OPKO CHILE S.A.

ESTUDIO DE ESTABILIDAD

DOLERTAB CÁPSULAS 200 MG

DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

PROTOCOLO DE ESTABILIDAD

1. INTRODUCCION

Con el fin de estudiar la estabilidad de CELECOXIB CÁPSULAS 200 mg, fue realizado el siguiente estudio, de acuerdo con los requerimientos de la OMS, a través de un estudio de estabilidad acelerado y un estudio de estabilidad a largo plazo de 24 meses.

Esto se requiere para proveer evidencia de como la calidad del producto terminado varía en el tiempo bajo la influencia de factores ambientales tales como temperatura y humedad y también permitir recomendar una condición de almacenamiento y establecer un periodo de eficacia.

2. ALCANCE

Este protocolo brinda detalles sobre la generación de datos de estabilidad en el material de envase primario para DOLERTAB CÁPSULAS 200 mg, tres lotes comerciales fabricados en BAROQUE PHARMACEUTICALS PVT. LTD. Este protocolo se ha preparado con la marca comercial del producto y es aplicable a todas las marcas comerciales y así como el nombre genérico de los productos que tengan la misma fórmula y material de envase.

Nombre y país del Fabricante del Producto Terminado:
SHARON BIO-MEDICINE LIMITED
Add: Selaqui Industrial Area Dehradun Uttarakhand 248001, India.

Nombre y país del Fabricante del Principio Activo:
AARTI DRUGS LTD.
Add: Plot. No. W-60(B) W-61 (B) W-62(B) W-71 (B) W-72 (B) W-73(B), MIDC, TARAPUR, DIST THANE 401506 MAHARASHTRA STATE, INDIA.

Nombre y país de la planta que realiza el Estudio de Estabilidad:
SHARON BIO-MEDICINE LIMITED
Add: Selaqui Industrial Area Dehradun Uttarakhand 248001, India.

DOLERTAB CÁPSULAS 200 MG
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CONDICIONES DEL ESTUDIO DE ESTABILIDAD

Tabla 1: Detalle de los lotes:

Lote N°	Fecha de Fabricación	Tamaño de Lote	Tiempo de Estudio	
			Inicio	Final
AEC5001A	Mayo 2015	110.000 Cápsulas	01/jun/2015	01/dic./2017
AEC5002A	Mayo 2015	110.000 Cápsulas	01/jun/2015	01/dic./2017
AEC5003B	Mayo 2015	110.000 Cápsulas	01/jun/2015	01/dic./2017

Tabla 2: Detalle del material de Envase Primario

Lote N°	Tipo de Envase
AEC5001A AEC5002A AEC5003B	blíster de PVC-PVDC incoloro/Aluminio impreso

Diseño de estabilidad:

El diseño del estudio de estabilidad de DOLERTAB CÁPSULAS 200 mg se ha planeado de la siguiente forma:

Tabla 3:

Condiciones	Temperatura	Humedad Relativa
Condición 1: Acelerada	40°C ± 2°C	75% ± 5% HR
Condición 2: Largo plazo	30°C ± 2°C	65% ± 5% HR

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Tabla 4:

N°	Condiciones (meses)	0	3	6	9	12	18	24
1	**Acelerada** 40°C ± 2°C/75% + 5% HR	X	X	X	NA	NA	NA	NA
2	**Largo Plazo** 30°C ± 2°C/65% ± 5% HR	X	X	X	X	X	X	X

DOLERTAB CÁPSULAS 200 MG

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Tabla 5: Se detallan las especificaciones del producto terminado a continuación:

ANÁLISIS	ESPECIFICACIONES	MÉTODO
DESCRIPCIÓN	Cápsula dura N° 2 de gelatina con tapa color rojo oscuro y cuerpo color blanco que contiene polvo color blanco.	Inspección visual
IDENTIFICACIÓN DE CELECOXIB (Por Valoración)	El tiempo de retención del peak principal del cromatograma de la preparación de la valoración debe corresponder al peak de la preparación estándar.	**Método In House** Técnica de Cuantificación HPLC
PESO PROMEDIO DE LAS CÁPSULAS LLENAS	333,0 mg ± 3,0% (323,01 mg – 342,99 mg)	Gravimétrico
PESO PROMEDIO DEL CONTENIDO DE LA CÁPSULA	270,0 mg ± 3,0% (261,90 mg – 278,10 mg)	Gravimétrico
DISOLUCIÓN (por UV)	No menos de 80% (Q) de la cantidad declarada de Celecoxib se disuelve en 60 minutos. Aparato: N°2 (paleta) Velocidad: 50 rpm Nivel I: (0,04 M fosfato trisódico dodecahidrato pH 12,0 con 1% Lauril Sulfato de Sodio 1%), No menos de 80% (Q) de la cantidad declarada de Celecoxib es disuelta en 60 minutos. Nivel II: Fluido gástrico simulado USP (incluidas pepsina), No menos de 80% (Q) de la cantidad declarada de Celecoxib es disuelta en 60 minutos. (Proceder para análisis Nivel II (S1, S2 & S3) solamente si el criterio para en nivel I no cumple	**Método In House** Técnica de Cuantificación UV
UNIFORMIDAD DE DOSIS POR VARIACIÓN DE PESO	AV ≤ L1 = 15,0	USP <905>

DOLERTAB CÁPSULAS 200 MG

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DEL CONTENIDO DE LA CÁPSULA		
SUSTANCIAS RELACIONADAS	Impureza A: no más de 0,2% Impureza desconocida mayor: no más de 0,2% Impurezas totales: no más de 1,5%	**Método In House** Técnica de cuantificación HPLC
VALORACIÓN DE CELECOXIB	Teórico: 200 mg CELECOXIB/ cápsula Límites: 190 – 210 mg CELECOXIB/ cápsula 95,0 – 105,0% de la cantidad declarada	**Método In House** Técnica de cuantificación HPLC
TIPO DE ENVASE	Estuche de cartulina que contiene envase blíster de PVC-PVDC incoloro/Aluminio impreso, más folleto de información al paciente, todo debidamente rotulado	Inspección visual

DOLERTAB CÁPSULAS 200 MG

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DECLARACION DE FÓRMULA CELECOXIB CÁPSULAS 200 MG

Cada Cápsula contiene:

INGREDIENTES	CANTIDAD (mg)
Celecoxib	200,0
Lactosa Monohidrato	43,15
Croscarmelosa Sódica	3,0
Povidona K-30	6,75
Lauril Sulfato de Sodio	8,10
Estearato de Magnesio	9,0

***COMPOSICIÓN DE LA CÁPSULA*:**

Composición de la tapa de color Rojo
Gelatina
Metilparabeno de Sodio
Propilparabeno de Sodio
Agua Purificada
Carmoisina
Amarillo Crepúsculo
Ponceau 4R
Dioxido de Titanio

Composición del cuerpo de color Blanco
Gelatina
Metilparabeno de Sodio
Propilparabeno de Sodio
Agua Purificada
Dioxido de Titanio

Materia prima utilizada y posteriormente eliminada durante el proceso de fabricación:
Agua Purificada

REPORTE DEL ESTUDIO DE ESTABILIDAD EN CONDICIONES ACELERADAS

DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

ACCELERATED STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remark
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be Recorded
Reference A.R. NO.			FP150568	SS151097	SS151164	SS151337	SS151952	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.5 % w/w	1.6 % w/w	1.5 % w/w	1.94 % w/w	1.62 % w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	89 – 99 %	88 – 92 %	92 – 98 %	93 – 99 %	95 – 98 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	98.9 %	100.3 %	99.6 %	99.8 %	100 .0 %	Complies
5.	Related substances (By HPLC) A) Impurity A	A) Not more than 0.2 %	0.09 %	0.08 %	0.08 %	0.08 %	0.08 %	Complies
	B) Highest unknown impurity	B) Not more than 0.2 %	0.02 %	0.01 %	0.02 %	0.02 %	0.02 %	
	C) Total impurity	C) Not more than 1.5 %	0.13 %	0.12 %	0.13 %	0.13 %	0.1 %	

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

ACCELERATED STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remarks
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be Recorded
Reference A.R. NO.			FP150568	SS151097	SS151164	SS151337	SS151952	
6.	** Total Viable aerobic count-Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa Staphylococcus aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	NA	NA	Absent	Complies
Sample withdrawn on :			NA	09/07/15	30/07/15	03/09/15	03/12/15	NA
Analysis completed on :			NA	09/08/15	17/08/15	16/09/15	12/12/15	NA
Remarks : Accelerated stability study of 06 month complies/~~Does not comply~~ as per specifications								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

ACCELERATED STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 , Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remark
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be Recorded
Reference A.R. NO.			FP150574	SS151096	SS151165	SS151336	SS151951	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.0 % w/w	1.9 % w/w	1.6 % w/w	1.9 % w/w	1.25 % w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of celecoxib is dissolved in 60 minutes.	96 – 101 %	87 – 92 %	93 – 98 %	90 – 97 %	93 – 95 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	101.9 %	100.1 %	99.2 %	99.4 %	99.4 %	Complies
5.	Related substances (By HPLC) A) Impurity A B) Highest unknown impurity C) Total impurity	A) Not more than 0.2 % B) Not more than 0.2 % C) Not more than 1.5 %	0.09 % 0.08 % 0.21 %	0.09 % 0.01 % 0.13 %	0.08 % 0.02 % 0.12 %	BDL 0.09 % 0.12 %	0.08 % 0.02 % 0.12 %	Complies

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

ACCELERATED STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 , Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remarks
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be Recorded
Reference A.R. NO.			FP150574	SS151096	SS151165	SS151336	SS151951	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa Staphylococcus aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	NA	NA	Absent	Complies
Sample withdrawn on :			NA	09/07/15	30/07/15	03/09/15	03/12/15	NA
Analysis completed on :			NA	09/08/15	17/08/15	16/09/15	12/12/15	NA
Remarks : Accelerated stability study of 06 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

ACCELERATED STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017,Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5003B
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remark
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be recorded
Reference A.R. NO.			FP150582	SS151023	SS151206	SS151330	SS151950	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.6 % w/w	1.8 % w/w	1.4 % w/w	1.8 % w/w	1.75% w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	97 – 100 %	88 – 93 %	92 – 99 %	91 – 99 %	93 – 95 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	97.7 %	100.1 %	99.5 %	99.7 %	99.5 %	Complies
5.	Related substances (By HPLC)							Complies
	A) Impurity A	A) Not more than 0.2 %	0.09 %	0.08 %	0.08 %	BDL	0.08%	
	B) Highest unknown impurity	B) Not more than 0.2 %	0.13 %	0.02 %	0.02 %	0.09 %	0.02%	
	C) Total impurity	C) Not more than 1.5 %	0.27 %	0.13 %	0.13 %	0.12 %	0.1 %	

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

ACCELERATED STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's
Protocol Reference : SS19017,Rev-00 Equipment I.D.: OQST 06 - 01

Batch No. : AEC5003B
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 40± 2°C/ 75± 5% RH

Sr. No.	Test	Specifications	Accelerated stability study results					Remarks
			Initial	Month				
				1 MONTHS	2 MONTHS	3 MONTHS	6 MONTHS	To be Recorded
Reference A.R. NO.			FP150582	SS151023	SS151206	SS151330	SS151950	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa Staphylococcus aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	NA	NA	Absent	Complies
Sample withdrawn on :			NA	02/07/15	06/08/15	03/09/15	03/12/15	NA
Analysis completed on :			NA	27/07/15	17/08/15	16/09/15	12/12/15	NA
Remarks : Accelerated stability study of 06 month ~~complies/Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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REPORTE DEL ESTUDIO DE ESTABILIDAD EN CONDICIONES A LARGO PLAZO

DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017,Rev -00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remark
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be recorded
Reference A.R. NO.			FP150568	SS151335	SS151955	SS160268	SS160858	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.5 % w/w	1.92 % w/w	1.62 % w/w	2.6 % w/w	2.2 % w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	89 – 99 %	90 – 97 %	93 – 96 %	96 – 100 %	95 – 99 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	98.9 %	100.0 %	101.0 %	98.9 %	99.53 %	Complies
5.	Related substances (By HPLC)							Complies
	A. Impurity A	A) Not more than 0.2 %	0.09 %	0.091%	0.08 %	0.03 %	ND	
	B. Highest unknown impurity	B) Not more than 0.2 %	0.02 %	0.012 %	0.02 %	0.05 %	0.02 %	
	C. Total impurity	C) Not more than 1.5 %	0.13 %	0.12 %	0.10 %	0.09 %	0.06 %	

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Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017,Rev -00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remarks
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be recorded
Reference A.R. NO.			FP150568	SS151335	SS151955	SS160268	SS160858	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa S. aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	NA	NA	Absent	Complies
Sample withdrawn on :			NA	03/09/15	03/12/15	25/02/16	02/06/16	NA
Analysis completed on :			NA	16/09/15	12/12/15	10/03/16	21/06/16	NA
Remarks : Long term stability study of 30 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

Compiled by	Checked by	Approved by
23/10/19	25/10/19	25/10/19
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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD
LONG TERM STABILITY SUMMARY REPORT

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017,Rev -00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remark
			Initial	Month				
				18 MONTHS	24 MONTHS	30 MONTHS		
Reference A.R. NO.			FP150568	SS161743	SS170838	SS171623		To be recorded
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies		Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.5 % w/w	1.5 % w/w	2.13 % w/w	2.12 % w/w		
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	89 – 99 %	96 – 103 %	93 – 101 %	94%,95%,98%, 97%,95%,95% Avg.- 96 %,		Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	98.9 %	99.27 %	99.16 %	99.53 %		Complies
5.	Related substances (By HPLC) A) Impurity A B) Highest unknown impurity C). Total impurity	 A) Not more than 0.2 % B) Not more than 0.2 % C) Not more than 1.5 %	 0.09 % 0.02 % 0.13 %	 ND 0.07 % 0.07 %	 ND 0.02 % 0.03 %	 ND 0.055 % 0.096 %		Complies

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's)
Protocol Reference : SS19017,Rev -00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5001A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remarks
			Initial	Month				
				18 MONTHS	24 MONTHS	30 MONTHS		
Reference A.R. NO.			FP150568	SS161743	SS170838	SS171623		To be recorded
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g		Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g		Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa S. aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	Absent	Absent		Complies
Sample withdrawn on :			NA	01/12/16	01/06/17	30/11/17		NA
Analysis completed on :			NA	09/12/16	19/06/17	09/12/17		NA
Remarks : Long term stability study of 30 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06-03

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remark
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be Recorded
Reference A.R. NO.			FP150574	SS151334	SS151951	SS160267	SS160859	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.0 % w/w	1.77 % w/w	1.25% w/w	2.4 % w/w	2.7% w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	96 – 101 %	93 – 102 %	93 – 95 %	97 – 100 %	95 – 98 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	101.9 %	99.9 %	99.4%	100.1 %	99.16 %	Complies
5.	Related substances (By HPLC) A. Impurity A B. Highest unknown impurity C. Total impurity	 A. Not more than 0.2 % B. Not more than 0.2 % C. Not more than 1.5 %	 0.09 % 0.08 % 0.21 %	 BDL 0.09 % 0.11 %	 0.08 % 0.02 % 0.1 %	 ND 0.04 % 0.04 %	 ND 0.04 % 0.12 %	Complies

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06-03

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No	Test	Specifications	Long term stability study results					Remarks
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be Recorded
Reference A.R. NO.			FP150574	SS151334	SS151951	SS160267	SS190859	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	Less than10cfu/g	NA	Less than10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	NA	Less than10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa S.aureus	Should be absent /10g Should be absent / g Should be absent / g Should be absent / g	Absent	NA	Absent	NA	Absent	Complies
Sample withdrawn on :			NA	03/09/15	03/12/15	25/02/16	02/06/16	NA
Analysis completed on :			NA	16/09/15	12/12/15	10/03/16	21/06/16	NA
Remarks : Long Term stability study of 30 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06-03

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remark
			Initial	Month				
				18 MONTHS	24 MONTHS	30 MONTHS		To be Recorded
Reference A.R. NO.			FP150574	SS161742	SS170839	SS171622		
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies		Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.0 % w/w	1.6 % w/w	2.10 % w/w	2.47 % w/w		Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	96 – 101 %	97 – 103 %	92 – 102 %	94 – 97 %		Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	101.9 %	100.23 %	99.0 %	101.62 %		Complies
5.	Related substances (By HPLC) A. Impurity A B. Highest unknown impurity C. Total impurity	 A. Not more than 0.2 % B. Not more than 0.2 % C. Not more than 1.5 %	 0.09 % 0.08 % 0.21 %	 ND 0.07 % 0.07 %	 ND 0.02 % 0.03 %	 ND 0.055 % 0.095 %		Complies

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac. Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017 ,Rev-00 Equipment I.D.: OQST 06-03

Batch No. : AEC5002A
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remarks
			Initial	Month				
				18 MONTHS	24 MONTHS	30 MONTHS		To be Recorded
Reference A.R. NO.			FP150574	SS161742	SS170839	SS171622		
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g		Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g		Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa S. aureus	Should be absent /10g Should be absent / g Should be absent / g Should be absent / g	Absent	NA	Absent	Absent		Complies
Sample withdrawn on :			NA	01/12/16	01/06/17	30/11/17		NA
Analysis completed on :			NA	09/12/16	20/06/17	09/12/17		NA
Remarks : Long Term stability study of 30 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017,Rev-00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5003B
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remark
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be recorded
Reference A.R. NO.			FP150582	SS151326	SS151953	SS160302	SS160865	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.6 % w/w	1.73% w/w	1.55% w/w	2.4 % w/w	2.4 % w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	97 – 100 %	89– 101 %	94– 95 %	96 – 100 %	96 – 100 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	97.7 %	99.0 %	100.1 %	98.5 %	99.14 %	Complies
5.	Related substances (By HPLC) A. Impurity A	A. Not more than 0.2 %	0.09 %	0.09%	0.08 %	0.03 %	ND	Complies
	B. Highest unknown impurity	B. Not more than 0.2 %	0.13 %	0.011 %	0.02 %	0.04 %	0.04%	
	C. Total impurity	C. Not more than 1.5 %	0.27 %	0.11 %	0.1 %	0.08 %	0.06%	

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.
Packing details : Blister Pack (3x10's
Protocol Reference : SS19017,Rev-00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5003B
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results					Remarks
			Initial	Month				
				3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	To be Recorded
Reference A.R. NO.			FP150582	SS151326	SS151953	SS160302	SS160865	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	NA	NA	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa Staphylococcus aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	NA	NA	Absent	Complies
Sample withdrawn on :			NA	03/09/15	03/12/15	03/03/16	02/06/16	NA
Analysis completed on :			NA	16/09/15	12/12/15	10/03/16	21/06/16	NA
Remarks : Long Term stability study of 30 month complies/~~Does not comply~~ as per specifications.								
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than								

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

Sharon Bio-Medicine Ltd

LONG TERM STABILITY SUMMARY REPORT

Product Name : Celecoxib Capsule 200 mg
Batch Size : 1.10 Lac.Capsules (0.151 Lac pack)
Label claim Each Hard gelatin Capsule contains
Celecoxib : 200 mg
Excipients : q.s.

Packing details : Blister Pack (3x10's
Protocol Reference : SS19017,Rev-00 Equipment I.D.: OQST 06 - 03

Batch No. : AEC5003B
Overages : Nil
Manufacturing Date : 05/2015
Expiry Date : 05/2017
Shelf Life : 24 Months
Stability Started on : 01/06/2015
Stability condition : 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results				Remark
			Initial	Month			
				18 MONTHS	24 MONTHS	30 MONTHS	To be recorded
Reference A.R. NO.			FP150582	SS161738	SS170837	SS171669	
1.	Description	Size "2" Hard Gelatine Capsule dark red cap and white body containing white coloured powder.	Complies	Complies	Complies	Complies	Complies
2.	Water content (By KF)	Not more than 5 % w/w	1.6 % w/w	1.5 % w/w	2.16 % w/w	1.73 % w/w	Complies
3.	Dissolution (By UV)	Not less than 80 % (Q) of labeled amount of Celecoxib is dissolved in 60 minutes.	97 – 100 %	95 – 102 %	92 – 103 %	97 - 103 %	Complies
4.	Assay (By HPLC)	Not less than 90.0 % and not more than 110.0 % of labeled amount of celecoxib.	97.7 %	102.18 %	99.28 %	100.3 %	Complies
5.	Related substances (By HPLC) A. Impurity A	A. Not more than 0.2 %	0.09 %	ND	ND	ND	Complies
	B. Highest unknown impurity	B. Not more than 0.2 %	0.13 %	0.06 %	0.02 %	0.055 %	
	C. Total impurity	C. Not more than 1.5 %	0.27 %	0.06 %	0.03 %	0.096 %	

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DOLERTAB CÁPSULAS 200 MG

ESTUDIO DE ESTABILIDAD

LONG TERM STABILITY SUMMARY REPORT

Sharon

Product Name	: Celecoxib Capsule 200 mg	**Batch No.**	: AEC5003B
Batch Size	: 1.10 Lac.Capsules (0.151 Lac pack)	**Overages**	: Nil
Label claim	Each Hard gelatin Capsule contains	**Manufacturing Date**	: 05/2015
	Celecoxib : 200 mg	**Expiry Date**	: 05/2017
	Excipients : q.s.	**Shelf Life**	: 24 Months
Packing details	: Blister Pack (3x10's	**Stability Started on**	: 01/06/2015
Protocol Reference	: SS19017,Rev-00 Equipment I.D.: OQST 06 - 03	**Stability condition**	: 30± 2°C/ 65± 5% RH

Sr. No.	Test	Specifications	Long term stability study results				Remarks
			Initial	Month			
				18 MONTHS	24 MONTHS	30 MONTHS	To be Recorded
Reference A.R. NO.			FP150582	SS161738	SS170837	SS171669	
6.	** Total Viable aerobic count- Bacteria	Not more than 10^3cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g	Complies
7.	**Total Viable aerobic Count-Yeast & mould	Not more than 10^2cfu/g	Less than 10cfu/g	NA	Less than 10cfu/g	Less than 10cfu/g	Complies
8.	** Salmonella Escherichia Coli P.Aeruginosa Staphylococcus aureus	Should be absent/10g Should be absent/ g Should be absent/ g Should be absent/ g	Absent	NA	Absent	Absent	Complies
Sample withdrawn on :			NA	01/12/16	01/06/17	07/12/17	NA
Analysis completed on :			NA	09/12/16	20/06/17	11/12/17	NA
Remarks : Long Term stability study of 30 month complies/~~Does not comply~~ as per specifications.							
ND: Not detected, NA: Not applicable, (**):Microbial tests are designated as to be optional in the Shelf life specification, NMT :Not more than, NLT: Not Less Than							

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DOLERTAB CÁPSULAS 200 MG
ESTUDIO DE ESTABILIDAD

EVALUACION Y ANALISIS DE LOS RESULTADOS

De acuerdo a los resultados obtenidos en el estudio de estabilidad Acelerado en condiciones de temperatura y humedad de 40ºC ± 2ºC Y 75% ± 5% H; y estudio de estabilidad a Tiempo real, en condiciones de 30°C ± 2°C y 65% ± 5% HR, para los Lotes AEC5001A, AEC5002A, AEC5003B; se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase estudiado. No se evidencia una disminución significativa en la valoración del activo y los parámetros analizados se mantuvieron dentro de los límites especificados.

CONCLUSIONES

Basado en los datos adquiridos de los estudios de estabilidad a tiempo real y acelerado, se concluye que el producto DOLERTAB CÁPSULAS 200 mg es estable bajo un estudio de estabilidad de 30 meses, almacenado en su envase original y a una temperatura no mayor a 30º C, protegido del calor, la humedad y la luz.

Se propone periodo de eficacia para DOLERTAB CÁPSULAS 200 MG de 24 meses con una condición de almacenamiento no mayor a 30°C, a partir de su fecha de fabricación.