OPKO Chile S.A.

ESTUDIO DE ESTABILIDAD

ESCITALOPRAM COMPRIMIDOS RECUBIERTOS 10 mg

Escitalopram Oxalato

Subdepartamento Registros y Autorizaciones Sanitarias

Contenido

I. PROTOCOLO

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	40ºC ± 2ºC	30ºC ± 2ºC
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.

4. Análisis realizados y frecuencia de testeo:

a) Estudio acelerado

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

b) Estudio a tiempo real

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

NOTA: √ = Parámetro debe ser medido.
*** Estudio en curso, se informará actualización oportunamente.**

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.

5. Especificaciones del producto terminado para estabilidad:

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 ($C_{20}H_{21}FN_2O$) is Dissolved In 30 minutes.
4.	**Related Substances (By HPLC)** a) Citalopram related compound A[a] b) Citalopram related compound B[b] c) Citalopram related compound C d) Citalopram related compound E[c] e) Any other individual, unspecified impurity f) Total Impurities	 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 %
5.	**Assay (By HPLC)**	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).
6.	**Microbial Limit Test** a) Total aerobic microbial count b) Total combined Yeast and Molds count c) Pathogens	 Not more than 1000 cfu/gm Not more than 100 cfu/gm Should be absent per gm

II. FÓRMULA CUALI-CUANTITATIVA

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 (Coated 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.

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MANAGER PRODUCTION

NEEL-NAYAN PHARMA PVT. LTD. Gandevi Gujarat

ESCITALOPRAM TABLETS USP 10 MG
Original Submission

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

$$= \frac{10 \times 414.43}{324.392} = 12.78 = 12.78 \text{ mg/Tab}$$

Calculation of Escitalopram Oxalate

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

$$= \frac{12.78 \times 100}{\text{Assay on Anhydrous basis}} \times \frac{100}{(100 - \text{Water Content})} \times \text{Total Batch Size in Million Tablets}$$

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 standards	Percentage (% w/w)
1	HPMC 2910 / Hypromellose	USP	62.500
2	Titanium Dioxide (77891)	USP	31.250
3	Macrogol/PEG	NF	6.250

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NEEL-NAYAN PHARMA PVT. LTD. Gandevi * Gujarat *

ESCITALOPRAM TABLETS USP 10 MG
Original Submission

III. RESULTADOS

a) Estudio de estabilidad acelerado:

NEEL-VAYAN 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.

Accelerated Stability Summary Data

Name of Products	: Escitalopram Tablets USP 10 mg	**Mfg. Date**	: 11/2016
Batch No	: T07000216	**Expiry Date**	: 10/2018
Batch Size	: 100,000 Tablets.	**Stability Condition**	: $40^0 \pm 2^0$ C; 75%$\pm$5%RH.
Date of Initiation	: 28/11/2016	**Pack size**	: 3 x 10 Tablets.
Date of Completion	: 29/05/2017	**Pack Style**	: PVC-Alu Blister
		Page No	: 1 of 1.

Sr. No	Tests	Specification	Initial 28/11/2016	1 Month 28/12/2016	2 Months 28/01/2017	3 Months 28/02/2017	6 Months 29/05/2017
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 94.8 % Max- 98.6 % Mean- 96.5%	Min- 94.4 % Max- 98.4% Mean-96.3%	Min- 94.1% Max- 98.1% Mean-96.0%	Min- 93.7% Max- 97.7% Mean-95.8%	Min- 93.3% Max- 97.4% Mean-95.2%
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the abeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.47%	99.23%	99.10%	99.00%	98.83%
05	Related Substances (By HPLC) a) Citalopram related compound A[a] b) Citalopram related compound B[b] c) Citalopram related compound C d) Citalopram related compound E[c] e) Any other individual, unspecified impurity f) Total Impurities	Not more than 0.3 % Not more than 0.5 % Not more than 0.3% Not more than 0.2 % Not more than 0.20% Not more than 2.0 %	0.02% 0.19% 0.17% 0.09% 0.09% 0.58%	0.03% 0.20% 0.18% 0.10% 0.10% 0.63%	0.04% 0.20% 0.19% 0.10% 0.11% 0.66%	0.05% 0.21% 0.20% 0.11% 0.11% 0.70%	0.06% 0.22% 0.21% 0.12% 0.13% 0.76%
06	Microbial Limit Test a) Total aerobic microbial count b)Total combined Yeast and Molds count c) Pathogens	Not more than 1000 cfu/g Not more than 100 cfu/g Absent	70 cfu/gm <10 cfu/gm Absent	80 cfu/gm <10 cfu/gm Absent	- - -	- - -	90 cfu/gm <10 cfu/gm 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 product is considerable stable up to shelf life.

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

NEEL-VAYAN 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.

Accelerated Stability Summary Data

Name of Products	**: Escitalopram Tablets USP 10 mg**	**Mfg. Date**	**: 11/2016**
Batch No	**: T07000316**	**Expiry Date**	**: 10/2018**
Batch Size	**: 100,000 Tablets.**	**Stability Condition**	**: $40^0 \pm 2^0$ C; 75%± 5%RH.**
Date of Initiation	**: 28/11/2016**	**Pack size**	**: 3 x 10 Tablets.**
Date of Completion	**: 29/05/2017**	**Pack Style**	**: PVC-Alu Blister**
		Page No	**: 1 of 1.**

Sr. No	Tests	Specification	Initial 28/11/2016	1 Month 28/12/2016	2 Months 28/01/2017	3 Months 28/02/2017	6 Months 29/05/2017
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 93.6 % Max- 97.2 % Mean- 95.9%	Min- 93.3 % Max- 97.4 % Mean-95.7%	Min- 93.8% Max- 97.8% Mean-95.4%	Min- 93.5% Max- 97.2% Mean-95.2%	Min- 92.2% Max- 96.1% Mean-94.8%
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.87%	99.46%	99.12%	98.93%	98.63%
05	Related Substances (By HPLC) a) Citalopram related compound A[a] b) Citalopram related compound B[b] c) Citalopram related compound C d) Citalopram related compound E[c] e) Any other individual, unspecified impurity f) Total Impurities	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 %	0.04% 0.18% 0.20% 0.10% 0.08% 0.62%	0.05% 0.19% 0.18% 0.11% 0.10% 0.63%	0.05% 0.20% 0.19% 0.11% 0.13% 0.70%	0.06% 0.21% 0.20% 0.12% 0.13% 0.74%	0.06% 0.22% 0.21% 0.13% 0.14% 0.78%
06	Microbial Limit Test a) Total aerobic microbial count b)Total combined Yeast and Molds count c) Pathogens	Not more than 1000 cfu/g Not more than 100 cfu/g Absent	75 cfu/gm <10 cfu/gm Absent	80 cfu/gm <10 cfu/gm Absent	- - -	- - -	85 cfu/gm <10 cfu/gm 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 product is considerable stable up to shelf life.

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

INDEL-VALIAN 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.

Accelerated Stability Summary Data

Name of Products	: **Escitalopram Tablets USP 10 mg**	**Mfg. Date**	: **11/2016**
Batch No	: **T07000416**	**Expiry Date**	: **10/2018**
Batch Size	: **100,000 Tablets.**	**Stability Condition**	: **$40^0 \pm 2^0$ C; 75%± 5%RH.**
Date of Initiation	: **28/11/2016**	**Pack size**	: **3 x 10 Tablets.**
Date of Completion	: **29/05/2017**	**Pack Style**	: **PVC-Alu Blister**
		Page No	: **1 of 1.**

Sr. No	Tests	Specification	Initial 28/11/2016	1 Month 28/12/2016	2 Months 28/01/2017	3 Months 28/02/2017	6 Months 29/05/2017
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 94.2 % Max- 98.2% Mean-96.9%	Min- 94.4% Max- 98.1% Mean-96.7%	Min- 94.1% Max- 98.0% Mean-96.5%	Min- 93.8% Max- 98.7% Mean-96.3%	Min- 93.5% Max- 97.5% Mean-95.9%
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.18 %	99.00%	98.71%	98.47%	98.13%
05	Related Substances (By HPLC) a) Citalopram related compound A[a] b) Citalopram related compound B[b] c) Citalopram related compound C d) Citalopram related compound E[c] e) Any other individual, unspecified impurity f) Total Impurities	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 %	0.03% 0.20% 0.18% 0.08% 0.07% 0.59%	0.04% 0.21% 0.19% 0.09% 0.08% 0.63%	0.04% 0.23% 0.19% 0.09% 0.09% 0.66%	0.06% 0.23% 0.20% 0.10% 0.09% 0.70%	0.07% 0.24% 0.20% 0.10% 0.10% 0.73%
06	Microbial Limit Test a) Total aerobic microbial count b)Total combined Yeast and Molds count c) Pathogens	Not more than 1000 cfu/g Not more than 100 cfu/g Absent	65 cfu/gm <10 cfu/gm Absent	75 cfu/gm <10 cfu/gm Absent	- - -	- - -	90 cfu/gm <10 cfu/gm 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 product is considerable stable up to shelf life.

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

b) Estudio de estabilidad a tiempo real:

NEEL-NAYAN PHARMA PVT. LTD.

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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	**Mfg. Date**	: 11/2016
Batch No	: T07000216	**Expiry Date**	: 10/2018
Batch Size	: 100,000 Tablets.	**Stability Condition**	: $30^{0}\pm2^{0}$ C; 65%± 5%RH.
Date of Initiation	: 28/11/2016	**Pack Size**	: 3 x 10 Tablets.
Date of Completion	: 28/11/2017	**Pack style**	: PVC-Alu Blister
		Page No	: 1 of 2

Sr. No	Tests	Specification	Initial 28/11/2016	3 Months 28/02/2017	6 Months 29/05/2017	9 Months 28/08/2017	12 Months 28/11/2017	18 Months 28/05/2018	24 Months 28/11/2018
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*		
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 94.8 % Max- 98.6 % Mean- 96.5%	Min- 94.2 % Max- 98.5 % Mean- 96.2%	Min- 93.5% Max- 97.9% Mean- 95.8%	Min- 93.3% Max- 97.6% Mean- 95.2%	Min- 92.5% Max- 97.1% Mean- 94.3%		
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.47%	99.22%	99.15%	99.04%	98.87%		

	Prepared By	Checked By	Approved By
Signature			
Date	28/11/2017	29/11/2017	01/12/2017
Designation	**Sr. Officer QC**	**Executive QC**	**Head QA/QC**

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Real Time Stability Summary Data

Name of Products	**: Escitalopram Tablets USP 10 mg**	**Mfg. Date**	**: 11/2016**
Batch No	**: T07000216**	**Expiry Date**	**: 10/2018**
Batch Size	**: 100,000 Tablets.**	**Stability Condition**	**: $30^0 \pm 2^0$ C; 65%± 5%RH.**
Date of Initiation	**: 28/11/2016**	**Pack Size**	**: 3 x 10 Tablets.**
Date of Completion	**: 28/11/2017**	**Pack style**	**: PVC-Alu Blister**
		Page No	**: 2 of 2**

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

* 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.

	Prepared By	Checked By	Approved By
Signature			
Date	28/11/2017	29/11/2017	01/12/2017
Designation	**Sr. Officer QC**	**Executive QC**	**Head QA/QC**

NEEL-NAYAN PHARMA PVT. LTD.

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POSTAL ADDRESS : P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

Name of Products	: **Escitalopram Tablets USP 10 mg**	**Mfg. Date**	: **11/2016**
Batch No	: **T07000316**	**Expiry Date**	: **10/2018**
Batch Size	: **100,000 Tablets.**	**Stability Condition**	: **$30^0 \pm 2^0$ C; 65%± 5%RH.**
Date of Initiation	: **28/11/2016**	**Pack Size**	: **3 x 10 Tablets.**
Date of Completion	: **28/11/2017**	**Pack style**	: **PVC-Alu Blister**
		Page No	: **1 of 2**

Sr. No	Tests	Specification	Initial 28/11/2016	3 Months 28/02/2017	6 Months 29/05/2017	9 Months 28/08/2017	12 Months 28/11/2017	18 Months 28/05/2018	24 Months 28/11/2018
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*		
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 93.6 % Max- 97.2 % Mean- 95.9%	Min- 93.8 % Max- 97.4 % Mean- 95.6%	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%		
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.87%	99.72%	99.58%	99.26%	98.92%		

	Prepared By	Checked By	Approved By
Signature			
Date	28/11/2017	29/11/2017	01/12/2017
Designation	**Sr. Officer QC**	**Executive QC**	**Head QA/QC**

NEEL-NAYAN PHARMA PVT. LTD.
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POSTAL ADDRESS : P.O. BOX 18, GANDEVI-396 360. INDIA.

Real Time Stability Summary Data

Name of Products	**: Escitalopram Tablets USP 10 mg**				**Mfg. Date**	**: 11/2016**				
Batch No	**: T07000316**				**Expiry Date**	**: 10/2018**				
Batch Size	**: 100,000 Tablets.**				**Stability Condition**	**: $30^0 \pm 2^0$ C; 65%± 5%RH.**				
Date of Initiation	**: 28/11/2016**				**Pack Size**	**: 3 x 10 Tablets.**				
Date of Completion	**: 28/11/2017**				**Pack style**	**: PVC-Alu Blister**				
					Page No	**: 2 of 2**				
05	Related Substances (By HPLC)									
	a) Citalopram related compound A[a]	Not more than 0.3 %	0.04%	0.04%	0.05%	0.05%	0.05%	0.06%		
	b) Citalopram related compound B[b]	Not more than 0.5 %	0.18%	0.19%	0.20%	0.20%	0.21%	0.21%		
	c) Citalopram related compound C	Not more than 0.5%	0.20%	0.20%	0.21%	0.22%	0.23%			
	d) Citalopram related compound E[c]	Not more than 0.2 %	0.10%	0.11%	0.12%	0.13%	0.13%			
	e) Any other individual, unspecified impurity	Not more than 0.20%	0.08%	0.09%	0.10%	0.11%	0.12%			
	f) Total Impurities	Not more than 2.0 %	0.62%	0.65%	0.70%	0.72%	0.76%			
06	Microbial Limit Test									
	a) Total aerobic microbial count	Not more than 1000 cfu/g	75 cfu/gm	-	-	-	-			
	b)Total combined Yeast and Molds count	Not more than 100 cfu/g	<10 cfu/gm	-	-	-	-			
	c) Pathogens	Absent	Absent	-	-	-	-			

* 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.

	Prepared By	Checked By	Approved By
Signature			
Date	28/11/2017	29/11/2017	01/12/2017
Designation	**Sr. Officer QC**	**Executive QC**	**Head QA/QC**

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.

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Sr. No	Tests	Specification	Initial 28/11/2016	3 Months 28/02/2017	6 Months 29/05/2017	9 Months 28/08/2017	12 Months 28/11/2017	18 Months 28/05/2018	24 Months 28/11/2018
01	Description	White colored, round shaped, biconvex, film coated tablet, embossed with "11" on one side and plain on other side.	*	*	*	*	*		
02	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 ($C_{20}H_{21}FN_2O$) is dissolved in 30 minutes.	Min- 94.2 % Max- 98.2% Mean-96.9%	Min- 94.7 % Max- 98.6 % Mean- 96.4%	Min- 94.2% Max- 98.9% Mean- 96.1%	Min- 93.2% Max- 97.6% Mean- 95.8%	Min- 92.8% Max- 97.9% Mean- 95.1%		
04	Assay (By HPLC)	Not less than 90.0% and Not more than 110.0% of the labeled amount of Escitalopram ($C_{20}H_{21}FN_2O$).	99.18 %	99.04%	98.89%	98.77%	98.52%		

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					Page No	**: 2 of 2**				
05	Related Substances (By HPLC)									
	a) Citalopram related compound A*	Not more than 0.3 %	0.03%	0.04%	0.04%	0.05%	0.06%			
	b) Citalopram related compound B[b]	Not more than 0.5 %	0.20%	0.20%	0.21%	0.22%	0.23%			
	c) Citalopram related compound C	Not more than 0.5%	0.18%	0.19%	0.20%	0.21%	0.21%			
	d) Citalopram related compound E[c]	Not more than 0.2 %	0.08%	0.09%	0.10%	0.11%	0.12%			
	e) Any other individual, unspecified impurity	Not more than 0.20%	0.07%	0.08%	0.09%	0.09%	0.10%			
	f) Total Impurities	Not more than 2.0 %	0.59%	0.62%	0.66%	0.68%	0.73%			
06	Microbial Limit Test									
	a) Total aerobic microbial count	Not more than 1000 cfu/g	65 cfu/gm	-	-	-	-			
	b)Total combined Yeast and Molds count	Not more than 100 cfu/g	<10 cfu/gm	-	-	-	-			
	c) Pathogens	Absent	Absent	-	-	-	-			

* 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.

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IV. DISCUSIÓN

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. CONCLUSIÓN

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°C ± 2°C y una humedad ambiental de 65% ± 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°C ± 2°C, protegido de la humedad y la luz.