OPKO Chile S.A.

ESTUDIO DE ESTABILIDAD

LACTULOSA SOLUCIÓN ORAL 66,7%

Subdepartamento Registros y Autorizaciones Sanitarias

I. PROTOCOLO

Se llevaron a cabo estudios de estabilidad de Lactulosa solución 66,7%, fabricados por Sanpras Healthcare Private Limited, utilizando materia prima suministrada por Cepham Milk Specialities Ltd; en tiempo real, durante 24 meses y acelerado, durante 06 meses; para tres lotes consecutivos y un lote anual.

A continuación, los lotes a analizar:

Número de lote	Fecha de manufactura	Tamaño de lote
SH191604	12- 2016	1000 L
SH191605	12- 2016	1000 L
SH191606	12- 2016	1000 L

1. Condiciones y fecha de inicio – culminación del estudio de estabilidad

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 % HR	75 % ± 5 % HR
Fecha de Inicio del estudio	10 Junio 2015	10 Junio 2015
Fecha de culminación	14 Diciembre 2015	13 Junio 2017

2. Tipo de envase

Estuche de cartón conteniendo un frasco PET ámbar rotulado con tapa HDPE, más folleto de información al paciente, todo debidamente rotulado y sellado.

3. Análisis realizados y frecuencia de testeo:

a. Estudio acelerado

Parámetros medidos	Inicial	3 meses	6 meses
Descripción	√	√	√
Identificación			
Densidad	√	√	√
pH	√	√	√
Volumen de llenado	√	√	√
Sustancias Relacionadas	√	√	√
Valoración	√	√	√
Recuento microbiano	√	√	√

b. Estudio a tiempo real

Parámetros medidos	Inicial	3 M	6 M	9 M	12 M	18 M	24 M
Descripción	√	√	√	√	√	√	√
Identificación	√	√	√	√	√	√	√
Densidad	√	√	√	√	√	√	√
pH	√	√	√	√	√	√	√
Volumen de llenado	√	√	√	√	√	√	√
Sustancias Relacionadas	√	√	√	√	√	√	√
Valoración	√	√	√	√	√	√	√
Recuento microbiano	√	√	√	√	√	√	√

NOTA: √ = Parámetro medido.

Cabe destacar que la metodología utilizada para la medición de los diferentes parámetros en el estudio de estabilidad del producto LACTULOSA SOLUCIÓN ORAL 66,7% es la misma declarada en la metodología original para el análisis del producto terminado.

4. Especificaciones del producto terminado para estabilidad (Vida útil)

ANÁLISIS	ESPECIFICACIONES	MÉTODO
Descripción	Solución viscosa, pasando de incolora a café-amarillo claro	Inspección Visual
Identificación	Tiempo de retención muestra y estándar similares	HPLC
Peso Específico	1.30 – 1.40 mg/mL	Picnómetro
Volumen de llenado	No menos de 200 mL	Volumétrico
pH	2,5 – 6,5	PH metro
Valoración	90,0 % - 110,0 % de lo declarado	HPLC
Sustancias Relacionadas*	a.- Fructosa: No más de 1% b.- Galactosa: No más de 16% c.- Epilactosa: No más de 8% d.- Lactosa: No más de 12% e.- Tagatosa: Nomas de 4%	HPLC
Control microbiológico	Recuento aerobios mesófilos: < 100 ufc/mL Recuento hongos y levadura: < 10 ufc/mL Escherichia coli: Ausente Salmonella spp: Ausente	USP <62> USP <61>

II. FÓRMULA CUALI-CUANTITATIVA

Cada 100 mL contiene:

INGREDIENTES/EXCIPIENTES	CANTIDAD (g)
Lactulosa (como lactulosa concentrada al 70%)*	66,7
Sabor Fanta Naranja ***	0,46
Agua Purificada**	c.s.p

*La cantidad de lactulosa es calculada sobre lactulosa concentrada al 70%. El valor podria ser recalculado basado sobre la potencia actual de la maeria prima del proveedor.
**La cantidad de diluyente podria tambien ser cambiada para mantener la cantidad final de la solución de lactulosa al 66,7%, basado sobre el cambio de la potencia de lactulosa concentrada.
***Composición del sabor Fanta Naranja: Propilenglicol, agente saborizante.

Sanpras Healthcare Pvt. Ltd.

QUALITATIVE QUANTITATIVE COMPOSITION

LACTULOSE ORAL SOLUTION 66,7%

Each 100 mL of oral solution contains:

Ingredient	Quantity	Specification	Function
Lactulose (as Lactulose Concentrate at 70%)	66,70 g	USP	Active
Flavour Orange Fanta***	0.46 g	IHS	Flavouringagent
Purified Water**	c.s.	BP	Diluent .

*The amount of Lactulose is calculated on Lactulose concentrated at 70%. The value could be recalculated based on the actual potency of the supplier's raw material.
**The amount of diluent could also be changed to maintain the final amount of the Lactulose solution at 66.7%., based on the change in the potency of concentrated Lactulose
***Fanta Orange flavor composition: Propylene glycol, flavoring agent

Prepared By:

Checked By:

SANPRAS HEALTHCARE PVT LTD SINNAR

III. RESULTADOS

a. Estudio de estabilidad acelerado

SH191604

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Accelerated time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191604
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	12.12.2016	**Final Analysis Date:**	12.06.2017
Batch size:	1000 liters	**Storage Condition:**	Temperature: 40^0C± 5^0C ,relative humidity: 75 %± 5%

Results:

Test Month and date / Test Items	Initial	3 months	6 months
	12.12.16	14.03.17	13.06.17
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies
pH(2.5 to 6.5)	5.35	5.46	5.58
Weight per ml(1.30 to 1.40 gm/ ml)	1.3240	1.3246	1.3255
Assay-Lactulose concentrate USP Each 5 ml contains Lactulose concentrate 3.35 gm	103.26% (3.459/5ml)	101.03% (3.384/5ml)	99.06% (3.318/5ml)

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Related Substance: Fructose(NMT 1%)	0.1452 %	0.1588%	0.1626%
Tagatose(NMT 4%)	1.2665%	1.2547%	1.6589%
Galactose(NMT 16%)	2.1451 %	2.8864%	2.6588%
Epilactose(NMT 8%)	1.3258 %	1.3144%	1.1626%
Lactose(NMT 12%)	3.1456 %	3.2488%	3.1451%
Filled Volume :(NLT 200.0ml)	200.5	201.4	201.5
Total aerobic microbial count	20 cfu/ml	25 cfu/ml	25cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli *Salmonella sp*	Absent Absent	Absent Absent	Absent Absent

Conclusion: The accelerated time Stability study of Lactulose solution USP, **Batch No SH191604,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 18/06/2017

Checked by: 18/06/2017

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SH191605

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Accelerated time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191605
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	13.12.2016	**Final Analysis Date:**	13.06.2017
Batch size:	1000 liters	**Storage Condition:**	Temperature: 40°C± 5°C ,relative humidity: 75 %± 5%

Results:

Test-Month and date / **Test Items**	Initial	3 months	6 months
	13.12.16	15.03.17	14.06.17
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies
pH(2.5 to 6.5)	5.36	5.40	5.51
Weight per ml(1.30 to 1.40 gm/ ml)	1.3212	1.3245	1.3250
Assay-Lactulose concentrate USP Each 5 ml contains Lactulose concentrate 3.35 gm	105.12% (3.521/5ml)	101.14% (3.388/5ml)	100.26% (3.358/5ml)

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Related Substance: Fructose(NMT 1%)	0.2618 %	0.2612%	0.2755%
Tagatose(NMT 4%)	1.3658%	1.5478%	1.6987%
Galactose(NMT 16%)	4.1561 %	3.5588%	3.6869%
Epilactose(NMT 8%)	1.2212 %	1.9765%	1.8861%
Lactose(NMT 12%)	3.2657 %	3.2618%	3.7501%
Filled Volume :(NLT 200.0ml)	201.4	200.9	200.8
Total aerobic microbial count	10 cfu/ml	15 cfu/ml	15 cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli	Absent	Absent	Absent
Salmonella sp	Absent	Absent	Absent

Conclusion: The accelerated time Stability study of Lactulose solution USP, **Batch No SH191605,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 20/06/2017

Checked by: 20/06/2017

SH191606

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Accelarated time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191606
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	14.12.2016	**Final Analysis Date:**	14.06.2017
Batch size:	1000 liters	**Storage Condition:**	Temperature: 40°C± 5°C ,relative humidity: 75 %± 5%

Results:

Test Month and date / **Test Items**	Initial	3 months	6 months
	14.12.16	16.03.17	15.06.17
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies
pH(2.5 to 6.5)	5.40	5.45	5.58
Weight per ml(1.30 to 1.40 gm/ ml)	1.3237	1.3238	1.3249
Assay-Lactulose concentrate USP Each 5 ml contains Lactulose concentrate 3.35 gm	102.28% (3.426/5ml)	101.14% (3.388/5ml)	100.44% (3.364/5ml)

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Related Substance: Fructose(NMT 1%)	0.2218 %	0.1857%	0.2651%
Tagatose(NMT 4%)	1.6564%	1.5478%	1.6987%
Galactose(NMT 16%)	4.5568 %	4.3751%	4.8867%
Epilactose(NMT 8%)	1.3757 %	1.6755%	1.5169%
Lactose(NMT 12%)	3.8874 %	3.3148%	3.6987%
Filled Volume :(NLT 200.0ml)	201.4	202.1	200.6
Total aerobic microbial count	10 cfu/ml	10 cfu/ml	20cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli *Salmonella sp*	Absent Absent	Absent Absent	Absent Absent

Conclusion: The accelerated time Stability study of Lactulose solution USP, **Batch No SH191606,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 21/06/2017

Checked by: 21/06/2017

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b. Estudio de estabilidad tiempo real

SH191604

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Real time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191604
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	12.12.2016	**Final Analysis Date:**	12.12.2018
Batch size:	1000 liters	**Storage Condition:**	Temperature: 30°C± 5°C ,relative humidity: 75 %± 5%

Results:

Test Month and date / Test Items	Initial	3 months	6 months	9 months	12 months	18 Months	24 Months
	12.12.16	14.03.17	13.06.17	15.09.17	16.12.17	18.06.18	12.12.2018
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH(2.5 to 6.5)	5.35	5.38	5.40	5.44	5.48	5.50	5.52
Weight per ml(1.30 to 1.40 gm/ ml)	1.3240	1.3244	1.3258	1.3265	1.3267	1.3275	1.3334

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Estudio de estabilidad

SANPRAS HEALTHCARE PVT.LTD.
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Assay- Each 5 ml contains Lactulose 3.35 gm	103.26% (3.459/5ml)	102.78% (3.504/5ml)	102.55% (3.443/5ml)	101.44% (3.398/5ml)	100.02% (3.350/5ml)	99.40% (3.330/5ml)	98.03% (3.284/5ml)
Related Substance: Fructose(NMT 1%)	0.1452 %	0.1628%	0.1217%	0.1519%	0.1218%	0.1245%	0.1157%
Tagatose(NMT 4%)	1.2561%	1.4589%	1.2664%	1.2646%	1.2565%	1.2358%	1.2566%
Galactose(NMT 16%)	2.1451 %	3.1047%	3.2145%	2.2122%	2.0874%	2.1765%	2.1856%
Epilactose(NMT 8%)	1.3258 %	1.2856%	1.1555%	1.1417%	1.1354%	1.1658%	1.1987%
Lactose(NMT 12%)	3.1456 %	3.2589%	3.2569%	3.2145%	3.1456%	3.1514%	3.570%
Filled Volume :(NLT 200.0ml)	201.2	201.4	200.8	201.2	201.8	201.6	201.4
Total aerobic microbial count	20 cfu/ml	20 cfu/ml	25cfu/ml	25cfu/ml	30cfu/ml	30cfu/ml	30cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli *Salmonella sp*	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent

Conclusion: The real time Stability study of Lactulose solution USP, **Batch No SH191604,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 18/12/2018.

Checked by: 18/12/2018

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SH191605

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Real time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191605
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	13.12.2016	**Final Analysis Date:**	13.12.2018
Batch size:	1000 liters	**Storage Condition:**	Temperature: 30°C± 5°C ,relative humidity: 75 %+ 5%

Results:

Test Month and date / Test Items	Initial	3 months	6 months	9 months	12 months	18 Months	24months
	13.12.16	15.03.17	14.06.17	16.09.17	17.12.17	19.06.18	13.12.2018
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH (2.5 to 6.5)	5.36	5.45	5.55	5.57	5.65	5.70	5.84
Weight per ml(1.30 to 1.40 gm/ ml)	1.3212	1.3219	1.3225	1.3235	1.3248	1.3251	1.3268

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Assay- Each 5 ml contains Lactulose 3.35 gm	105.12% (3.521/5ml)	104.68% (3.506/5ml)	103.14% (3.455/5ml)	102.11% (3.420/5ml)	101.48% (3.399/5ml)	100.69% (3.373/5ml)	99.04% (3.317/5ml)
Related Substance: Fructose(NMT 1%)	0.2618 %	0.2217%	0.2571%	0.2179%	0.2214%	0.2781%	0.2564%
Tagatose(NMT 4%)	1.3256%	1.2145%	1.5698%	1.2654%	1.2565%	1.2869%	1.2940%
Galactose(NMT 16%)	4.1561 %	3.8181%	3.1722%	3.3737%	3.3687%	3.3985%	3.4041%
Epilactose(NMT 8%)	1.2212 %	1.5754%	1.5698%	1.1245%	1.1248%	1.1563%	1.1718%
Lactose(NMT 12%)	3.2657 %	3.1245%	3.4578%	3.1258%	3.1458%	3.1678%	3.1621%
Filled Volume(NLT 200.0ml)	202.0	201.8	201.6	200.5	200.2	200.6	201.1
Total aerobic microbial count	10 cfu/ml	15 cfu/ml	15 cfu/ml	15 cfu/ml	15 cfu/ml	15 cfu/ml	20 cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli *Salmonella sp*	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent

Conclusion: The real time Stability study of Lactulose solution USP, **Batch No SH191605,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 19/12/2018

Checked by: 19/12/2018

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SH191606

SANPRAS HEALTHCARE PVT.LTD.
81, S.T.I.C.E, Musalgaon, Tal. Sinnar, Dist.Nashik-422112

Real time stability study

Product:	LACTULOSE SOLUTION USP	**Batch No:**	SH191606
Manufacturer:	SANPRAS HEALTHCARE Pvt. Ltd.	**Packaging:**	200 ML
Initial Analysis Date:	14.12.2016	**Final Analysis Date:**	14.12.2018
Batch size:	1000 liters	**Storage Condition:**	Temperature: 30°C± 5°C ,relative humidity: 75 %± 5%

Results:

Test Month and date / **Test Items**	Initial	3 months	6 months	9 months	12 months	18 months	24 months
	14.12.16	16.03.17	15.06.17	17.09.17	18.12.17	20.06.18	14.12.2018
Description A colorless or pale brownish yellow clear or not more than slightly opalescent viscous solution	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification A. The retention time of major peak in the chromatogram of the assay preparation is correspond to that in the chromatogram of standard preparation, as obtained in the assay B.A red precipitate of cuprous oxide is formed.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
pH(2.5 to 6.5)	5.40	5.41	5.45	5.48	5.65	5.72	5.85
Weight per ml(1.30 to 1.40 gm/ ml)	1.3237	1.3245	1.3249	1.3255	1.3258	1.3658	1.3768

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Estudio de estabilidad

SANPRAS HEALTHCARE PVT.LTD.
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Assay- Each 5 ml contains Lactulose 3.35 gm	102.28% (3.426/5ml)	102.11% (3.420/5ml)	101.87% (3.412/5ml)	101.15% (3.388/5ml)	101.03% (3.384/5ml)	99.52% (3.333/5ml)	98.40% (3.296/5ml)
Related Substance: Fructose(NMT 1%)	0.2218 %	0.2225%	0.2737%	0.2518%	0.2547%	0.2689%	0.2765%
Tagatose(NMT 4%)	1.21654%	1.4587%	1.3256%	1.2541%	1.2658%	1.6987%	1.7284%
Galactose(NMT 16%)	4.3120 %	4.1245%	4.5897%	4.1256%	4.1456%	4.189%	4.2215%
Epilactose(NMT 8%)	1.3757 %	1.1246%	1.8867%	1.3751%	1.3256%	1.3698%	1.3791%
Lactose(NMT 12%)	3.8874 %	3.5546%	3.5795%	3.5868%	3.4587%	3.4987	3.652%
Filled Volume(NLT 200.0ml)	201.5	201.6	200.7	201.4	201.3	202.3	201.5
Total aerobic microbial count	10 cfu/ml	10 cfu/ml	10cfu/ml	20cfu/ml	20cfu/ml	20cfu/ml	25cfu/ml
Total yeast and mold count	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml	< 10 cfu/ml
Escherichia coli *Salmonella sp*	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent

Conclusion: The real time Stability study of Lactulose solution USP, **Batch No SH191606,** is completed and results found satisfactory when kept under recommended storage conditions.

Prepared by: 20/12/2018

Checked by: 20/12/2018

SANPRAS HEALTHCARE PVT LTD. SINNAR

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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 SH191604, SH191605, y SH191606 se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase utilizado (Estuche de cartón conteniendo un frasco PET ámbar rotulado con tapa HDPE, más folleto de información al paciente, todo debidamente rotulado y sellado), no se evidencia una disminución significativa en la valoración del activo, y los parámetros analizados se mantuvieron dentro de los límites especificados, durante 24 meses en el estudio a tiempo real y durante 6 meses en el estudio acelerado.

V. CONCLUSIÓN

Basado en los datos de los estudios de estabilidad a tiempo real y acelerado, se concluye 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 75% ± 5%.

VI. ESPECIFICACIÓN DE LA VIDA ÚTIL

Se propone un periodo de eficacia para LACTULOSA SOLUCIÓN ORAL 66,7% de 24 meses a partir de su fecha de fabricación almacenándolo en su envase original (Estuche de cartón conteniendo un frasco PET ámbar rotulado con tapa HDPE, más folleto de información al paciente, todo debidamente rotulado y sellado) cerrado, a una temperatura ambiente no mayor a 30°C ± 2°C, protegido de la humedad y la luz