OPKO CHILE S.A.

ESTUDIO DE ESTABILIDAD DEL PRODUCTO TERMINADO

ESOMEPRAZOL COMPRIMIDOS CON RECUBRIMIENTO ENTÉRICO 20 mg

ESTUDIO DE ESTABILIDAD

Objetivo:

Proveer y establecer evidencia documentada de la estabilidad del producto Esomeprazol comprimidos con recubrimiento entérico 20 mg, elaborado por Pell Tech Health Care Pvt Ltd.

Fórmula Cualicuantitativa de Esomeprazol comprimidos con recubrimiento entérico 20 mg:

Cada comprimido con recubrimiento entérico contiene:

Ingrediente	Función	Cantidad (mg)
Núcleo (comprimido no recubierto)		
Esomeprazol magnésico trihidrato (Equivalentes a 20 mg de Esomeprazol)	Principio Activo	22,30 mg + 5% exceso
Carbonato de Calcio	Diluyente/ Estabilizador	26,67
Óxido de Magnesio	Diluyente/ Estabilizador	19,91
Crospovidona	Desintegrante	5,00
Povidona (PVPK 30)	Aglutinante	3,00
Talco purificado	Fluidificante	3,00
Estearato de Magnesio	Lubricante	1,50
Recubrimiento sellado (comprimido recubierto sellado)		
Hidroxipropil metilcelulosa	Polímero	1,00 (1,10**)
Etilcelulosa	Polímero	0,266 (0,292**)
Talco purificado	Agente antiaglutinante	0,379 (0,417**)
Dióxido de titanio	Opacificador	0,355 (0,390**)
Recubrimiento entérico (comprimido con recubrimiento entérico)		
Instacoat EN-HPMCP (***)	Polímero entérico	8,00 (8,80**)
Total		**92,50 mg**

IH = In House**; BPv** = Farmacopea Británica vigente**; USPv=** Farmacopea de Estados unidos vigente

Alcohol isopropílico y Diclorometano son solventes utilizados y eliminados durante el proceso de manufactura, por lo tanto, no se encuentran en el producto terminado.

(**) 10% extra de material de recubrimiento entérico y sellado para compensar la pérdida durante el proceso de recubrimiento.

(***) Composición cuantitativa de Instacoat EN-HPMCP en %p/p:

- Hipromelosa Ftalato 77,50%
- Dietil Ftalato 10,00%
- Dióxido de Titanio 10,00%
- Óxido de Hierro rojo 2,50%

ESTABILIDAD ACELERADA

Condiciones del estudio:

Temperatura y Humedad Relativa	**:**	40ºC ± 2ºC y 75% ± 5% H.R.
Lotes analizados	**:**	7621001; 7621002 y 7621003
Fechas de Fabricación	**:**	Mayo 2010
Tipo y Tamaño de lotes	**:**	Lotes Piloto de 200.000 comprimidos
Tipo de material de envase	**:**	Blister Alu-Alu

Fabricante de API empleado en el Estudio:
Metrochem API Pvt. Ltd.
Dirección:
Plot No 62/C/6, Pipeline Road, Phase – I, IDA., Jeedimetla, Hyderabad – 500 055, Telangana, India**.**

Fabricante del producto terminado empleado en el Estudio:
Pell Tech Health Care Pvt Ltd.
Dirección:
Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-wada, Thane 421312 Maharashtra State, India.

Laboratorio que desarrolla el Estudio de Estabilidad:
Pell Tech Health Care Pvt Ltd.
Dirección:
Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-wada, Thane 421312 Maharashtra State, India.

Especificaciones, análisis realizados y frecuencia de testeo:

Tiempo(meses) →		Inicial 0	1	2	3	6
Test ↓	**Especificación ↓**					
Descripción	Comprimidos con recubrimiento entérico de color café, circulares y biconvexos	x	x	x	x	x
Peso promedio	92,50 mg ± 7,5%. (85,56 mg - 99,44 mg)	x	x	x	x	x
Tiempo de desintegración	a) 0,1N HCl por 2 horas no hay ningún fragmento. b) En buffer fosfato pH 6,8: No más de 45 minutos	x	x	x	x	x
Disolución	**Medio:** 900 ml de HCl 0,1 N por 2 horas. 900 ml de buffer fosfato pH 6,8 por 45 minutos **Aparato:** USP Tipo 2 (paleta); **Velocidad:** 100 rpm. **Temperatura:** 37°C ± 0,5 °C **Tiempo:** • 2 horas *(No más del 10% de la cantidad etiquetada liberada después de 2 horas en HCl 0,1 N)* • 45 minutos (No menos que el 75% (Q) liberada en buffer pH 6,8 en 45 minutos)	x	x	x	x	x
Impurezas Orgánicas	• Omeprazol Sulfona: No más de 0,5% • Cualquier otra impureza individual: No más de 0,2% • Impurezas totales: No más de 2%	x	x	x	x	x
Uniformidad de Unidad de Dosis (por contenido)	Entre 85% y 115%					
Valoración:	90% - 110% de la cantidad declarada (18,0 mg – 22,0 mg)	x	x	x	x	x

En donde se indica con una “equis”, significa que se hará (Hizo) la determinación analítica indicada.

ESTABILIDAD A TIEMPO REAL

Temperatura y Humedad Relativa	**:**	30ºC ± 2ºC y 65% ± 5% H.R.
Lotes analizados	**:**	7621001; 7621002 y 7621003
Fechas de Fabricación	**:**	Mayo 2010
Tipo y Tamaño de lotes	**:**	Lotes Piloto de 200.000 comprimidos
Tipo de material de envase	**:**	Blister Alu-Alu

Fabricante de API empleado en el Estudio:
Metrochem API Pvt. Ltd.
Dirección:
Plot No 62/C/6, Pipeline Road, Phase – I, IDA., Jeedimetla, Hyderabad – 500 055, Telangana, India**.**

Fabricante del producto terminado empleado en el Estudio:
Pell Tech Health Care Pvt Ltd.
Dirección:
Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-wada, Thane 421312 Maharashtra State, India.

Laboratorio que desarrolla el Estudio de Estabilidad:
Pell Tech Health Care Pvt Lda.
Dirección:
Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-wada, Thane 421312 Maharashtra State, India.

Especificaciones, análisis realizados y frecuencia de testeo:

Tiempo(meses) → / Tiempo (meses) →	Especificación ↓	Inicial 0	3	6	9	12	18	24	36
Test ↓	**Especificación ↓**								
Descripción	Comprimidos con recubrimiento entérico de color café, circulares y biconvexos	x	x	x	x	x	x	x	x
Peso promedio	92,50 mg ± 7,5%. (85,56 mg - 99,44 mg)	x	x	x	x	x	x	x	x
Tiempo de desintegración	c) 0,1N HCl por 2 horas no hay ningún fragmento. d) En buffer fosfato pH 6,8: No más de 45 minutos	x	x	x	x	x	x	x	x
Disolución	**Medio:** 900 ml de HCl 0,1 N por 2 horas. 900 ml de buffer fosfato pH 6,8 por 45 minutos **Aparato:** USP Tipo 2 (paleta); **Velocidad:** 100 rpm. **Temperatura:** 37°C ± 0,5 °C **Tiempo:** • 2 horas *(No más del 10% de la cantidad etiquetada liberada después de 2 horas en HCl 0,1 N)* • 45 minutos (No menos que el 75% (Q) liberada en buffer pH 6,8 en 45 minutos)	x	x	x	x	x	x	x	x
Impurezas Orgánicas	• Omeprazol Sulfona: No más de 0,5% • Cualquier otra impureza individual: No más de 0,2% • Impurezas totales: No más de 2%	x	x	x	x	x	x	x	x
Uniformidad de Unidad de Dosis (por contenido)	Entre 85% y 115%	x	x	x	x	x	x	x	x
Valoración:	90% - 110% de la cantidad declarada (18,0 mg – 22,0 mg)	x	x	x	x	x	x	x	x

En donde se indica con una “equis”, significa que se hará (Hizo) la determinación analítica indicada.

Método de análisis del Producto Terminado:

El método de análisis de producto terminado empleado en este Estudio de Estabilidad, responde a la metodología de producto terminado entregada en dossier de registro de este producto.

Evaluación y análisis de los resultados:

De acuerdo a los resultados obtenidos en el Estudio de Estabilidad Acelerado (40ºC ± 2ºC; 75 ± 5% HR) y en el Estudio de Estabilidad a Tiempo Real (30°C ± 2° C; 65% ± 5% HR) para los Lotes 7621001; 7621002 y 7621003, se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el material de envase utilizado. No se evidencia una disminución significativa en la valoración del activo y los parámetros analizados se mantuvieron dentro de los límites especificados.

Conclusiones:

Los resultados obtenidos nos permiten proponer para el producto Esomeprazol comprimidos con recubrimiento entérico 20 mg, un período de eficacia de 36 meses, almacenado en su envase original a una temperatura no mayor a 30ºC.

En las páginas siguientes se adjunta el Protocolo del Estudio de Estabilidad de origen y las tablas de resultados de los Estudios de Estabilidad realizados por el fabricante del producto a los Lotes 7621001; 7621002 y 7621003 en las condiciones de temperatura y humedad anteriormente señaladas.

Name of Dept: R & D	**STABILITY STUDY PROTOCOL FOR** ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg	
Issued on: 20/04/2010, Reprinted on:11/05/2016		
Revision No. :00		
Document No. : SSP/762/10/001		

OBJECTIVE: To provide and establish documented evidence for the stability study to be monitored, for the Development manufactured in Pelltech Healthcare Pvt. Ltd. in support of the proposed shelf life of the product.

Dosage Form: Tablets

Strength/Label Claim: **Each enteric coated tablet contains:**
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s.
Titanium Dioxide & Red Oxide

PURPOSE: DEVELOPMENT

RESPONSIBILITY: R & D DEPARMENT

PRODUCT DETAIL:

Batch No.	**7621001**	**7621002**	**7621003**	**Pack Profile**
Mfg. Date	May – 2010	May - 2010	May - 2010	10 Tablets packed in Alu-Alu Blister.
Exp. Date	April - 2013	April - 2013	April - 2013	
Batch size	200000 Tablets	200000 Tablets	200000 Tablets	
Analytical Report (T0) Initial	RDR/7621001/ 01/10	RDR/7621002 /01/10	RDR/7621003 /01/10	
Active Raw Material (API)	Esomeprazole Magnesium Trihydrate USP			

Name of Dept: R & D	**STABILITY STUDY PROTOCOL FOR** ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg	
Issued on: 20/04/2010, Reprinted on:11/05/2016		
Revision No. :00		
Document No. : SSP/762/10/001		

Qualitative & Quantitative Formula :

Sr. No.	Ingredients	Specification	Rationale	Label Claim (mg)	Over-ages (%)	Qty / Per Tablet (in mg)
	CORE TABLETS (Uncoated Tablets)					
1.	Esomeprazole mg trihydrate	USP	Active	22.3	5	23.42
	equivalent to Esomeprazole			20	-	-
2.	Calcium carbonate	BP	Diluent / Stabiliser	-	-	26.67
3.	Light Magnesium oxide	BP	Diluent / Stabiliser	-	-	19.91
4.	Cros Povidone	BP	Disintegrant	-	-	5.00
5.	Povidone (PVPK 30)	BP	Binder	-	-	3.00
6.	Purified Talc	BP	Glidant	-	-	3.00
7.	Magnesium Stearate	BP	Lubricant	-	-	1.5
8.	Isopropyl alcohol*	BP	Solvent	-	-	21.2
	SEAL COATING (Seal Coated Tablets)					
9.	Hydroxypropyl Methylcellulose E5	BP	Polymer	-	-	1.00 (1.10**)
10.	Ethyl cellulose N20	BP	Polymer	-	-	0.266 (0.292**)
11.	Purified Talc	BP	Anticacking agent	-	-	0.379 (0.417**)
12.	Titanium dioxide	BP	Opacifier	-	-	0.355 (0.390**)
13.	Isopropyl alcohol*	BP	Solvent	-	-	12.80 (14.08**)
14.	Dichloromethane*	BP	Solvent	-	-	31.92 (35.11**)
	ENTERIC COATING (Enteric Coated Tablets)					
15.	Instacoat EN-HPMC P @	IH	Enteric Polymer	-	-	8.0 (8.80**)
16.	Isopropyl alcohol*	BP	Solvent	-	-	51.20 (56.32**)
17.	Dichloromethane*	BP	Solvent	-	-	127.68 (140.44**)
	TOTAL					**92.50**

* Not present in final product.

** 10% Extra Seal & Enteric coating material taken to compensate process loss during coating.

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Qualitative and Quantitative Formula	
Instacoat EN-HPMC P	
Ingredients	Quantitative Composition (% w/w)
Hypromellose Phthalate	77.5%
Diethyl Phthalate	10.0%
Titanium Dioxide	10.0%
Red Iron Oxide	2.50%

Name of Dept: R & D	**STABILITY STUDY PROTOCOL FOR** ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg	
Issued on: 20/04/2010, Reprinted on:11/05/2016		
Revision No. :00		
Document No. : SSP/762/10/001		

METHOD OF ANALYSIS & SPECIFICATIONS :
Reference No. : FPS/FG762/01/14; SAP/FG762/01/14

TEST SET	
X1	All tests
X2	At client's request only
X3	Test 1,4,8,9,10,11,12 (Stability Review)

TIME INTERVAL & TESTS :

INTERVAL (Month)/ CONDITIONS	**0**	**1**	**2**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
30°C/ 65%RH	**X3**			**X3**	**X3**	**X3**	**X3**	**X3**	**X3**	**X3**
40°C/ 75%RH	**X3**	**X3**	**X3**	**X3**	**X3**					

REPORT :

All the documents such as Bill of Material, certificate of analysis, raw data, stability request, sample Request etc shall be kept with the report as raw data in Q.A. file.

The Tabulated results shall be reported for all Time Intervals in format as Annexure III

APPROVAL OF PROTOCOL : (For reprinting)

Prepared By	**Checked By**	**Approved By**
11/05/2016	11/5/16	11/05/2016
R&D Officer	R&D Manager	Q.A. Manager

TABLAS RESUMEN DE RESULTADOS

Pell Tech Health Care Pvt. Ltd.
Corp. Off.: 202, Sonmur Apts., Daruwala Compound, S.V. Road, Malad (W), Mumbai-400 064, INDIA.
Tele : 91-22 42935123 / 67525364, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 17.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/001	

ACCELERATED STABILITY STUDY REPORT

Product Name: Esomeprazole Enteric Coated Tablets 20mg

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH NUMBER: 7621001

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 **Exp. Date:** April-2013
Set Up Date :27.05.2010 **STUDY COMPLETION DATE:** 02.12.2010

BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 40°C± 2°C/75% ± 5 %RH

TEST	SPECIFICATION	Initial	1 months	2months	3 months	6 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	92.12mg	92.22mg	93.48mg	93.61mg	93.83mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b) 5 mins	a)No any fragments found b) 6mins	a)No any fragments found b) 7mins	a)No any fragments found b) 8 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 3.9 % 89.3%	 3.85 % 89.43%	 3.76 % 89.45%	 3.68% 89.49%	 3.22% 89.52%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.11% 0.04% 0.57%	0.12% 0.045% 0.58%	0.13% 0.049% 0.59%	0.14% 0.053% 0.61%	0.15% 0.058% 0.62%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	101.25%	101.18%	101.08%	101.01%	100.95%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	101.85%	101.64%	100.72%	100.21%	99.82%
Sample removal Date		12.05.2010	27.06.2010	27.07.2010	27.08.2010	27.11.2010
Sample Analysis Date		17.05.2010	02.07.2010	03.08.2010	02.09.2010	02.12.2010
AR NO		RDR/7621001/01/10	RDR/7621001/02/10	RDR/7621001/03/10	RDR/7621001/04/10	RDR/7621001/05/10
RDS NO		RDS/7621001/01/10	RDS/7621001/02/10	RDS/7621001/03/10	RDS/7621001/04/10	RDS/7621001/05/10

Remark : **The product is found to be stable for 6Months at 40°C± 2°C/75% ±5 %RH and hence the projected shelf life of 36 months can be given to the product**

NAME: K. Satyanarayan — SIGN & DATE: 27/5/2016 — SR & D.MANAGER

NAME: Shobha Rao — SIGN & DATE: 27/05/2016 — Q.C.MANAGER

NAME: Vikas Bhopale — SIGN & DATE: 31/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Tele : 91-22 42935123 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 17.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/001	

LONG TERM STABILITY STUDY REPORT

Product Name: Esomeprazole Enteric Coated Tablets 20mg

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH NUMBER: 7621001

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 **Exp. Date:** April-2013
Set Up Date :27.05.2010 **STUDY COMPLETION DATE:** 03.06.2013

BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%

TEST	SPECIFICATION	Initial	3 months	6 months	9 months	12 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	92.12mg	93.38mg	93.72mg	94.11mg	94.48mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b) 6 mins	a)No any fragments found b) 7 mins	a)No any fragments found b) 8 mins	a)No any fragments found b) 7 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	3.9 % 89.3%	3.89 % 89.43%	3.87 % 89.49%	3.85 % 89.53%	3.82% 89.60%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.10% 0.038% 0.55%	0.12% 0.041% 0.56%	0.13% 0.044% 0.57%	0.14% 0.046% 0.58%	0.15% 0.051% 0.59%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	101.25%	101.16%	101.08%	100.95%	100.85%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	101.85%	101.64%	101.42%	101.24%	100.72%
Sample removal Date		12.05.2010	27.08.2010	27.11.2010	27.02.2011	27.05.2011
Sample Analysis Date		17.05.2010	03.09.2010	03.12.2010	03.03.2011	04.06.2011
AR NO		RDR/7621001/01/10	RDR/7621001/06/10	RDR/7621001/07/10	RDR/7621001/08/11	RDR/7621001/09/11
RDS NO		RDS/7621001/01/10	RDS/7621001/06/10	RDS/7621001/07/10	RDS/7621001/08/11	RDS/7621001/09/11

CONTD FOR FURTHER MONTHS ON NEXT PAGE

NAME: K. Satyanarayan — SIGN & DATE: 29/4/2016 — Sr. R & D.MANAGER
NAME: Shobhnath Tiwari — SIGN & DATE: 29/4/2016 — Q.C.MANAGER
NAME: Vikas Bhopale — SIGN & DATE: 3/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg
Issued on : 19.06.2013, Reprinted on 02/05/2016	
Document No. : SSR/762/10/001	

LONG TERM STABILITY STUDY REPORT

Product Name: Esomeprazole Enteric Coated Tablets 20mg — **BATCH NUMBER:** 7621001

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 — **Exp. Date:** April-2013
Set Up Date :27.05.2010 — **STUDY COMPLETION DATE:** 03.06.2013
BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%

TEST	SPECIFICATION	18 months	24 months	36 months		
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.		
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	94.78mg	95.18mg	95.34 mg		
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b) 8 mins	a)No any fragments found b) 9 mins	a)No any fragments found b) 10 mins		
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 3.8 % 89.73%	 3.78 % 89.82%	 2.87 % 90.22%		
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.17% 0.058% 0.59%	0.19% 0.064% 0.61%	0.23% 0.071% 0.66%		
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	100.79%	100.68%	100.59%		
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	97.32%	96.98%	95.52%		
Sample removal Date		27.11.2011	27.05.2012	27.05.2013		
Sample Analysis Date		02.12.2011	03.06.2012	03.06.2013		
AR NO		RDR/7621001/10/11	RDR/7621001/11/12	RDR/7621001/12/13		
RDS NO		RDS/7621001/10/11	RDS/7621001/11/12	RDS/7621001/12/13		

Remark : The product is found to be stable for 36Months at 30°C±2°C & RH 65%±5%and hence the projected shelf life of 36 months can be given to the product

NAME: K. Satyanarayan — NAME: Prathmesh Tikar — NAME: Vikas Bhapale

SIGN & DATE: 25/5/2016 — SR & D.MANAGER — SIGN & DATE: — Q.C.MANAGER — SIGN & DATE: 25/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
Corp. Off.: 202, Sonmur Apts., Daruwala Compound, S.V. Road, Malad (W), Mumbai-400 064, INDIA.
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Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg
Issued on : 19.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/002	

ACCELERATED STABILITY STUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg					**BATCH NUMBER:** 7621002	
Each enteric coated tablet contains: Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg Excipients q.s Titanium Dioxide & Red Oxide					**BATCH SIZE:** 200000 Tablets	
Mfg. Date: May-2010	**Exp. Date:** April-2013				**BATCH TYPE:** Commercial	
Set Up Date :05.06.2010	**STUDY COMPLETION DATE:** 10.12.2010				**Pack Details :** 10 tablets packed in Alu-Alu blister.	
STORAGE CONDITIONS: Temperature.: 40°C± 2°C/75% ± 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**1 months**	**2months**	**3 months**	**6 months**
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured,circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	92.32 mg	92.65mg	93.93mg	93.08mg	93.35 mg
Disintegration Time	a) 0.1N-HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)5 mins	a)No any fragments found b)6 mins	a)No any fragments found b)7 mins	a)No any fragments found b) 8mins	a)No any fragments found b) 9 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	 USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 4.68 % 86.3%	 4.12 % 87.32%	 3.91 % 88.97%	 3.68 % 90.32%	 2.52 % 92.63%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.10% 0.039% 0.58%	0.11% 0.044% 0.60%	0.12% 0.049% 0.63%	0.15% 0.054% 0.65%	0.21% 0.067% 0.70%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	101%	100.92%	100.88%	100.71%	100.65%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	101.63%	101.52%	100.18%	99.41%	97.33%
Sample removal Date		18.05.2010	05.07.2010	05.08.2010	05.09.2010	05.12.2010
Sample Analysis Date		23.05.2010	10.07.2010	11.08.2010	10.09.2010	10.12.2010
AR NO		RDR/7621002/01/10	RDR/7621002/02/10	RDR/7621002/03/10	RDR/7621002/04/10	RDR/7621002/05/10
RDS NO		RDS/7621002/01/10	RDS/7621002/02/10	RDS/7621002/03/10	RDS/7621002/04/10	RDS/7621002/05/10

Remark : The product is found to be stable for 6Months at 40°C± 2°C/75% ± 5 %RH and hence the projected shelf life of 36 months can be given to the product

NAME: K-Satyanarayana — SIGN & DATE: 27/5/2016 — Sr R & D.MANAGER

NAME: Mohammad Ghouse — SIGN & DATE: 27/5/2016 — Q.C.MANAGER

NAME: Vikas Bhopale — SIGN & DATE: 31/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
Corp. Off.: 202, Sonmur Apts., Daruwala Compound, S.V. Road, Malad (W), Mumbai-400 064, INDIA.
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Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 19.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/002	

LONG TERM STABILITYSTUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH NUMBER: 7621002

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 **Exp. Date:** April-2013
Set Up Date :05.06.2010 **STUDY COMPLETION DATE:** 11.06.2013

BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%

TEST	SPECIFICATION	Initial	3 months	6 months	9 months	12 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	92.32 mg	92.88 mg	93.17mg	93.38 mg	94.06mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval :	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45min 100RPM 37°C± 0.5°C					
2 hrs	NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid .	4.68%	4.61 %	3.89 %	3.68 %	3.55 %
45 mins	NLT 75 (Q)% released in pH 6.8 buffer	86.3%	86.45%	87.12%	87.93%	88.12%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.10% 0.039% 0.58%	0.11% 0.042% 0.56%	0.13% 0.046% 0.58%	0.14% 0.051% 0.60%	0.16% 0.056% 0.62%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	101%	100.92%	100.78%	100.69%	100.54%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	101.63%	101.52%	101.01%	100.52%	100.12%
Sample removal Date		18.05.2010	05.09.2010	05.12.2010	05.03.2011	05.06.2011
Sample Analysis Date		23.05.2010	10.09.2010	10.12.2010	10.03.2011	11.06.2011
AR NO		RDR/7621002/01/10	RDR/7621002/06/10	RDR/7621002/07/10	RDR/7621002/08/11	RDR/7621002/09/11
RDS NO		RDS/7621002/01/10	RDS/7621002/06/10	RDS/7621002/07/10	RDS/7621002/08/11	RDS/7621002/09/11

CONTD FOR FURTHER MONTHS ON NEXT PAGE

NAME: K. Satyanarayana SIGN & DATE: 21/5/2016 S.R. & D.MANAGER

NAME: Shobhnath Ghosh SIGN & DATE: 21/5/2016 Q.C.MANAGER

NAME: Vikas Bhopale SIGN & DATE: 23/5/2016 Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 26.06.2013, Reprinted on 02/05/2016	
Document No. : SSR/762/10/002	

LONG TERM STABILITY STUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg				**BATCH NUMBER: 7621002**		
Each enteric coated tablet contains: Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg Excipients q.s Titanium Dioxide & Red Oxide				**BATCH SIZE: 200000 Tablets**		
Mfg. Date: May-2010	**Exp. Date:** April-2013			**BATCH TYPE: Commercial**		
Set Up Date :05.06.2010	**STUDY COMPLETION DATE:** 11.06.2013			**Pack Details :** 10 tablets packed in Alu-Alu blister.		
STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%						
TEST	**SPECIFICATION**	**18 months**	**24 months**	**36 months**		
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured,circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.		
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	94.26 mg	94.52 mg	94.83 mg		
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins	a)No any fragments found b)4 mins		
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	 USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 3.22 % 89.63%	 2.89 % 90.32%	 2.58 % 91.22%		
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.19% 0.064% 0.64%	0.22% 0.071% 0.67%	0.28% 0.080% 0.72%		
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	100.48%	100.39%	100.28%		
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	99.74%	99.01%	96.01%		
Sample removal Date		05.12.2011	05.06.2012	05.06.2013		
Sample Analysis Date		11.12.2011	10.06.2012	11.06.2013		
AR NO		RDR/7621002/10/11	RDR/7621002/11/12	RDR/7621002/12/13		
RDS NO		RDS/7621002/10/11	RDS/7621002/11/12	RDS/7621002/12/13		

Remark : The product is found to be stable for 36Months at 30°C±2°C & RH 65%±5%and hence the projected shelf life of 36 months can be given to the product

NAME: K. Satyanarayana — SIGN & DATE: — Sr. R & D.MANAGER

NAME: Chethan Bhat — SIGN & DATE: — Q.C.MANAGER

NAME: Vikas Bhopale — SIGN & DATE: 13/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 26.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/003	

ACCELERATED STABILITY STUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH NUMBER: 7621003

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 **Exp. Date:** April-2013
Set Up Date : 10.06.2010 **STUDY COMPLETION DATE:** 16.12.2010

BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 40°C+ 2°C/75% + 5 %RH

TEST	SPECIFICATION	Initial	1 months	2months	3 months	6 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	93.11 mg	93.49 mg	93.87 mg	94.14 mg	94.37 mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b)5 mins	a)No any fragments found b) 6 mins	a)No any fragments found b) 7 mins	a)No any fragments found b) 8 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 3.88 % 85.11%	 3.22% 85.63%	 3.17 % 86.45%	 3.11 % 87.23%	 2.89 % 89.63%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.11% 0.041% 0.57%	0.12% 0.047% 0.58%	0.13% 0.055% 0.59%	0.15% 0.059% 0.60%	0.19% 0.069% 0.71%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	100.95%	100.92%	100.85%	100.76%	100.69%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	102.53%	101.82%	100.82%	100.01%	98.21%
Sample removal Date		22.05.2010	10.07.2010	10.08.2010	10.09.2010	10.12.2010
Sample Analysis Date		27.05.2010	15.07.2010	16.08.2010	15.09.2010	16.12.2010
AR NO		RDR/7621003/01/10	RDR/7621003/02/10	RDR/7621003/03/10	RDR/7621003/04/10	RDR/7621003/05/10
RDS NO		RDS/7621003/01/10	RDS/7621003/02/10	RDS/7621003/03/10	RDS/7621003/04/10	RDS/7621003/05/10

Remark : **The product is found to be stable for 6Months at 40°C± 2°C/75%± 5 %RH and hence the projected shelf life of 36 months can be given to the product**

NAME: K. Satyanarayana — SIGN & DATE: 3/5/2016 — Sr. R & D.MANAGER

NAME: Shrikant Khilare — SIGN & DATE: 3/5/2016 — Q.C.MANAGER

NAME: Vikas Bhopale — SIGN & DATE: 3/5/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 26.12.2010, Reprinted on 02/05/2016	
Document No. : SSR/762/10/003	

LONG TERM STABILITY STUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg — **BATCH NUMBER:** 7621003

Each enteric coated tablet contains:
Esomeprazole Magnesium Trihydrate USP
Equivalent to Esomeprazole 20mg
Excipients q.s
Titanium Dioxide & Red Oxide

BATCH SIZE: 200000 Tablets

Mfg. Date: May-2010 — **Exp. Date:** April-2013
Set Up Date : 10.06.2010 — **STUDY COMPLETION DATE:** 15.06.2013
BATCH TYPE: Commercial
Pack Details : 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%

TEST	SPECIFICATION	Initial	3 months	6 months	9 months	12 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	93.11 mg	94.22 mg	94.79 mg	94.91 mg	95.12 mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b)4 mins	a)No any fragments found b) 5mins	a)No any fragments found b) 6 mins	a)No any fragments found b) 7 mins	a)No any fragments found b) 8 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval : 2 hrs 45 mins	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid . NLT 75 (Q)% released in pH 6.8 buffer	 3.88 % 85.11%	 3.8 % 85.25%	 3.77 % 85.33%	 3.56 % 85.63%	 3.51 % 85.93%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.11% 0.041% 0.57%	0.13% 0.042% 0.57%	0.14% 0.045% 0.61%	0.16% 0.049% 0.64%	0.17% 0.052% 066%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	100.95%	100.91%	100.86%	100.79%	100.69%
Assay: Each enteric coated tablet contains:						
Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	102.53%	102.05%	101.78%	101.64%	101.22%
Sample removal Date		22.05.2010	10.09.2010	10.12.2010	10.03.2011	10.06.2011
Sample Analysis Date		27.05.2010	16.09.2010	16.12.2010	15.03.2011	16.06.2011
AR NO		RDR/7621003/01/10	RDR/7621003/06/10	RDR/7621003/07/10	RDR/7621003/08/11	RDR/7621003/09/11
RDS NO		RDS/7621003/01/10	RDS/7621003/06/10	RDS/7621003/07/10	RDS/7621003/08/11	RDS/7621003/09/11

CONTD FOR FURTHER MONTHS ON NEXT PAGE

NAME: E. Satyanarayan — SIGN & DATE: 27 Feb 16 — Sr. R & D.MANAGER
NAME: Shobhnath Tiwari — SIGN & DATE: 27/2/2016 — Q.C.MANAGER
NAME: Nikas Bhopale — SIGN & DATE: 3/3/2016 — Q.A.MANAGER

Format No: QA-068 GEN/F3

Pell Tech Health Care Pvt. Ltd.
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Name of Dept : R & D	**STABILITY STUDY REPORT FOR ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg**
Issued on : 28.06.2013, Reprinted on 02/05/2016	
Document No. : SSR/762/10/003	

LONG TERM STABILITY STUDY REPORT

Product Name: ESOMEPRAZOLE ENTERIC COATED TABLETS 20mg	**BATCH NUMBER: 7621003**
Each enteric coated tablet contains: Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg Excipients q.s Titanium Dioxide & Red Oxide	**BATCH SIZE: 200000 Tablets**
Mfg. Date: May-2010 — **Exp. Date:** April-2013	**BATCH TYPE: Commercial**
Set Up Date : 10.06.2010 — **STUDY COMPLETION DATE: 15.06.2013**	**Pack Details :** 10 tablets packed in Alu-Alu blister.

STORAGE CONDITIONS: Temperature.: 30°C±2°C & RH 65%±5%

TEST	SPECIFICATION	18 months	24 months	36 months
Description	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.	Brown coloured, circular, biconvex, enteric coated tablets.
Average Weight of Tablet	92.5mg ± 7.5% (85.56mg – 99.44 mg)	95.43 mg	95.68 mg	95.87 mg
Disintegration Time	a) 0.1N HCl for 2 hours no any fragments b) In mixed phosphate buffer pH 6.8 NMT 45 minutes	a)No any fragments found b) 9 mins	a)No any fragments found b) 10 mins	a)No any fragments found b) 11 mins
Dissolution Apparatus : Medium : Speed : Temperature : Time Interval :	USP Type II (Paddle) 900ml of 0.1N Hydrochloric Acid for 2 hrs 900 ml pH 6.8 Phosphate buffer for 45 min 100RPM 37°C± 0.5°C			
2 hrs	NMT 10% of labelled amount released after 2hrs in 0.1N hydrochloric acid .	3.28 %	3.12 %	3.07 %
45 mins	NLT 75 (Q)% released in pH 6.8 buffer	86.33%	86.75%	86.98%
Organic Impurities	Omeprazole Sulfone - NMT 0.5% Any Other Individual impurity - NMT 0.2% Total Impurities - NMT 2.0%	0.21% 0.058% 0.69%	0.26% 0.063% 0.72%	0.32% 0.072% 0.79%
Uniformity dosage unit(by content)	Between 85.0% to 115.0%	100.58%	100.48%	100.39%
Assay: Each enteric coated tablet contains: Esomeprazole Magnesium Trihydrate USP Equivalent to Esomeprazole 20mg	Between 90.0% to 110.0% of labelled amount (Between 18.0mg to 22.0mg)	100.72%	99.17%	97.23%
Sample removal Date		10.12.2011	10.06.2012	10.06.2013
Sample Analysis Date		16.12.2011	15.06.2012	15.06.2013
AR NO		RDR/7621003/10/11	RDR/7621003/11/12	RDR/7621003/12/13
RDS NO		RDS/7621003/10/11	RDS/7621003/11/12	RDS/7621003/12/13

Remark : The product is found to be stable for 36Months at 30°C± 2°C & RH 65%±5%and hence the projected shelf life of 36 months can be given to the product

NAME: [illegible]	NAME: [illegible]	NAME: [illegible]
SIGN & DATE: [illegible]	SIGN & DATE: [illegible]	SIGN & DATE: [illegible]
Sr. R & D.MANAGER	Q.C.MANAGER	Q.A.MANAGER

Format No: QA-068 GEN/F3