



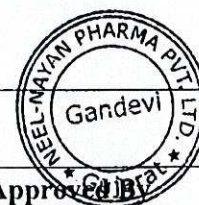
QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

Release Date : 14/01/2020

Report No. : 2019/NNP/ESC/0082

Name of Product	: Escitalopram 10 mg (Escitalopram Tablets USP 10 mg)	Batch No.	: T11700119
Active ingredient	: Each film coated tablet contains :	Batch Size	: 300,000 Tablets.
& Label Claim	Escitalopram Oxalate USP	Mfg. Date	: 11/2019
	Eq. to Escitalopram 10 mg	Exp. Date	: 10/2021
	Excipients Q.S.	Sample Date	: 22/12/2019
	Colour: Titanium Dioxide	Qty. of Sample	: 100 Tablets
		Pack Size	: 3X10 Tablets
Analysed as per	: USP Specification.		

Sr. No.	Tests	Specifications	Result
1.	Description	White colored, round shaped, biconvex, film coated tablets plain on both sides.	White colored, round shaped, biconvex, film coated tablets plain on both sides.
2.	Average weight	255.0 mg \pm 3.0%	253.85 mg
3.	Weight variation	\pm 7.5% of Average weight	Min : -2.70% Max : 2.94%
4.	Thickness	4.00 mm \pm 0.3 mm	4.06 mm
5.	Diameter	8.5 mm \pm 0.2 mm	8.52 mm
6.	Disintegration Time	Not more than 30 minutes	1 min 21 Sec
7.	Identification		
	A) By HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies
8.	Dissolution	Not less than 80% (Q) of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$) is dissolved in 30 min.	Min: 100.67 % Max: 106.50 % Mean: 103.23 %
9.	Uniformity of Dosage Unit (By Content Uniformity)	The acceptance value (AV) of 10 dosage units \leq 15.	4.70



Signature	Prepared By	Checked By	Approved By
	<i>NPati</i>	<i>Madhuri</i>	<i>Bati</i>
Date	14/01/2020	14/01/2020	14/01/2020
Designation	Sr. Officer QC	Executive QC	Head QA/QC

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Corp. Office: A-63, TTC Industrial Area, MIDC Kharine, Navi Mumbai – 400 705. Tel: +91 22 27630003/18

IRREVOCABLE Documentary Credit Number : 827073300000647

Date of Issue :20191202



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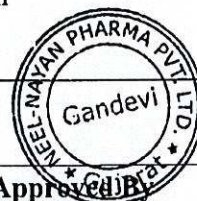
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Sr. No.	Tests	Specifications	Result
10.	Related Substances (By HPLC)		
	a) Citalopram related compound A ^a	Not more than 0.3%	Not Detected
	b) Citalopram related compound B ^b	Not more than 0.5%	0.04%
	c) Citalopram related compound C (3-oxocitalopram)	Not more than 0.5%	0.19%
	d) Citalopram related compound E ^c (Citalopram N-Oxide)	Not more than 0.2%	Not Detected
	e) Any Other individual, unspecified impurity	Not more than 0.2%	0.02%
	f) Total Impurities	Not more than 2.0%	0.26%
11.	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O).	99.78%
12.	Microbial Limit Test		
	a) Total aerobic microbial count	Not more than 1000 cfu/gm	40 cfu/gm
	b) Total combined Yeast and Molds count	Not more than 100 cfu/gm	<10 cfu/gm
	c) Pathogens	Should be absent per gm	Absent

Results : Sample is ~~Complies~~ **Complies** as per USP specifications.



Signature	Prepared By	Checked By	Approved By
	<i>N. Pati</i>	<i>I. Maheshwari</i>	<i>S. K. S.</i>
Date	14/01/2020	14/01/2020	14/01/2020
Designation	Sr. Officer QC	Executive QC	Head QA/QC

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