

ESTUDIO DE ESTABILIDAD

ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg

Escitalopram Oxalato

Subdepartamento Registros y Autorizaciones Sanitarias

ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg

Estudio de estabilidad

Contenido

I.		PROTOCOLO	2
2	L.	Condiciones	2
2	2.	Tipo de envase	2
3	3.	Fecha de inicio y fin del estudio de estabilidad	2
4	1.	Análisis realizados y frecuencia de testeo:	3
į	5.	Especificaciones del producto terminado	4
II.		FÓRMULA CUALI-CUANTITA	5
III.		RESULTADOS	7
-	L.	Estudio de estabilidad Acelerado	7
2	2.	Estudio de estabilidad a tiempo real	10
IV.		DISCUSIÓN	16
٧.		CONCLUSIÓN	16
VI.		ESPECIFICACIÓN DE LA VIDA ÚTIL	16



I. <u>PROTOCOLO</u>

Se realizó una evaluación de la estabilidad de tres lotes de ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg fabricados por Neel-Nayan Pharma Pvt. Ltd., utilizando materia prima suministrada por Similax Laboratories Limited. El estudio se llevará a cabo a dos tiempos y condiciones ambientales.

A continuación los lotes a analizar:

Número de lote	Fecha de manufactura	Tamaño de lote	
T07000216	Noviembre 2016	100.000	
T07000316	Noviembre 2016	100.000	
T07000416	Noviembre 2016	100.000	

1. Condiciones

El estudio se realizó almacenando muestras, en las siguientes condiciones de temperatura y humedad relativa:

	Estudio Acelerado	Estudio a tiempo real
Temperatura	40°C ± 2°C	30°C ± 2°C
Humedad	75 % ± 5 % H. R.	65 % ± 5 % H. R

2. Tipo de envase

Estuche de cartulina impresa que contiene Blíster PVC transparente/ALU, más folleto de información al paciente, todo debidamente rotulado y sellado.

3. Fecha de inicio y fin del estudio de estabilidad

- Fecha de inicio: El estudio se inició el 28 de Noviembre de 2016.
- Fecha de término: El estudio aún sigue en curso.



ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg

Estudio de estabilidad

4. Análisis realizados y frecuencia de testeo:

a) Estudio acelerado

Parámetros medidos	Inicial	1 mes	2 meses	3 meses	6 meses
Descripción	٧	٧	٧	٧	٧
Identificación	٧	٧	٧	٧	٧
Disolución	٧	٧	٧	٧	٧
Valoración	٧	٧	٧	٧	٧
Sustancias relacionadas	٧	٧	٧	٧	٧
Recuento microbiano	٧	٧	-	-	٧

b) Estudio a tiempo real

Parámetros medidos	Inicial	3 M	6 M	9 M	12 M	18 M	24 M	36 M
Descripción	٧	٧	٧	٧	٧			
Identificación	٧	٧	٧	٧	٧			
Disolución	٧	٧	٧	٧	٧			
Valoración	٧	٧	٧	٧	٧			
Sustancias relacionadas	٧	٧	٧	٧	٧			
Recuento microbiano	٧	-	-	-	-			

NOTA: √ = Parámetro debe ser medido.

Cabe destacar que la metodología utilizada para la medición de los diferentes parámetros en el estudio de estabilidad del producto ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg es la misma declarada en la metodología original para el análisis del producto terminado.



^{*} Estudio en curso, se informará actualización oportunamente.

ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg $\,$

Estudio de estabilidad

5. <u>Especificaciones del producto terminado para estabilidad:</u>

Sr. No.	Tests	Specifications
1.	Description	White colored, round shaped, biconvex, film coated tablet,
		embossed with "11" on one side and plain on other side.
2.	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.
3.	Dissolution	NLT 80% (Q) of The labeled amount of Escitalopram
		(C ₂₀ H ₂₁ FN ₂ O) is Dissolved In 30 minutes.
4.	Related Substances (By HPLC)	
	a) Citalopram related compound A ^a	Not more than 0.3 %
	b) Citalopram related compound B ^b	Not more than 0.5 %
	c) Citalopram related compound C	Not more than 0.5%
	d) Citalopram related compound E ^c	Not more than 0.2 %
	e) Any other individual, unspecified	Not more than 0.20%
	impurity	
	f) Total Impurities	Not more than 2.0 %
5.	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).
6.	Microbial Limit Test	
	a) Total aerobic microbial count	Not more than 1000 cfu/gm
	b) Total combined Yeast and Molds count	Not more than 100 cfu/gm
	c) Pathogens	Should be absent per gm

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



II. <u>FÓRMULA CUALI-CUANTITATIVA</u>

NEEL-NAYAN PHARMA PVT. LTD.

(Subsidiary of Pantson Laboratories Pvt. Limited)



Description and Composition of the Drug Product Drug Product Name :

ESCITALOPRAM TABLETS USP 10mg

Dosage Form: Tablet (film coated)

Description: White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Composition:

The quantitative composition and function of each ingredient in ESCITALOPRAM TABLETS USP 10mg is provided in the table given below:

Sr. No.	Name of the Materials	Spec.	Rationale	Qty./ Tablet in mg	Qty./Batch in kg	
1	Escitalopram Oxalate* (Equivalent to Escitalopram 10 mg)	USP	Active ingredient	12.78	1.278	
2	Microcrystalline Cellulose**	USP/NF	Diluent	198.90	19.890	
3	Colloidal Silicon Dioxide	USP/NF	Glidant	5.00	0.500	
4	Croscarmellose Sodium	USP/NF	Disintegrant	25.00	2.500	
5	Talc	USP	Glidant	3.32	0.332	
6	Magnesium Stearate	USP/NF	Lubricant	5.00	0.500	
	Total Weight (Core Tablet) 250.00 mg 25.00					
7	Opadry II White	IHS	Coating Material	5.0	0.500	
8	Purified Water***	BP	Solvent	Q.S.	Q.S.	
	Total	Weight (Coa	ted Tablet)	255.0 mg	25.50	

Note: Dispensed materials must be taken for processing within 30 days.

- * The quantity of the Escitalopram Oxalate is calculated based on assay and Water Content.
- **Quantity of Microcrystalline Cellulose to be compensated as per Active material quantity to keep the average Weight of tablet constant.
- *** Solvent will not contribute to the final weight of the tablet.



ESCITALOPRAM TABLETS USP 10 MG Original Submission

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



(Subsidiary of Pantson Laboratories Pvt. Limited)



Calculation for actual quantity of Escitalopram Oxalate to be taken: -

*Quantity of Escitalopram Oxalate to be taken (X):

Molecular weight of Escitalopram = 324.392

Molecular weight of Oxalate = 90.038

Molecular weight of Escitalopram Oxalate = 414.43

= 10 x 414.43 = 12.78 = 12.78 mg/Tab 324.392

Calculation of Escitalopram Oxalate

*Actual Quantity of Escitalopram Oxalate to be taken (X):

Calculation of Microcrystalline Cellulose

** Actual quantity of Microcrystalline Cellulose to be dispensed (Y) =

[{(Standard quantity of Escitalopram Oxalate + Standard quantity of Microcrystalline
Cellulose)}-X]

Quantitative Formula For Opadry II White:

Sr. No.	Name of ingredients	Quality	Percentage
		standards	(% w/w)
1	HPMC 2910 / Hypromellose	USP	62.500
2	Titanium Dioxide (77891)	USP	31.250
3	Macrogol/PEG	NF	6.250





ESCITALOPRAM TABLETS USP 10 MG

Original Submission

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



III. **RESULTADOS**

Estudio de estabilidad acelerado:

Subsidiary of PANTSON LABORATORIES PVT. LTD. IVEEL-IVAYAIN PHAKMA PVI. LID. MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360. INDIA.

Accelerated Stability Summary Data

Expire Stability Condition: 10/2018 Stability Condition: 40°±2°C; 75%±5%RH. Pack size: 3 x 10 Tablets. : 11/2016 : 10/2018 Mfg. Date : Escitalopram Tablets USP 10 mg : 100,000 Tablets. : 28/11/2016 Date of Completion: 29/05/2017 : T07000216 Name of Products Date of Initiation Batch Size Batch No

	Page No		: 1 of 1.	-	
_	Initial	1 Month	2 Months	3 Months	6 Months
	2000000000	********			

6 Months	***************************************	Complies	Min- 93.3% Max- 97.4% Mean-95.2%	98.83%	0.06% 0.22% 0.21% 0.112% 0.13% 0.76%	90 cfu/gm <10 cfu/gm Absent
3 Months	*	Complies	Min- 93.7% Max- 97.7% Mean-95.8%	99.00%	0.05% 0.21% 0.20% 0.11% 0.11%	
2 Months	*	Complies	Min- 94.1% Max- 98.1% Mean-96.0%	99.10%	0.04% 0.20% 0.19% 0.10% 0.11% 0.66%	
I Month		Complies	Min- 94.4 % Max- 98.4% Mean-96.3%	99.23%	0.03% 0.20% 0.18% 0.10% 0.10% 0.63%	80 cfu/gm <10 cfu/gm Absent
Initial 28/11/2016	*	Complies	Min- 94.8 % Max- 98.6 % Mean- 96.5%	99.47%	0.02% 0.19% 0.17% 0.09% 0.09%	70 cfu/gm <10 cfu/gm Absent
Specification	White colored, round shaped, bloonvex, film coated tablet, embossed with "11" on one side and plain on other side.	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	NLT 80% (Q) of The labeled amount of Esctalopram (C ₂₀ H ₂₁ FN ₂ O) is dissolved in 30 minutes.	Not less than 90.0% and Not more than 110.0% of the abeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O).	Not more than 0.3 % Not more than 0.5 % Not more than 0.5 % Not more than 0.2 % Not more than 0.20% Not more than 2.0 %	Not more than 1000 cftw/g Not more than 100 cftw/g. Absent
Tests	Description	Identification	Dissolution	Assay (By HPLC)	Related Substances (By HPLC) a) Citalopram related compound A ⁸ b) Citalopram related compound B ⁸ c) Citalopram related compound C d) Citalopram related compound E ^g e) Any other individual, unspecified impurity f) Total Impurities	Microbial Limit Test a) Total aerobic microbial count b) Total combined Yeast and Molds count c) Pathogens
s. S	10	05	03	ŧ	90	90

Hence the months. 8 Pathogens
 White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: The results show that there is no significant physical or chemical changes when the product is kept at 40°C ± 2°C and 75% ± 5% RH for the results show that there is no significant physical or chemical changes when the product is kept at 40°C ± 2°C and 75% ± 5% RH for the results show that there is no significant physical or chemical changes when the product is kept at 40°C ± 2°C and 75% ± 5% RH for the results show that there is no significant physical or chemical changes.

Approved By	: - Stenens	01/06/2017	Head OA/OC
Checked By	Oust	31/05/2017	Executive QC
Prepared By	E. Madelit	29/05/2017	Sr. Officer QC
	Signature	Date	Designation





product is considerable stable up to shelf life.



Subsidiary of PANTSON LABORATORIES PVT. LTD. MANUFACTURE OF PHARMACHITICAL DEDUCTS

MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360, INDIA.

Accelerated Stability Summary Data

Name of Products: Es	Batch No : TO	3 atch Size : 10	Date of Initiation : 28/11/2016	Date of Completion: 29/05/2017
Name of Products : Escitalopram Tablets USP 10 mg	T07000316	100,000 Tablets.	11/2016	05/2017

ie : PVC-Alu Blister : 1 of 1.	Month 2 Months 3 Months 6 Months
Pack Style Page No	-
2 2	Initial

Mig. Date : 11/2016 Expiry Date : 10/2018 Stability Condition : 40° ± 2° C; 75% ± 5%RH. Pack size : 3 x 10 Tablets.

		-		_		
6 Months 29/05/2017	*	Complies	Min- 92.2% Max- 96.1% Mean-94.8%	98.63%	0.06% 0.22% 0.21% 0.13% 0.14%	85 cfu/gm <10 cfu/gm Absent
3 Months 28/02/2017		Complies	Min- 93.5% Max- 97.2% Mesn-95.2%	98.93%	0.06% 0.21% 0.20% 0.12% 0.13%	
2 Months 28/01/2017	*	Complies	Min- 93.8% Max- 97.8% Mean-95.4%	99.12%	0.05% 0.20% 0.19% 0.11% 0.13%	
1 Month 28/12/2016	•	Complies	Min- 93.3 % Max- 97.4 % Mean-95.7%	99.46%	0.05% 0.19% 0.18% 0.11% 0.10%	80 cfu/gm <10 cfu/gm Absent
Initial 28/11/2016	*	Complies	Min- 93.6 % Max- 97.2 % Mean- 95.9%	96.87%	0.04% 0.18% 0.20% 0.10% 0.08%	75 cfu/gm <10 cfu/gm Absent
Specification	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	NLT. 80% (Q) of The labeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O) is dissolved in 30 minutes.	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram (C ₂₀ H ₂ ,FN ₂ O).	Not more than 0.3 % Not more than 0.5 % Not more than 0.5 % Not more than 0.2 % Not more than 0.2 % Not more than 2.0 %	Not more than 1000 cfu/g Not more than 100 cfu/g Absent
Tests	Description	Identification	Dissolution	Assay (By HPLC)	Related Substances (By HPLC) a) Citalopram related compound A ³ b) Citalopram related compound B ^b c) Citalopram related compound C d) Citalopram related compound E ^E e) Any other individual, unspecified impurity f) Total Impurities	Microbial Limit Test a) Total aerobic microbial count b) Total combined Yeast and Molds count c) Pathogens
s s	10	0.5	03	25	05	90

* White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: The results show that there is no significant physical or chemical changes when the product is kept at 40°C ± 2°C and 75% ± 5% RH for 06 months. Hence is

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Approved By	· · the	01/06/2017	Head QA/QC
Checked By	O.st.	31/05/2017	Executive QC
Prepared By	G. Marie	29/05/2017	Sr. Officer QC
	Signature	Date	Designation





IVEEL-IVA IAIV FHAKWA PVI, LID, Subsidiary of PANTSON LABORATORIES PVT, LTD, MANUFACTURE OF PHARMACHITICAL PRODUCTS

MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360, INDIA.

Accelerated Stability Summary Data

Name of Products : Escitalopram Tablets USP 10 mg
Batch No : T07000416
Batch Size : 100,000 Tablets.
Date of Initiation : 28/11/2016
Date of Completion : 29/05/2017

Mfg. Date : 11/2016

Expiry Date : 10/2018

Stability Condition : 40⁰ ± 2⁰ C; 75% ± 5%RH.

Pack size : 3 x 10 Tablets.

Pack Style : PVC-Alu Blister

Page No : 1 of 1.

Tests		Specification	Initial	1 Month	2 Months	3 Months	6 Months
			28/11/2016	28/12/2016	28/01/2017	28/02/2017	29/05/2017
Description White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	White colored, round shaped, bi tablet, embossed with "Il" on or other side.	convex, film coated ne side and plain on		*		*	٠
Identification The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	The retention time of the major p solution corresponds to that of the as obtained in the Assay.	seak of the Sample Standard solution,	Complies	Complies	Complies	Complies	Complies
Dissolution NLC 80% (Q) of The lab	80% (Q) of The	labeled amount of	Min- 94.2 %	Min- 94,4%	Min- 94.1%	Min- 93.8%	Min- 93.5%
Escitalopram (C ₁₀ H ₂ ,FN ₂ O) is dissolved 30 crimites	Escitalopram (C ₂₀ H ₂₁ FN ₂ O) is	dissolved in	Max- 98.2%	Max- 98.1% Mesn-06.7%	Max- 98.0%	Max- 98.7%	Max- 97.5%
Assay (Ry HPI C) Not lase than \$0.000 and Mat many than 110.000 at	Not lose than 90 095 and Not mass	thon 110.00/ ac	MICHIE 20.7 / 0	DV I TO THE TOTAL TO	0.000 month	(VICGIF 70.3 78	MC8IP93.976
	the labeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O).	% 81.66	960066	98.71%	98.47%	98.13%
Related Substances (By HPLC)							
a) Citalopram related compound A ^a Not more than 0.3 %	Not more than 0.3 %		20000	0000			
b) Citalopram related compound B ^b Not more than 0.5 %	Not more than 0.5 %		0.03%	0.04%	0.04%	0.06%	0.07%
c) Citalopram related compound C Not more than 0.5%	Not more than 0.5%		0.20%	0.21%	0.23%	0.23%	0.24%
	Not more than 0.2 %		0.18%	0.19%	0.19%	0.20%	0.20%
c) Any other individual, unspecified Not more than 0.20%	Not more than 0.20%		0.08%	0.09%	0.09%	0.10%	0.10%
impurity			0.07%	0.08%	%60.0	0.09%	0.10%
f) Total Impurities Not more than 2.0 %	Not more than 2.0 %		0.59%	0.63%	0.66%	0.70%	0.73%
Microbial Limit Test							
_	Non-section of Assessing						
b)Total combined Yeast and Molds Not more than 1000 ctu/g	Not more than 1000 cfu/g		65 cfu/gm	75 cfu/gm		,	90 cfu/gm
count	Not more than 100 cfu/g		<10 cfu/gm	<10 cfu/gm		,	<10 cfu/gm
c) Pathogens	Absent		Absent	Absent			Absent

* White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: The results show that there is no significant physical or chemical changes when the product is kept at 40°C ± 2°C and 75% ± 5% RH for 06 months. Hence the

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Approved By	Charles	01/06/2017	Head QA/QC
Checked By	0.34	31/05/2017	Executive QC
Prepared By	Laper	29/05/2017	Sr. Officer QC
	Signature	Date	Designation



b) Estudio de estabilidad a tiempo real:

Mfg. Date : 10/2018

Expiry Date : 10/2018

Stability Condition : 30 ± 2° C; 65% ± 5%RH.

: 3 x 10 Tablets.

: 1 of 2

Pack style Page No

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Real Time Stability Summary Data

Name of Products : Escitalopram Tablets USP 10 mg	T07000216	100,000 Tablets.	: 28/11/2016	1/2017	
Se	107	8	28	287	
••			••		
Name of Products	Batch No	Batch Size	Date of Initiation	Date of Completion: 28/11/2017	

ž 2 5	Tests Description	Specification White colored, round shaped, biconvex, film coated tablet,	Initial	3 Months	6 Months	6 Months 9 Months 12 Months	12 Months	18 Months	24 Months
	Description	White colored, round shaped, biconvex, film coated tablet,	200711/00				CHARGO TATA	TO MORENIA	54 PROBLES
	Description dentification	White colored, round shaped, biconvex, film coated tablet,	20/11/2010	28/02/2017	29/05/2017	28/08/2017	28/11/2017	28/05/2018	28/11/2018
	dentification	biconvex, film coated tablet,							
	dentification			•	٠	,			
-	dentification	embossed with "11" on one side	,		٠	•	×		
_	dentification	and plain on other side.							
_		The retention time of the major	Complian	Committee	1		:		
		peak of the Sample solution	combines	compiles	Compines	Complies	Complies		
		corresponds to that of the							
		Standard solution, as obtained							
-		in the Assay.							
03 D	Dissolution	NLT 80% (Q) of The labeled	Min- 94.8 %	Min- 94.2 % Min- 93.5% Min- 93.3% Min- 92.5%	Min- 93.5%	Min- 93.3%	Min- 92 5%		
		amount of Escitalopram	Max- 98.6 %	Max- 98.5 % Max- 97.9% Max- 97.6% Max- 97.1%	Max- 97.9%	Max- 97.6%	Max- 97 1%		
		(C20H21FN2O) is dissolved in	Mean- 96.5%	Mean- 96.2% Mean- 95.8% Mean- 95.2% Mean- 94.3%	Mean- 95.8%	Mean- 95.2%	Mean- 94.3%		
		30 minutes.							
94 A	Assay (By HPLC)	Not less than 90.0% and Not	700 4707	200000	100				
		more than 110.0% of the	99.4176	227766	99.13%	99.04%	98.87%		
		labeled amount of Escitalopram							
		(C ₂₀ H ₂₁ FN ₂ O).							

	Prepared By	Checked By	Approved By
Signature	Lagary	Oust	: toward
Date	28/11/2017	29/11/2017	01/12/2017
Designation	Sr. Officer QC	Executive QC	Head OA/OC





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Real Time Stability Summary Data

	MIG. Date : 11/2016	Expiry Date : 10/2018	Stability Condition : 300 + 20 C: 65% + 5% BH	Pack Size : 3 x 10 Tablets	Pack style : PVC-Alu Blister	Page No : 2 of 2
Name of Products - Realisations Tablete IND 10 mm	The course of th	Batch No : T07000216	Batch Size : 100,000 Tablets.	Date of Initiation : 28/11/2016	Date of Completion: 28/11/2017	

		0.04%	0.22%	0.21%	0.11%	0.12%		0.71%			,	
		0.04%	0.21%	0.19%	0.11%	0.11%		0.66%			,	
		0.03%	0.20%	0.19%	0.10%	0.10%		0.64%		,	,	
		0.03%	0.19%	0.18%	%60.0	0.10%		0.61%			•	
		0.02%	0.19%	0.17%	0.09%	0.09%		0.58%	70 cfu/gm	<10 cfu/gm	Absent	
and the second s		Not more than 0.3 %	Not more than 0.5 %	Not more than 0.5%	Not more than 0.2 %	Not more than 0.20%		Not more than 2.0 %	Not more than 1000 cfu/g	Not more than 100 cfu/g	Absent	
	05 Related Substances (By FPLC)	a) Citalopram related compound Aa	b) Citalopram related compound B [®]	c) Citalopram related compound C	d) Citalopram related compound E	e) Any other individual, unspecified	impurity	f) Total Impurities	06 Microbial Limit Test a) Total aerobic microbial count	b)Total combined Yeast and Molds	count c) Pathogens	
	Ö				_		_		5			

^{*} White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: Till the 12 months data the results show that there is no significant physical or chemical changes when the product is kept at 30°C ± 2°C and 65% ± 5% RH And real time stability study is still ongoing.

	Approved By	- Jumes	2000000	01/12/2017	Head OA/OC	Diam's
3	Checked By	Ost	7100/11/00	107/11/77	Executive OC	
Durana Durana	rrepared by	Thomas of	28/11/2017	2000	Sr. Officer OC	
	į	Signature	Date	Decisionation	Designation	





NEEL-NAYAN PHARMA PVT. LTD.

Subsidiary of PANTSON LABORATORIES PVT. LTD. MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

: 11/2016	Expiry Date : 10/2018	tion: 30" ± 2" C; 65%± 5%RH.	: 3 x 10 Tablets.	: PVC-Alu Blister	: 1 of 2
Mfg. Date	Expiry Date	Stability Condi	Pack Size	Pack style	Page No
fablets USP 10 mg		8			
Escitalopram	: T07000316	: 100,000 Tablets	: 28/11/2016	: 28/11/2017	
Name of Products : Escitalopram Tablets USP 10 mg	Batch No :	Batch Size	Date of Initiation : 28/11/2016	Date of Completion: 28/11/2017	

Sr.	Tests	Specification	Initial 28/11/2016	3 Months 28/02/2017	6 Months 29/05/2017		9 Months 12 Months 18 Months 24 Months 28/08/2017 28/11/2018 28/11/2018	18 Months 28/05/2018	24 Months 28/11/2018
5	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*				
05	Identification	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies		
03	Dissolution	NLT 80% (Q) of The labeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O) is dissolved in 30 minutes.	Min- 93.6 % Max- 97.2 % Mean- 95.9%	Min- 93.8 % Min- 93.3% Min- 93.2% Min- 93.4% Max- 97.4 % Max- 97.6% Max- 97.5% Max- 96.7% Max- 96.7% Mean- 95.6% Mean- 95.2% Mean- 94.1%	Min- 93.3% Max- 97.6% Mean- 95.2%	Min- 93.2% Max- 97.5% Mean- 94.8%	Min- 93.4% Max- 96.7% Mean- 94.1%		
40	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).	99.87%	99.72%	99.58%	99.26%	98.92%		

	Prepared By	Checked By	Approved By
Signature	legali	Oust	·· - Trans
Date	28/11/2017	29/11/2017	01/12/2017
Designation	Sr. Officer QC	Executive QC	Head QA/QC





Subsidiary of PANTSON LABORATORIES PVT. LTD, MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

Stability Condition: $30^{9} \pm 2^{9}$ C; $65\% \pm 5\%$ RH. Pack Size : 3×10 Tablets. : PVC-Alu Blister : 11/2016 : 10/2018 : 2 of 2 Expiry Date Pack Size Pack style Mfg. Date Page No : Escitalopram Tablets USP 10 mg : 100,000 Tablets. : 28/11/2016 : T07000316 Date of Completion: 28/11/2017 Name of Products Date of Initiation Batch Size Batch No

	0.06%	0.21%	0.23%	0.13%	0.12%		0.76%					,	
	0.05%	0.21%	0.22%	0.13%	0.11%		0.72%						
	0.05%	0.20%	0.21%	0.12%	0.10%		0.70%		,	,			
	0.04%	0.19%	0.20%	0.11%	0.09%		0.65%						
	0.04%	0.18%	0.20%	0.10%	%80.0		0.62%		75 cfu/gm	<10 cfu/gm		Absent	
	Not more than 0.3 %	Not more than 0.5 %	Not more than 0.5%	Not more than 0.2 %	Not more than 0.20%		Not more than 2.0 %		Not more than 1000 cfu/g	Not more than 100 cfu/g		Absent	
Related Substances (By HPLC)	a) Citalopram related compound Aa				e) Any other individual,	unspecified impurity	f) Total Impurities	Microbial Limit Test	a) Total aerobic microbial count	spi	count	c) Pathogens	

* White colored, round slaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: Till the 12 months data the results show that there is no significant physical or chemical changes when the product is kept at 30°C ± 2°C and 65% ± 5% RH And real time stability study is still ongoing.

•	Prepared By	Checked By	Approved By
Signature	Lagar	Oxt	: -
Date	28/11/2017	29/11/2017	01/12/2017
Designation	Sr. Officer QC	Executive QC	Head QA/QC



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Subsidiary of PANTSON LABORATORIES PVT. LTD. MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

Name of Products : Escitalopram Tablets USP 10 mg : 100,000 Tablets. T07000416 : 28/11/2016 Date of Completion: 28/11/2017 Batch Size Date of Initiation Batch No

T07000416 T07000416 Stability Date : 10/2018 Stability Condition : 30° ± 2° C; 65% ± 5%RH. Pack Size : 3 x 10 Tablets. Pack style : PVC-Alu Blister Page No : 1 of 2	Escitalopram Tablets	ets USP 10 mg	2	ffg. Date	: 11/2016
	T07000416		<u>а</u>	xpiry Date	: 10/2018
	100,000 Tablets.		S	tability Condition	$n: 30^{6} \pm 2^{6} C; 65\% + 5\% RH.$
Pack style Page No	28/11/2016		4	ack Size	: 3 x 10 Tablets.
	28/11/2017		<u>a.</u>	ack style	: PVC-Alu Blister
			4	age No	: 1 of 2

		T		
24 Months				
18 Months				
6 Months 9 Months 12 Months 29/05/2017 28/08/2017	1	Complies	Min- 92.8% Max- 97.9% Mean- 95.1%	98.52%
6 Months 9 Months 29/05/2017 28/08/2017	*	Complies Complies	Min- 94.7 % Min- 94.2% Min- 93.2% Min- 92.8% Max- 98.9% Max- 97.6% Max- 97.9% Mean- 96.4% Mean- 96.1% Mean- 95.8% Mean- 95.1%	98.77%
6 Months 29/05/2017	*	Complies	Min- 94.2% Max- 98.9% Mean- 96.1%	98.89%
3 Months 28/02/2017	*	Complies	Min-94.7 % Min-94.2% Min-93.2% Min-92.8% Max-97.9% Max-98.6 % Max-98.9% Max-97.6% Max-97.9% Mean-96.4% Mean-96.1% Mean-95.8% Mean-95.1%	99.04%
Initial 28/11/2016	*	Complies	Min- 94.2% Min- 94.7% Min- 94.2% Min- 93.2% Min- 92.8% Max- 98.2% Max- 98.6% Max- 98.9% Max- 97.6% Max- 97.9% Mean- 96.4% Mean- 96.1% Mean- 96.1% Mean- 96.1% Mean- 96.1%	99.18%
Specification	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	NLT 80% (Q) of The labeled amount of Escitalopram (C ₂₀ H ₂₁ FN ₂ O) is dissolved in 30 minutes.	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram (C _n H ₂ FN ₂ O).
Tests	Description	Identification	Dissolution	Assay (By HPLC)
Sr.	10	00	03	4

	Prepared By	Checked By	Approved By
Signature	flaged?	Oust	: source
Date	28/11/2017	29/11/2017	01/12/2017
Designation	Sr. Officer QC	Executive QC	Head OA/OC







Subsidiary of PANTSON LABORATORIES PVT. LTD. MANUFACTURE OF PHARMACEUTICAL PRODUCTS FACTORY- P.O. PATI, GANDEVI-CHIKHALI ROAD, GANDEVI POSTAL ADDRESS: P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

Stability Condition : $30^{0} \pm 2^{0}$ C; $65\% \pm 5\%$ RH. Pack Size : 3×10 Tablets. : PVC-Alu Blister 11/2016 : 10/2018 : 2 of 2 Mfg. Date Expiry Date Pack style Page No : Escitalopram Tablets USP 10 mg : 100,000 Tablets. : 28/11/2016 T07000416 Date of Completion: 28/11/2017 Name of Products Date of Initiation Batch Size Batch No

		%90.0	0.23%	0.21%	0.12%	0.10%		0.73%		,			,	
		0.05%	0.22%	0.21%	0.11%	%60.0		%89.0		,				
The second secon		0.04%	0.21%	0.20%	0.10%	%60.0		0.66%				,		
		0.04%	0.20%	0.19%	%60.0	0.08%		0.62%		,				
The same of the sa		0.03%	0.20%	0.18%	%80.0	0.07%		0.59%		65 cfu/gm	<10 oft/om	mama oi	Absent	
		Not more than 0.3 %	Not more than 0.5 %	Not more than 0.5%	Not more than 0.2 %	Not more than 0.20%		Not more than 2.0 %		Not more than 1000 cfu/g	Not more than 100 cfu/o	0	Absent	
	Related Substances (By HPLC)	a) Citalopram related compound A*	b) Citalopram related compound Bb	c) Citalopram related compound C	d) Citalopram related compound E ^c	e) Any other individual, unspecified	impurity	f) Total Impurities	Microbial Limit Test	a) Total aerobic microbial count	b)Total combined Yeast and Molds	count	c) Pathogens	

* White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.

Conclusion: Till the 12 months data the results show that there is no significant physical or chemical changes when the product is kept at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $65\% \pm 5\%$ RH And real time stability study is still ongoing.

Approved By	· · · · · ·	01/12/2017	Head OA/OC
Checked By	Oust	29/11/2017	Executive QC
Prepared By	Phopus.	28/11/2017	Sr. Officer QC
	Signature	Date	Designation



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03

ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg Estudio de estabilidad

IV. <u>DISCUSIÓN</u>

De acuerdo a los resultados obtenidos en el Estudio de Estabilidad, tanto Acelerado como a Tiempo Real de los lotes T07000216, T07000316 y T07000416 se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase utilizado (Blíster PVC transparente/ALU), no se evidencia una disminución significativa en la valoración del activo, y los parámetros analizados se mantuvieron dentro de los límites especificados, durante 6 meses en el estudio acelerado y durante al menos 12 meses en el estudio a tiempo real, el cual sigue en curso.

V. <u>CONCLUSIÓN</u>

Basado en los datos adquiridos de los estudios de estabilidad a tiempo real y acelerado, se concluye provisoriamente que el producto analizado es estable por un periodo de 24 meses si se almacena en su envase original cerrado, a una temperatura no mayor a $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ y una humedad ambiental de $65\% \pm 5\%$.

VI. ESPECIFICACIÓN DE LA VIDA ÚTIL

Se propone un periodo de eficacia para ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg de 24 meses a partir de su fecha de fabricación almacenándolo en su envase original (Estuche de cartulina impresa que contiene Blíster PVC transparente/ALU, más folleto de información al paciente, todo debidamente rotulado y sellado), a una temperatura ambiente no mayor a $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$, protegido de la humedad y la luz.

