Description	Indian Pharmacopoeia 2018	-	—	-	White colour round shaped , biconvex film coated tablet engraved with EN on one side plain on other side.
2	Leak test	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies
3	Uniformity of Weight	Indian Pharmacopoeia 2018	-	%	(±) 10.0	AvgWt : 60.76mg, (-) dev : 3.28, (+) dev :3.36, Complies
4	Identification By TLC	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies



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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
5	Uniformity Content By HPLC	Indian Pharmacopoeia 2018	0.15, 0.03 mg/tab	% of L.C.	85.0 - 115.0	Levonorgestrel :Avg : 98.78, Min : 94.81, Max : 104.11, Ethinyloestradiol :Avg : 97.69, Min : 91.35, Max : 107.73, Complies
6	Assay of Levonorgestrel: Each White film coated tablet contains Levonorgestrel IP.	Indian Pharmacopoeia 2018	0.15 mg/tab	% of L.C.	(0.135 - 0.165) mg/tab, 90.0 - 11	(0.1492 mg/tab) i.e, 33.49, Complies
7	Disintegration Test	Indian Pharmacopoeia 2018	-	Min./Sec.	NMT : 30	Min : 3 min 55 sec, Max : 8 min 42 sec, Complies
8	Assay of Ethinyloestradiol Each White film coated tablet contains Ethinyloestradiol IP.	Indian Pharmacopoeia 2018	0.03 mg/tab	% of L.C.	(0.027 - 0.033) mg/tab, 90.0 - 11	(0.0297 mg/tab) i.e, 99.08, Complies
9	Description of Ferrous Fumarate	Indian Pharmacopoeia 2018	-	—	-	Brown colour, round shaped, biconvex film coated tablet.
10	Identification A (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies
11	Identification B (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies
12	Identification C (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies
13	Ferric Iron (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	—	Should Comply	Complies

Research & Analysis Centre: Subhas Nagar PO: Nilgunj Bazar Barasat Kolkata 700 121

Phone +91 33 7112 2800 Fax: +91 33 7112 2801 Email: efraclab@efrac.org

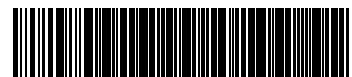
www.efrac.org



Authorized Signatory
Satyendra Kumar
Sr. Chemist



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Chankayapuri - 110021	PAGE NO	: 3 of 3
MFG. LICENCE No : N/A		

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
14	Disintegration Time (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	Min./Sec.	NMT : 60 min	Min :11 min 16 sec,Max :20 min29 sec,Complies
15	Uniformity of weight (Ferrous Fumarate)	Indian Pharmacopoeia 2018	-	%	(±) 7.5	Avg Wt : 90.96mg, (-) dev : 4.65, (+) dev : 3.77, Complies
16	Assay (Each Brown film coated tablet contains) : Ferrous Fumarate IP	Indian Pharmacopoeia 2018	60 mg/tab	% of L.C.	(54 - 63)mg/tab, 90.0 - 105.0	(59.10 mg/tab) i.e,98.50, Complies

In the opinion of the undersigned, the Sample referred to above is of Standard Quality / is not of Standard Quality
as defined in the Act or the Rules made thereunder for the reasons given below:

-END OF THE TEST REPORT-