NEEL-NAYAN PHARMA PVT. LTD.

(Subsidiary of Pantson Laboratories Pvt. Limited)

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 & Label Claim	: Each film coated tablet contains : Escitalopram Oxalate USP Eq. to Escitalopram 10 mg Excipients Q.S. Colour: Titanium Dioxide	Batch Size	: 300,000 Tablets.
		Mfg. Date	: 11/2019
		Exp. Date	: 10/2021
		Sample Date	: 22/12/2019
		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 ± 3.0%	253.85 mg
3.	**Weight variation**	± 7.5% of Average weight	Min : -2.70% Max : 2.94%
4.	**Thickness**	4.00 mm ± 0.3 mm	4.06 mm
5.	**Diameter**	8.5 mm ± 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 ≤ 15.	4.70

NEEL-NAYAN PHARMA PVT. LTD. Gandevi Gujarat

	Prepared By	Checked By	Approved By
Signature	NPatil	DMadhuri	Basil
Date	14/01/2020	14/01/2020	14/01/2020
Designation	Sr. Officer QC	Executive QC	Head QA/QC

Reg. Office & Facility: P.O. Pati, Gandevi-Chikhali Road, Gandevi-396 360. Gujarat, India. Tel: +91 2634 262377
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

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 & Label Claim	: Each film coated tablet contains : Escitalopram Oxalate USP Eq. to Escitalopram 10 mg Excipients Q.S. Colour: Titanium Dioxide	Batch Size	: 300,000 Tablets.
		Mfg. Date	: 11/2019
		Exp. Date	: 10/2021
		Sample Date	: 22/12/2019
		Qty. of Sample	: 100 Tablets
		Pack Size	: 3X10 Tablets
Analysed as per	: USP Specification.		

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 ($C_{20}H_{21}FN_2O$).	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/~~Not Complies~~ as per USP specifications.

NEEL-NAYAN PHARMA PVT. LTD. Gandevi Gujarat

	Prepared By	Checked By	Approved By
Signature	Patil	Madhuri	Patil
Date	14/01/2020	14/01/2020	14/01/2020
Designation	Sr. Officer QC	Executive QC	Head QA/QC

Reg. Office & Facility: P.O. Pati, Gandevi-Chikhali Road, Gandevi-396 360. Gujarat, India. Tel: +91 2634 262377
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