ATENOLOL COMPRIMIDOS 50 mg
ESTUDIO DE ESTABILIDAD
Diseño- Estudio – Tabla Resumen

1.- RESUMEN : DISEÑO Y ESTUDIO DE ESTABILIDAD

ESTABILIDAD ACELERADA

Temperatura **:** 40ºC ± 2ºC y Humedad Residual: 75% ± 5%
Lotes analizados **:** 7511401; 7511402 y 7511403
Fechas de Fabricación **:** Diciembre 2014
Fecha de inicio del estudio **:** 16 Diciembre 2014
Fecha de término del estudio : 22 Junio 2014
Tipo y Tamaño de lotes : Lotes productivos de 600.000 comprimidos
Tipo de material de envase : Blister ALU-PVC (impreso).

Fabricante de API empleado en Estudio:
Kopran Research Laboratories Limited.
Dirección: K-4/4, Additional MIDC, At/Post: Birwadi, Tal: Mahad, Dist: Raigad, Pin 402302, Maharshtra, India.

Fabricante y dirección del sitio de Fabricación:
Pell Tech Health Care Pvt Ltd.
Dirección: Plot.N°20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

Laboratorio que desarrolla el Estudio de Estabilidad:
Pell Tech Health Care Pvt Ltd.
Dirección: Plot.N°20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

Tiempo(meses) →		**Inicial 0**	**1**	**2**	**3**	**6**
Test ↓	**Especificación ↓**					
Descripción	Comprimidos blancos redondos y planos, con línea de fraccionamiento en uno de sus lados	**x**	**x**	**x**	**x**	**x**
Peso promedio	**Peso teórico del comprimido** **Límite**:180 mg: ± 5%. (171,0 mg - 189,0 mg)	**x**	**x**	**x**	**x**	**x**
Tiempo de desintegración	No más de 30,0 minutos	**x**	**x**	**x**	**x**	**x**
Disolución **Medio**: Buffer acetato 0.1 N, pH 4,6, **Volumen:** 900 mL. **Aparato:** USP Tipo 2(paletas); **Velocidad**: 50 rpm. **Temperatura:**37°C ± 0,5 °C **Tiempo:** 30 minutos.	No menos del 80% (Q) de la cantidad declarada de $C_{14}H_{22}N_2O_3$ en la etiqueta del envase de venta, se disuelve en 30 minutos	**x**	**x**	**x**	**x**	**x**
Valoración: **Cada comprimido contiene:** **Atenolol 50 mg**	**Límite:** Cada comprimido contiene entre 45,0 mg hasta 55,0 mg. Entre un 90 % al 110% de la cantidad declarada	**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 EN DESARROLLO

Temperatura **:** 30ºC ± 2ºC y Humedad Residual: 65% ± 5%

Lotes analizados **:** 7511401; 7511402 y 7511403
Fechas de Fabricación **:** Diciembre 2014
Fecha de inicio del estudio **:** 16 Diciembre 2014
Fecha de término del estudio : 22 Junio 2014
Tipo y Tamaño de lotes : Lotes productivos de 600.000 comprimidos
Tipo de material de envase : Blister ALU-PVC (impreso).

Fabricante de API empleado en Estudio:
Kopran Research Laboratories Limited.
Dirección: K-4/4, Additional MIDC, At/Post: Birwadi, Tal: Mahad, Dist: Raigad, Pin 402302, Maharshtra, India.

Fabricante y dirección del sitio de Fabricación:
Pell Tech Health Care Pvt Ltd.
Dirección: Plot.N°20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

Laboratorio que desarrolla el Estudio de Estabilidad:
Pell Tech Health Care Pvt Ltd.
Dirección: Plot.N°20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

Tiempo(meses) →		**Inicial 0**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Test ↓	**Especificación ↓**								
Descripción	Comprimidos blancos redondos y planos, con línea de fraccionamiento en uno de sus lados	**x**	**x**	**x**	**x**	**x**	**-**	**-**	**-**
Peso promedio	**Peso teórico del comprimido** **Límite**:180 mg: ± 5%. (171,0 mg - 189,0 mg)	**x**	**x**	**x**	**x**	**x**	**-**	**-**	**-**
Tiempo de desintegración	No más de 30,0 minutos	**x**	**x**	**x**	**x**	**x**	**-**	**-**	**-**
Disolución **Medio**: Buffer acetato 0.1 N, pH 4,6, **Volumen:** 900 mL. **Aparato:** USP Tipo 2(paletas); **Velocidad**: 50 rpm. **Temperatura:**37°C ± 0,5 °C **Tiempo:** 30 minutos.	No menos del 80% (Q) de la cantidad declarada de $C_{14}H_{22}N_2O_3$ en la etiqueta del envase de venta, se disuelve en 30 minutos	**x**	**x**	**x**	**x**	**x**	**-**	**-**	**-**
Valoración: **Cada comprimido contiene:** **Atenolol 50 mg**	**Límite:** Cada comprimido contiene entre 45,0 mg hasta 55,0 mg. Entre un 90 % al 110% de la cantidad declarada	**x**	**x**	**x**	**x**	**x**	**-**	**-**	**-**

En donde se indica con una “equis”, significa que se hará (Hizo) la determinación analítica indicada. - = Pendiente o en desarrollo

2.- FÓRMULA CUALICUANTITATIVA

Ingredientes	Cantidad por unidad (mg)	Especificación Analítica
Atenolol	50.0	USP v
Almidón de maíz	79,17	BPv
Celulosa Microcristalina PH101	20,00	BPv
Almidón glicolato de sodio	15,00	BPv
Talco purificado	7,00	BPv
Dióxido de silicio colloidal(Aerosl)	2,50	BPv
Estearato de magnesio	2,00	BPv
Povidona(P.V.P.K30)	2,00	BPv
Lauril Sulfato de sodio	2,00	BPv
Parahidroximetilbenzoato de sodio (Metilparabeno sódico)	0,30	BPv
Parahidroxipropilbenzoato de sodio (Propilparabeno sódico)	0,03	BPv
Agua purificada *	c.s.	BPv
Peso teórico del comprimido	180,00	

*Agua purificada es un solvente que es removido durante el proceso de fabricación, no se encuentra en el producto final.
USPv= Farmacopea de Los Estados unidos de América vigente
BPv = Farmacopea Británica vigente

FORMULA CULICUANTITATIVA DE ORIGEN

Pell Tech Health Care Pvt. Ltd.

Reg. Office
202, Sonmur Apt.,
Near Marve Road Junction, S. V. Road,
Malad (W), Mumbai - 400 064. INDIA

WHO-GMP CERTIFIED

QUALITATIVE QUANTITATIVE FORMULA

Generic Name	Atenolol Tablets USP 500 mg	**Reference**	**USP** **Page no. 1 of 1**
Brand Name	----------	**Document No.**	QAQN/FG751/02/14
Product Code	FG751	**Supersedes No.**	QAQN/FG751/01/13
Shelf Life	36 months	**Effective Date**	27/05/2014
		Review Date	26/04/2019
		Reference FPS No.	FPS/FG751/02/14
Storage Condition: Preserve in well-closed container between 28°C-32°C			
Label Claim: Each uncoated tablet contains: Atenolol USP 50 mg Excipient q.s		**Pack Profile:** 10 tablets Packed in blisters 10X10 blister packed in carton	

Sr. No.	Ingredients	Specifications	Rationale	Label Claim (mg)	Overages (%)	Qty/tablets (mg)
1	Atenolol	USP	Active	50	-	50.00
2	Maize starch	BP	Diluent and Binder	-	-	79.17
3	Microcrystalline Cellulose PH 101	BP	Diluent	-	-	20.00
4	Colloidal Silicon Dioxide (Aerosil)	BP	Binder and Glidant	-	-	2.50
5	Sodium Methyl Parahydroxy Benzoate (Sodium methyl paraben)	BP	Preservative	-	-	0.30
6	Sodium Propyl Parahydroxy Benzoate (Sodium propyl paraben)	BP	Preservative	-	-	0.03
7	Povidone (P.V.P. K30)	BP	Binder	-	-	2.00
8	Purified Water*	BP	Vehicle	-	-	42.00
9	Magnesium stearate	BP	Lubricant	-	-	2.00
10	Purified Talc	BP	Glidant	-	-	7.00
11	Sodium Starch Glycolate	BP	Distintigrant	-	-	15.00
12	Sodium Lauryl Sulphate	BP	Lubricant	-	-	2.00
	TOTAL					**180.00 mg**

* Not present in final product

	Prepared By	Checked By	Approved By
Sign/date	Gaikwad 23/5/14	Satya 25/5/14	C.D.Tiwari 26/05/2014
Name	Ms. Dipti Gaikwad	Mr.Satyanarayana Kalva	Mr. C. D. Tiwari
Department	R. A. Officer	R & D Manager	Q. A. Manager

3.- MÉTODO DE ANÁLISIS 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.

4.- ESPECIFICACIONES DE PRDOUCTO TERMINADO PARA ESTUDIO DE ESTABILIDAD

Las especificaciones del producto terminado que se consideraron para determinar durante el estudio de estabilidad, se eligieron con el criterio de que son las que realmente reflejarían un eventual deterioro físico-químico del producto.

Test	Especificación
Descripción	Comprimidos blancos redondos y planos, con línea de fraccionamiento en uno de sus lados
Peso promedio	**Peso teórico del comprimido** **Límite**:180 mg: ± 5%. (171,0 mg - 189,0 mg)
Tiempo de desintegración	No más de 30,0 minutos
Disolución **Medio**: Buffer acetato 0.1 N, pH 4,6, **Volumen:** 900 mL. **Aparato:** USP Tipo 2(paletas); **Velocidad**: 50 rpm. **Temperatura:**37°C ± 0,5 °C **Tiempo:** 30 minutos.	No menos del 80% (Q) de la cantidad declarada de $C_{14}H_{22}N_2O_3$ en la etiqueta del envase de venta, se disuelve en 30 minutos
Valoración: **Cada comprimido contiene: Atenolol 50 mg**	**Límite:** Cada comprimido contiene entre 45,0 mg hasta 55,0 mg. Entre un 90 % al 110% de la cantidad declarada

5.- EVALUACION Y ANALISIS DE LOS RESULTADOS:

De acuerdo a los resultados obtenidos en el Estudio de Estabilidad Acelerado (40 ºC ± 2 ºC; HR : 75 ± 5%; INICIAL, 1,2, 3 Y 6 MESES) completo para los Lotes 7511401; 7511402 y 7511403. Y el Estudio de Estabilidad a Tiempo Real en curso, en condiciones de temperatura y humedad (Temperatura 30°C ± 2° C; Humedad relativa 65% ± 5%), del cual se presentan los puntos 0,3,6,9 y 12 meses, para los Lotes 7511401; 7511402 y 7511403. 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 hasta el momento, donde los mismos se mantuvieron dentro de los límites especificados.

6.- CONCLUSIONES:

Con los resultados obtenidos permiten proponer, para el producto **ATENOLOL *COMPRIMIDOS 50 mg***, un período de eficacia provisorio de 24 meses, almacenado en su envase original en un lugar fresco a una temperatura no mayor a 30ºC, protegido de la humedad y la luz.

En páginas siguientes se adjuntan Las tablas de resultados de los Estudios de Estabilidad señalados de los Lotes 7511401; 7511402 y 7511403. En las condiciones de temperatura y humedad señaladas.

ESTUDIO DE ESTABILIDAD ACELERADO

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 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : QA	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg
Issued on : 06.07.2015 Reprinted on: 09/06/2016	
Document No. : SSR/FG751/15/001	

ACCELERATED STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				BATCH NUMBER: 75115001		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				BATCH SIZE: 6,00,000 Tablets		
Mfg. Date: Jul-2015	Exp. Date: Jun-2018			BATCH TYPE: Process Validation & Commercial		
Set Up Date : 29/07/2015	STUDY COMPLETION DATE: 30/01/2016			Pack Details : 10 Tablets packed in Blister		
STORAGE CONDITIONS: Temperature.: 40°C+ 2°C/75% + 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**1 months**	**2 months**	**3 months**	**6 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average weight	180mg ± 5% (171.0mg – 189.0mg)	184.00 mg	185.10 mg	184.10 mg	184.50 mg	183.20 mg
Disintegration time	NMT 15 mins	3 min 13 sec	3 min 25 sec	3 min 01 sec	3 min 15 sec	3 min 20 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	96.9%	96.1%	95.5%	95.2%	94.5%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	99.6% (49.800 mg)	99.50% (49.750 mg)	99.40% (49.700 mg)	99.40% (49.700 mg)	99.20% (49.600 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00255	2015-16/SSR/75115001/01/A	2015-16/SSR/75115001/01/B	2015-16/SSR/75115001/01/C	2015-16/SSR/75115001/01/D

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

Date: 09/06/2016
NAME S.M. Pisal

Q.C.MANAGER

Date: 09/06/2016.
NAME Vijay Bhoir

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.
Tele : 91-22 42935123 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : QA	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg	
Issued on : 06.07.2015 Reprinted on: 09/06/2016		
Document No. : SSR/FG751/15/001		

ACCELERATED STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				**BATCH NUMBER: 75115002**		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				**BATCH SIZE: 6,00,000 Tablets**		
Mfg. Date: Jul-2015	**Exp. Date: Jun-2018**			**BATCH TYPE: Process Validation & Commercial**		
Set Up Date : 29/07/2015	**STUDY COMPLETION DATE: 30/01/2016**			**Pack Details : 10 Tablets packed in Blister**		
STORAGE CONDITIONS: Temperature.: 40°C+ 2°C/75% + 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**1 months**	**2 months**	**3 months**	**6 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average weight	180mg ± 5% (171.0mg – 189.0mg)	184.1 mg	185.20 mg	185.60 mg	185.10 mg	186.00 mg
Disintegration time	NMT 15 mins	3 min 55 sec	3 min 35 sec	3 min 31 sec	3 min 20 sec	3 min 18 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	97.0%	96.7%	96.5%	96.8%	95.5%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	101.2% (50.60 mg)	101.1% (50.55 mg)	100.8% (50.40 mg)	100.9% (50.45 mg)	100.7% (50.35 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00256	2015-16/SSR/75115002/01/A	2015-16/SSR/75115002/01/B	2015-16/SSR/75115002/01/C	2015-16/SSR/75115002/01/D

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

Date: 09/06/2016
NAME SN Bijlani

Q.C.MANAGER

Date: 09/06/2016
NAME Vijay Bhatt

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.
Tele : 91-22 42935123 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : QA	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg
Issued on : 06.07.2015 Reprinted on: 09/06/2016	
Document No. : SSR/FG751/15/001	

ACCELERATED STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				**BATCH NUMBER: 75115003**		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				**BATCH SIZE: 6,00,000 Tablets**		
Mfg. Date: Jul-2015		**Exp. Date: Jun-2018**		**BATCH TYPE: Process Validation & Commercial**		
Set Up Date : 29/07/2015		**STUDY COMPLETION DATE: 30/01/2016**		**Pack Details : 10 Tablets packed in Blister**		
STORAGE CONDITIONS: Temperature.: 40°C± 2°C/75% ± 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**1 months**	**2 months**	**3 months**	**6 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average Weight	180mg ± 5% (171.0mg – 189.0mg)	184.00 mg	185.60 mg	185.70 mg	185.40 mg	186.90 mg
Disintegration time	NMT 15 mins	3 min 38 sec	3 min 21 sec	3 min 15 sec	3 min 22 sec	3 min 25 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	97.2%	97.1%	96.9%	96.5%	96.6%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	101.30% (50.650 mg)	101.2% (50.60 mg)	101.4% (50.70 mg)	101.1% (50.55 mg)	100.8% (50.40 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00257	2015-16/SSR/75115003/01/A	2015-16/SSR/75115003/01/B	2015-16/SSR/75115003/01/C	2015-16/SSR/75115003/01/D

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

Date: 09/06/2016
NAME SM Qiwei

Q.C.MANAGER

Date: 09/06/2016
NAME Vijay Bhoir

Q.A.MANAGER

Format No: QA-068 GEN-F3

ESTABILIDAD A TIEMPO REAL

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 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : QA Issued on : 06.07.2015 Reprinted on: 09/06/2016 Document No. : SSR/FG751/15/001	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg	

LONG TERM STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				BATCH NUMBER: 75115001		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				BATCH SIZE: 6,00,000 Tablets		
Mfg. Date: Jul-2015	Exp. Date: Jun-2018			BATCH TYPE: Process Validation & Commercial		
Set Up Date : 29/07/2015	STUDY COMPLETION DATE: Ongoing			Pack Details : 10 Tablets packed in Blister		
STORAGE CONDITIONS: Temperature.: 30°C± 2°C/65% ± 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**3 months**	**6 months**	**9 months**	**12 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average weight	180mg ± 5% (171.0mg – 189.0mg)	184.00 mg	185.15 mg	184.18 mg	184.16 mg	183.20 mg
Disintegration time	NMT 15 mins	3 min 13 sec	3 min 23 sec	3 min 18 sec	3 min 26 sec	3 min 27 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	96.9%	96.2%	96.1%	96.0%	96.2%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	99.6% (49.800 mg)	99.50% (49.750 mg)	99.40% (49.700 mg)	99.20% (49.600 mg)	99.30% (49.650 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00255	2015-16/SSR/75115001/02/A	2015-16/SSR/75115001/02/B	2015-16/SSR/75115001/02/C	2015-16/SSR/75115001/02/D

Remark:- The product is found to be stable for 09 Months at 30°C± 2°C/65% ± 5 %RH.

Date: 09/06/2016
NAME SN Tipnis
Q.C.MANAGER

Date: 09/06/2016
NAME Vijay Bhair
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.
Tele : 91-22 42935123 / 67525354, Fax : 91-22- 42935149, Website : www.pelltechhealthcare.com
Email : sales@pelltechhealthcare.com, customerservice@pelltechhealthcare.com

Name of Dept : QA	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg
Issued on : 06.07.2015 Reprinted on: 09/06/2016	
Document No. : SSR/FG751/15/001	

LONG TERM STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				BATCH NUMBER: 75115002		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				BATCH SIZE: 6,00,000 Tablets		
Mfg. Date: Jul-2015	Exp. Date: Jun-2018			BATCH TYPE: Process Validation & Commercial		
Set Up Date : 29/07/2015	STUDY COMPLETION DATE: Ongoing			BATCH NUMBER: 75115001		
STORAGE CONDITIONS: Temperature.: 30°C+ 2°C/65% + 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**3 months**	**6 months**	**9 months**	**12 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average weight	180mg ± 5% (171.0mg – 189.0mg)	184.1 mg	185.22 mg	185.25 mg	185.20 mg	186.21 mg
Disintegration time	NMT 15 mins	3 min 55 sec	3 min 30 sec	3 min 31 sec	3 min 35 sec	3 min 28 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	97.0%	96.8%	96.7%	96.5%	96.1%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	101.2% (50.60 mg)	101.1% (50.55 mg)	100.9% (50.45 mg)	101.0% (50.50 mg)	100.8% (50.40 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00256	2015-16/SSR/75115002/02/A	2015-16/SSR/75115002/02/B	2015-16/SSR/75115002/02/C	2015-16/SSR/75115002/02/D

Remark:- The product is found to be stable for 09 Months at 30°C+ 2°C/65% + 5 %RH.

Date: 09/06/2016
NAME SM Bhosale
Q.C.MANAGER

Date: 09/06/2016
NAME Vijay Bhoir
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 : QA	STABILITY STUDY REPORT FOR ATENOLOL TABLETS USP 50 mg	
Issued on : 06.07.2015 Reprinted on: 09/06/2016		
Document No. : SSR/FG751/15/001		

LONG TERM STUDIES REPORT

Product Name: Atenolol Tablets USP 50mg				BATCH NUMBER: 75115003		
Label Claim: Each uncoated tablet contains: Atenolol USP 50mg				BATCH SIZE: 6,00,000 Tablets		
Mfg. Date: Jul-2015	Exp. Date: Jun-2018			BATCH TYPE: Process Validation & Commercial		
Set Up Date : 29/07/2015	STUDY COMPLETION DATE: Ongoing			Pack Details : 10 Tablets packed in Blister		
STORAGE CONDITIONS: Temperature.: 30°C± 2°C/65% ± 5 %RH						
TEST	**SPECIFICATION**	**Initial**	**3 months**	**6 months**	**9 months**	**12 months**
Description	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.	White circular flat uncoated tablet having breakline on one side of each tablet.
Average Weight	180mg ± 5% (171.0mg – 189.0mg)	184.00 mg	185.10 mg	185.15 mg	185.09 mg	185.25 mg
Disintegration time	NMT 15 mins	3 min 38 sec	3 min 32 sec	3 min 20 sec	3 min 22 sec	3 min 27 sec
Dissolution Apparatus : Medium : Speed : Temperature : Time interval : 30 mins	USP Type II (Paddle) 900ml, 0.1N Acetate Buffer, pH 4.6 50 rpm 37°± 0.5°C Not less than 80%(Q) of the labeled amount dissolved	97.2%	97.0%	96.8%	96.2%	97.0%
Assay : Each uncoated tablet contains						
Atenolol USP 50mg	Between 90% to 110% of labeled amount. (Between 45.0 mg to 55.0 mg)	101.30% (50.650 mg)	101.2% (50.60 mg)	101.0% (50.50 mg)	101.1% (50.55 mg)	100.9% (50.45 mg)
Sample removal Date		27/07/2015	29/08/2015	29/09/2015	29/10/2015	29/01/2016
Sample Analysis Date		29/07/2015	30/08/2015	30/09/2015	31/10/2015	31/01/2016
AR NO		2015-16/QCP/FGR/00257	2015-16/SSR/75115003/02/A	2015-16/SSR/75115003/02/B	2015-16/SSR/75115003/02/C	2015-16/SSR/75115003/02/D

Remark:- The product is found to be stable for 09 Months at 30°C± 2°C/65% ± 5 %RH.

Date: 09/06/2016
NAME SN Kadam
Q.C.MANAGER

Date: 09/06/2016
NAME Vijay Bhoir
Q.A.MANAGER

Format No: QA-068 GEN-F3

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WHO-GMP CERTIFIED

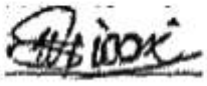
CONCLUSIONS OF THE STUDY:

Conclusion:

Based on the favorable results obtained in all the results of stability study performed at accelerated stability conditions (40°C ± 2°C /75 ± 5%RH) and real time (long term) stability conditions (30°C ± 2°C /65 ± 5%RH), it is possible to say that the product Atenolol 50 mg USP tablets is stable for the period of 6 months.

Further, as per the stability protocol the product is still kept at the Real time (long-term) upto the period of expected shelf life of 36 months.

Person In-charge of the study

Signature: 

Name: Mr. Shobhnath Tiwari

Designation: QC Manager