MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

1.- RESUMEN : DISEÑO Y ESTUDIO DE ESTABILIDAD

ESTABILIDAD ACELERADA

Temperatura : 40°C ± 2°C y Humedad Residual: 75% ±5%

Lotes analizados : BB21031; BB21032; BB21033, y

Fechas de Fabricación : Octubre 2011 Fecha de inicio del estudio : Octubre 2011 Fecha de término del estudio : Marzo de 2013

Tipo y Tamaño de lotes : Lotes productivos de 150.000 compr.rec

Tipo de material de envase : ALU - ALU impreso.

Fabricante de API empleado en Estudio:

Amoxicilina Trihidrato: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Clavulanato de potasio: Shandong New Time Pharmaceutical Co. Ltd. China.

Manufacturador y sitio de Fabricante:

Fabricado por Baroque Pharmaceuticals PVT. Ltd.192/2, Sokhada-388620, Khambhat, India

Laboratorio que desarrolla el Estudio de Estabilidad:

Baroque Pharmaceuticals PVT. Ltd.192/2, Sokhada-388620, Khambhat, India

Tiempo(meses)						•
			\rightarrow	Inicial 0	3	6
Test ↓	Especificación ↓					
Descripción	Comprimido recubiertos, oblongos, biconvexos, de color blanco y			X	X	X
	plano en ambos lados					
Peso promedio	1060,0 mg ± 5,0%			X	Х	Х
Tiempo de	No más de 30,0 minutos			Х	Х	x
desintegración						
Dureza	No menos de 3,0 Kp			Х	Х	X
	Amoxicilina USP		menos de 85% p/p(Q) de lo indicado	х	Х	X
Disolución	Amoxicilina USP		la etiqueta del producto se disuelve 30 minutos			
Disciusion	Ácido Clavulánico BP	• • •	menos de 80% p/p(Q) de lo indicado	x	x	x
	, torde Glavaranico Bi		la etiqueta del producto se disuelve	^		^
			30 minutos			
Contenido de	No más de 10,0% p/p	de 10,0% p/p			х	Х
agua						
Uniformidad de	Amoxicilina		El valor de aceptación debe ser ≤ 15	X	x	X
dosis unitaria	(por variación de peso)					
	Ácido Clavulánico	1-1	El valor de aceptación debe ser ≤ 15	X	х	Х
	(por uniformidad de contenio	-,				
	Amoxicilina USP (como		menos de 90,0% y no más de	X	X	Х
Valanasián	Trihidrato) equivalente a		0,0% de la cantidad declarada en la			
Valoración	Amoxicilina 500 mg		queta del producto terminado.			
(%declarado en el	Clavulanato de potasio		menos de 90,0% y no más de	Х	Х	X
rótulo)	diluido BP Equivalente a		0,0% de la cantidad declarada en la			
	Ácido Clavulánico 125 mg etiqueta del producto terminado.					
Control			aerobias totales: < 1000 UFC/g	Х	X	X
Microbiológico	TYMC = Recuento de hongo	s y l	evaduras : < 100 UFC/g	X	Х	X

En donde se indica con una "equis", significa que se hará la determinación de lo indicado.

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

ESTABILIDAD A TIEMPO REAL

Temperatura : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ y Humedad Residual: $65\% \pm 5\%$

Lotes analizados : BB21031; BB21032; BB21033, y

Fechas de Fabricación : Octubre 2011 Fecha de inicio del estudio : Octubre 2011 Fecha de término del estudio : Septiembre 2013

Tipo y Tamaño de lotes : Lotes productivos de 150.000 compr.rec.

Tipo de material de envase : ALU - ALU impreso.

Fabricante de API empleado en Estudio:

Amoxicilina Trihidrato: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Clavulanato de potasio:Shandong New Time Pharmaceutical Co. Ltd, China.

Manufacturador y sitio de Fabricación:

Fabricado por Baroque Pharmaceuticals PVT. Ltd.192/2, Sokhada-388620, Khambhat, India

Laboratorio que desarrolla el Estudio de Estabilidad:

Baroque Pharmaceuticals PVT. Ltd.192/2, Sokhada-388620, Khambhat, India

		Tiempo(meses) →	Inicial	3	6	9	12	18	24
Test ↓	Espec	cificación ↓	0						
Descripción	Comprimido recubiertos, oblongo plano en ambos lados	os, biconvexos, de color blanco y	х	х	Х	х	х	х	х
Peso promedio	1060,0 mg ± 5,0%		х	х	Х	х	х	х	Х
Tiempo de desintegración	No más de 30,0 minutos		х	Х	Х	х	х	х	х
Dureza	No menos de 3,0 Kp		х	Х	Х	Х	Х	Х	х
Disolución	Amoxicilina USP	No menos de 85% p/p(Q) de lo indicado en la etiqueta del producto se disuelve en 30 minutos	x	x	x	x	x	х	x
	Ácido Clavulánico BP	No menos de 80% p/p(Q) de lo indicado en la etiqueta del producto se disuelve en 30 minutos	x	x	x	x	x	х	х
Contenido de agua	No más de 10,0% p/p		х	х	Х	х	х	х	х
Uniformidad de dosis unitaria	Amoxicilina (por variación de peso)	El valor de aceptación debe ser ≤ 15	х	Х	Х	х	х	х	х
	Ácido Clavulánico (por uniformidad de contenido)	El valor de aceptación debe ser ≤ 15	х	Х	х	х	х	х	х
Valoración	Amoxicilina USP (como Trihidrato) equivalente a Amoxicilina 500 mg	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.	х	x	х	х	x	х	х
(%declarado en el rótulo)	Clavulanato de potasio diluido BP Equivalente a Ácido Clavulánico 125 mg	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.	x	x	х	х	х	х	х
Control	TAMC = Recuento de bacterias		X	Х	Х	Х	Х	Х	X
Microbiológico	TYMC = Recuento de hongos y l	levaduras : < 100 UFC/g	X	X	X	X	X	X	X

En donde se indica con una "equis", significa que se hará la determinación de lo indicado.

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

2.- FORMULA CUANTITATIVA DEL PRODUCTO

PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA- 388620, KHAMBHAT, DT: ANAND. (GUJ.)		DEPARTMENT	Doc. No.	BQE441
			Revision	00
		QUALITY CONTROL	Supersedes	NEW
			Page	5 of 14
TITLE STABILITY STUDY PROTOCOL OF AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP 625 MG				

7.0 GENERAL INSTRUCTION:

7.1 Introduction

Generic Name of Product: Amoxicillin And Clavulanate Potassium Tablets USP 625mg

Label Claim of Product:

Each film coated tablet contains: Amoxicillin USP (As Trihydrate)

Eq. to Amoxicillin Anhydrous 500 Mg.

Diluted Potassium Clavulanate B.P.

Eq. to Clavulanic Acid 125 Mg. Excipients Q.S.

Colour: Titanium dioxide B.P.

7.2 Composition:

Sr. No.	L. C. per Tablet (mg)	Ove	INGREDIENTS	Specific- ation	Item Code
			MIXING		V.
1.	500.0	5	Amoxicillin USP (as Trihydrate) eq. to Amoxicillin	USP	100006
2.	294.875 Eq. to 125.00	10	Diluted Potassium Clavulanate eq. to Clavulanic Acid	BP	100206
3.	30.00		Magnesium Stearate	BP	101013
4.	168.125		Sodium Starch Glycolate	BP	101025
5.	4.000		Croscarmellose Sodium	BP	101042
6.	15.00	100	Colloidal Anhydrous Silica	BP	101001
7.	8.00		Purified Talc	BP	101028
			COATING		
8.	40.00	-	Titanium Dioxide Moisture Protect	IHS	104040A
9.	Q.S.	-	Isopropyl Alcohol (Anhydrous)	BP	102002
10.	Q.S.	-	Methylene Chloride (Anhydrous)	USP	102003

Reference number of Batch Manufacturing Record: BQE/MFR/441

Prepared by: All

Checked by: ensured

Authorized By QA: Ashingd

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

FÓRMULA CUALITITIVA CUANTITATIVA

N°	Ingredientes.	Cantidad/ Comprimido (mg)	% de exceso por pérdidas en el proceso	Uso/Función	Especificación Analítica
	NUCLEO				
01.	Amoxicilina Trihidrato (Eq. a Amoxicilina anhidra 500 mg)(1)(5)	574,0	+ 5%	P. Activo Antibiótico Betalactámico	USP 32/ NF 27
02.	Clavulanato Potasio Diluido (1:1) Eq. A 125,0 mg Clavulanato Potasio Diluido (1)(5)	294,875	+ 10%	Inhibidor de β -lactamasas	BP 2012
03.	Estearato de Magnesio	30,0		Lubricante	BP 2012
04.	Almidón Glicolato de sodio (2)	168,125 (2)		Agente desintegrante	BP 2012
05.	Croscarmelosa Sódica	4,0		Agente desintegrante	BP 2012
06.	Silica Coloidal Anhidro	15,0		Deslizante	BP 2012
07.	Talco Purificado	8,0		Lubricante	BP 2012
	PESO NÚCLEO	1020			
	RECUBRIMIENTO				
08.	Dióxido de Titanio Moisture Protect (IC-MS-3582) (3)	40,0		Agente de recubrimiento	IHS
09.	Alcohol Isopropílico Anhidro (4)	-		Vehículo de recubrimiento	BP 2012
10.	Cloruro de Metileno Anhidro (4)	-		Vehículo de recubrimiento	USP 32/ NF 27
	PESO COMPRIMIDO RECUBIERTO	1060			

NOTA:

IHS = In House.

(1) La Cantidad de este material es variable de acuerdo a los cambios en la cantidad de material activo. Donde,

(1) = Cantidad a ser calculada en base a la potencia del ingrediente activo.

Para Amoxicilina: Calculada en base a una potencia de 871,08 mcg / mg de amoxicilina base

Para Clavulanato de Potasio con celulosa microcristalina (1:1):

Calculado en base a una potencia de 840 mcg / mg de Ácido Clavulánico.

- (2) El Almidón glicolato de sodio actúa como agente compensante y su cantidad depende de la valoración cuantitativa del principio activo y de la pérdida por secado. Como lo indica el proveedor en la fórmula original.
- (3) Composición del recubrimiento (IC-MS-3582) (Dióxido de Titanio Moister Protect):

Ingrediente	% w/w
Hipromelosa BP	54,00
Dietil Ftalato BP	12,00
Etil Cellulosa BP	5,00
Talco Purificado BP	4,00
Dióxido de Titanio BP	25,00

(4) Solventes ausentes en producto final, se eliminan durante el proceso

(5) Promedios en %. Para cada API se añade un exceso para compensar pérdidas por el proceso de producción.

Amoxicilina (como Trihidrato) = 5% Ácido Clavulánico (como Clavulanato) = 10%.

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

3.- METODOS ANALITICOS

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 ESTUDIO DE ESTABILIDAD:

Las especificaciones del producto terminado incluidas en este Estudio de Estabilidad son las entregadas junto al dossier de registro de este producto, y se eligieron con el criterio de que son las que realmente reflejarían un eventual deterioro físico-químico del producto.

Test ↓	Especificación ↓			
Descripción	Comprimido recubiertos, oblongos, biconvexos,	de color blanco y plano en ambos lados		
Peso promedio	1060,0 mg ± 5,0%			
Tiempo de desintegración	No más de 30,0 minutos			
Dureza	No menos de 3,0 Kp			
Disolución	Amoxicilina USP	No menos de 85% p/p(Q) de lo indicado en la etiqueta del producto se disuelve en 30 minutos		
	Ácido Clavulánico BP	No menos de 80% p/p(Q) de lo indicado en la etiqueta del producto se disuelve en 30 minutos		
Contenido de agua	No más de 10,0% p/p			
Uniformidad de dosis unitaria	Amoxicilina (por variación de peso)	El valor de aceptación debe ser ≤ 15		
	Ácido Clavulánico (por uniformidad de contenido)	El valor de aceptación debe ser ≤ 15		
Valoración	Amoxicilina USP (como Trihidrato) equivalente a Amoxicilina 500 mg	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.		
(%declarado en el rótulo)	Clavulanato de potasio diluido BP Equivalente a Ácido Clavulánico 125 mg	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.		
Control Microbiológico	TAMC = Recuento de bacterias aerobias totales: < 1000 UFC/g TYMC = Recuento de hongos y levaduras : < 100 UFC/g			

5.- EVALUACION Y ANALISIS DE LOS RESULTADOS:

De acuerdo a los resultados obtenidos en el Estudio Acelerado a la temperatura indicada (Temperatura $40^{\circ}\text{C} \pm 2^{\circ}\text{ C}$; Humedad relativa $75\% \pm 5\%$), de los cuales se presentan los puntos 0, 3 y 6 meses para 3 lotes comerciales, a saber: LOTE: BB21031; BB21032; BB21033. Y los resultados obtenidos en el Estudio en Tiempo Real (Temperatura $30^{\circ}\text{C} \pm 2^{\circ}\text{ C}$; Humedad relativa $65\% \pm 5\%$), de los cuales se presentan los puntos 0, 3, 6, 9, 12, 18 y 24 meses para 3 lotes comerciales, a saber: LOTE: BB21031; BB21032; BB21033, en base a esto se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase estudiado (Blister ALU/ALU)

No se evidencia una disminución significativa en la valoración de los principios activos de la asociación Amoxicilina / Ácido clavulánico comprimidos recubiertos y los parámetros analizados se mantuvieron dentro de los límites especificados.

6.- CONCLUSIONES:

Con los resultados obtenidos se propone, para el producto ZOLIMAX DUO comprimidos recubiertos 500/125 mg, un período de eficacia de 24 meses, almacenado en su envase original y a una temperatura no mayor a 30° C, protegido de la humedad y en un lugar seco.

En las páginas siguientes se adjuntan los informes de Estudios de Estabilidad de los 3 lotes comerciales, LOTE: BB21031; BB21032; BB21033, en condiciones de temperatura ambiente de 25°C de los puntos analizados.

TABLAS DE RESULTADOS

DE

ESTABILIDAD ACELERADA

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

n poole	DEPARTMENT	Dor. No.	SK/BQE441		
BARCQUE	Control of the Contro	Revision			
PHARMACEUTICALS PVT. LTB. 1922 & 3, SOKHADA-388628,	QUALITY CONTROL	Supersedes	ACM		
KHAMBUAT, DT: ANAND (GUJ.)		Page	1 of 15		
TITLE STABILITY STUDY REPORT FORMAT					

	ACCELERATED SCADILITY STUDY						
Name of Product:	AMONICULUN AND CLAVULANATE POTASSIUM TABLETS USP 625 MG	Storage Condition	4675±271.75%, RH±5%, REL	Mfg. Date Exp. Date	(X(1-200) SEP-2011		
\$ ah : 4 % fa .	Amosesilin USP (As Trihydrste) Eq. to Amosicilin Ashydrous — 560 Mg. Diluted Polassian Clavalanaec B.P.	ts ting deals:	Abrádu packing		150000 Tablets		
Lubei Chún -	Eq. in Chrysleric Acid 125 Mg. Exciplents Q.S. Colour: Tilmham Diedale BP	Sample Qiy.:	21 History of 14 Tables	Date of Jacobation	07-10-2011		
ીવા ત પ ેલ :	802/831	API Source:	Americillin USP: DSM Sinectem Pharmaceaticals India Pat. Ud. Dibated Petassium Clandanasc (IP; Shandong New Time Pharmaceutical Ce. Ltd.	Period	h Montes		

Test	Specification	India	3 Morth	6 Mouth
p	Windo or samuel and channel the	White coloured ovel stape	White coloured oral shape	White coloured and shape
Description	White enjoured rival shape film qualed tablet with on balli sides plain.	film coated tablet with co	film coated tablet with on	film coated tablet with ox
	Water fooler with his cent water high.	both side plain	hath side plain	both side plain
Average weight	1(60,0 mg ± 5,0%	1061.0 mg	1059.8 mg	1669.3 mg
 Disintegration test	Not more than 30.0 minutes	10 mie 35 sec	II mir, 10 sec	Home Street
Damerone	Mat Ison Skon 10 F a	Mainurs 12.0 Kp	Misimure, 11.0 Kg	Matimon: 10.6 Kp
 Hardnes	Not less than 3.0 Kp	Maximum : 15,0 Kp	Maximum : 14.0 Kg	Maximum : 13.0 Kp
	1) N.L.T 85.0% (CE Amoricillin ESP	1) Minimus; 100.27%	1) Michaum, 102.62%	1) Minimon: 1(0,71%
	a Near	Maximum : 105.92%	Maximum: 104.62%	Maximum ; 103,34%
Dissolution test		ja.		
	2) N.L.T. 89.074 (Q) Clavelanic acid	2) Madaman, 108-15%	2) Minimura: 106,38%	2) Miniman, 195,14%
 enten professorie polyectycy, was a posystemp op open	Phylonia.	Moximum : 110.81%	Masimum ; 109.01%	Maximian : 108.28%
 Valer	Not asons than 10.6 %	7.49 %	7,62%	7,85 %

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

DE DUMIE	DEPARTMENT	Doc, No.	SR/BQE411			
BAROQUE		Revision	90			
† PHARMACEUTICALS PVT, 1/TD 192/2 & 3, SOKHADA-388620,	QUALITY CONTROL	Supersedes	NEW			
KDAMBHAT, DT: ANAND (GEJ.		Page	2 of 15			
TITLE STABILITY STUDY REPORT FORMAT						

Test	Specification	Tullia)	J Month	6 Month
INFORMITY OF BOSAGE		in the first territories and the first the desirence and the second seco		
UNIT				
(n) Amoricillin	 Acceptance value should be ≤15 	1. 3.14	1. 3.31	1. 361
(B) Weight Variation)				
(b) Chrulanic acid	 Acceptance value should be ≤ 15. 	2. 2.16	2. 2.29	2, 241
(By Content Uniformity)		: 		
Assay of			Market No. 13 and the supplementary of the State of the S	
1) Americalin USP (As	i, NL1 90.0% and RMT	. 4) 104.92 %	11 103.81 %	D 102.24 %
Tribydraic)	120,0%	·		
Eq. to Amoxicillin 500 mg				
2) Displed Potassium	2. NLT 90.0% and NMT			
Geralauste B.P. Eq. To	120,9%	21 107,29%	2) 105.88%	2) 184.16%
Chivolania Acid 125 aug		,		
Microbial ourity	J. TANC: 10° CHUg	1. 21 CFU/g	L 21 CF1Hg	1. 21 CFU/g
: : : : : : : : : : : : : : : : : : :	2. TYMC: HE CHUR	l Mil	2. Nil	2. Nil
Protecol Ne.	SP/BQE441	A COMMETTER STATE OF THE PROPERTY OF THE PARTY OF THE PAR	er en en engele eg emper mysemmer mysemmer en	The state of the s
Coaclasion:	The product is found stable for 6 Menth	is at storage condition 40°C±2	C/75% RH ± 5% RH	THE PERSON NAMED IN COMPANY OF PERSONS ASSESSED.
Remark	The product is found stable for 6 Morain			The second of th
Papard.By: DARSIAN SSI		and the second s	Approved By :VINOD A F	MU. A
m 12	DN 2012 ==	33.12		leul !
(Q.C.OFFICER)	of exec	- constitution of the same of	1	
(Aurea caend)	Ar war	""" HINU19012	(Q.C MAN	Miles 17/04/28/2
The second state of the se	en de manuelle de la companya della companya della companya de la companya della	(iip ji		

UNCONTROLLED COPY Authorized By QA: Sylventral

BAROQUE	DEPARTMENT	Doc. No.	SR/BQE411
S. Jan.		Revision	00
FWARMACEUTICALS PVT, LTD. 192/2 & J, SOKHADA-388620.	QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANAND (GUL)		Page	6 of 15
THE STADILITY	STUDY REPORT FORMAT		Combination communication of the communication of t

	ACC	ELERATED ST	ABILATY STUDY		
Name of Product:	AMOXICHILIN AND CLAVULANATE POTASSIUM TABLETS ESP 625 MG	Sterage Condition	40°C+7°C (75% RH); 5% RH.		OCT-2011 SEP-2011
Enhal Claim Dibuted Petassium Cravalannic B.H. Eq. in Clavalanic Acid H	Eq. to Americallin Anhydrous — 500 Mg.	Partitug details :	Alw Alu peeking	Hatch size	150000 Tablets
	Excipients Q.S.	Snoople Qty.:	21 Stisters of 10 Taidets	inentation	16-10-2011
Bairli No. :	01121012	API Source:	Amoxicillin USP: DSM Sinochem Pharmacendeals India Pet, Ltd. Diluted Polassium Chemianare BP: Shandong New Time Pharmacentical Co. Ltd.	Period	6 Muatis

Test	Specification	leitial	3 Nonth	6 Month
Description	While columed oval shape film coated tablet with on both sides phain.	While enhaned aval shape film coaled tablet with on both side plain	White coloured or al shape from content tables with on both side plain	White coloured eval shape then costed tablet with on both side plain
Average neight	' 1966.0 mg ± 5.0%	1060.6 nig	1059.3 mg	1961.4 mg
Disintegration test	Not more than 30,0 minutes	10 min 10 sec	19 min 50 sec	11 min 30 sec
Hardness	Not its than 3.0 Kp	Minhoun: 13.0 Kp Maximon (16.0 Kp	Minimum: 11 0 Kp Maximum: 15 0 Kn	Minimum; 10,0 Kp Maximum : 13,0 Kn
Dissolution test	1) N.L.T 85.0% (Q) Amasicillia USP in 30 min. 2) N.L.T 80.0% (Q) Clavalanic acid	1) Madinani: 103,87% Maximum : 106,05% 2) Afidinanii: 198,69%	1) Minimum: 102,96 % Maximum: 164,88% 2) Alintiown: 187,19%	 Minionum: 101.24% Maximum: 102.64% Minimum: 105.93%
Water	BP in 30 min. Not more than 10.0 %	Maximusu : 111.63% 7.48 %	Maximura : 109,22% 7,81%	Maximum : 108.24% 7.99 %

ENCONTROLLED COPY

Anthorized By QA: Quarge (

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)		DEPARTMENT		SR/BQE441
			Revision	00
		QUALITY CONTROL	Supersedes	NEW
			Page	7 of 15
TITLE	STABILITY STUDY	REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month
UNIFORMITY OF DOSAGE UNIT (a) Amoxicillin	 Acceptance value should be ≤ 15 	1. 3.18	1. 3.39	1. 3.76
(By Weight Variation) (b) Clavulanic acid (By Content Uniformity)	2. Acceptance value should be ≤ 15	2. 2.25	2. 2.48	2. 2.71
Assay of 1) Amoxicillin USP (As Trihydrate)	1. NLT 90.0% and NMT 120.0%	1) 105.39 %	1) 103.75 %	1) 102.68 %
Eq. to Amoxicillin 500 mg 2) Diluted Potassium Clavulanate B.P. Eq. To Clavulanic Acid 125 mg	2. NLT 90.0% and NMT 120.0%	2) 107.98 %	2) 106.76%	2) 105.34 %
Microbial purity	1. TAMC: 10 ³ CFU/g 2. TYMC: 10 ² CFU/g	1. 21 CFU/g 2. Nil	1. 23 CFU/g 2. Nil	1. 25 CFU/g 2. Nil
Protocol No.	SP/BQE441			
Conclusion:	The product is found stable for 6 Months	s at storage condition 40°C± 2	2°C/75% RH ± 5% RH.	
Remark	The product is found stable for 6 Months	s at storage condition 40°C± 2	2°C/75% RH ± 5% RH.	
Prepared By: DARSHAN S SI P 26 (Q.C OFFICER)	Checked By :HARSHAD	utives 26/04/201	Approved By :VINOD /	A PATEL ANAGER) 26/04/2010

UNCONTROLLED COPY

Authorized By QA: Robarysed

PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)		DEPARTMENT	Doc. No.	SR/BQE441
			Revision	00
		QUALITY CONTROL	Supersedes	NEW
			Page	11 of 15
TITLE	STABILITY STUDY	REPORT FORMAT		

		ELERATED ST	ABILITY STUDY		
Name of Product:	AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP 625 MG	Storage Condition	40°C± 2°C /75% RH ± 5% RH.	Mfg. Date Exp. Date	OCT-2011 SEP-2013
Label Claim	Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin Anhydrous 500 Mg. Diluted Potassium Clavulanate B.P.	Packing details :	Alu/Alu packing	Batch size	150000 Tablets
Cather Craim	Eq. to Clavulanic Acid 125 Mg. Excipients Q.S. Colour: Titanium Dioxide BP	Sample Qty.:	21 blisters of 10 Tablets	Date of incubation	23-10-2011
Batch No. :	BB21033	API Source:	Amoxicillin USP: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Diluted Potassium Clavulanate BP: Shandong New Time Pharmaceutical Co. Ltd.	Period	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	White coloured oval shape film coated tablet with on both sides plain.	White coloured oval shape film coated tablet with on both side plain	White coloured oval shape film coated tablet with on both side plain	White coloured oval shape film coated tablet with on both side plain
Average weight	1060.0 mg ± 5.0%	1061.0 mg	1060.8 mg	1060.9 mg
Disintegration test	Not more than 30.0 minutes	10 min 30 sec	10 min 55 sec	11 min 40 sec
Hardness	Not less than 3.0 Kp	Minimum: 12.0 Kp Maximum: 15.0 Kp	Minimum: 11.0 Kp Maximum: 14.0 Kp	Minimum: 9.0 Kp Maximum: 12.0 Kp
Dissolution test	1) N.L.T 85.0% (Q) Amoxicillin USP in 30 min.	1) Minimum: 103.99% Maximum: 106.18%	1) Minimum: 102.96 % Maximum: 105.19%	1) Minimum: 101.18% Maximum: 103.83%
	2) N.L.T 80.0% (Q) Clavulanic acid BP in 30 min.	 Minimum: 109.04% Maximum: 111.84% 	2) Minimum: 107.82% Maximum: 110.04%	2) Minimum: 105.62% Maximum: 108.34%
Water.	Not more than 10.0 %	7.52 %	7.89%	8.21 %

UNCONTROLLED COPY

Authorized By QA: Releiged

PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620, KHAMBHAT, DT. ANAND (GUJ.)		DEPARTMENT	Doc. No.	SR/BQE441
			Revision	00
		QUALITY CONTROL	Supersedes	NEW
			Page	12 of 15
	STABILITY STUDY	REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month
UNIFORMITY OF DOSAGE UNIT (a) Amoxicillin (By Weight Variation) (b) Clavulanic acid (By Content Uniformity)	 3. Acceptance value should be ≤ 15 4. Acceptance value should be ≤ 15 	3. 3.07 4. 2.19	3. 3.35 4. 2.41	3. 3.70 4. 2.76
Assay of 1) Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 500 mg	3. NLT 90.0% and NMT 120.0%	3) 105.81 %	1) 103.99 %	1) 102.51 %
2) Diluted Potassium Clavulanate B.P. Eq. To Clavulanic Acid 125 mg	4. NLT 90.0% and NMT 120.0%	4) 108.26 %	2) 107.31%	2) 105.64 %
Microbial purity	3. TAMC: 10 ³ CFU/g 4. TYMC: 10 ² CFU/g	3. 22CFU/g 4. Nil	3. 24 CFU/g 4. Nil	3. 26 CFU/g 4. Nil
Protocol No.	SP/BQE441			
Conclusion:	The product is found stable for 6 Months	s at storage condition 40°C±	2°C/75% RH ± 5% RH.	
Remark	The product is found stable for 6 Months	s at storage condition 40°C±	2°C/75% RH ± 5% RH.	
Prepared By: DARSHAN S SI P 52 (Q.C OFFICER)	Checked By :HARSHAD	13 /20/2	Approved By :VINOD A	Quy)

UNCONTROLLED COPY

Authorized By QA: Sularged .

TABLAS DE RESULTADOS

DE

ESTABILIDAD A TIEMPO REAL

PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)		DEPARTMENT	Doc. No.	SR/BQE441
		QUALITY CONTROL	Revision	00
			Supersedes	NEW
			Page	3 of 15
TITLE	STABILITY STUDY	REPORT FORMAT		

	LON	G TERM STAB	ILITY STUDY				
		of Product: AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP 625 MG Condition 30°C± 2°C /65% RH ± 5% RH.		30 C± 2 C 20378 KH ± 378 KH.		Mfg. Date Exp. Date	OCT-2011 SEP-2013
	Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin Anhydrous 500 Mg. Diluted Potassium Clavulanate B.P.	Packing details :	Alu/Alu packing	Batch size	150000 Tablets		
Label Claim Eq. to Clavulanic Acid Excipients Colour: Titanium Dioxide BP	Eq. to Clavulanic Acid 125 Mg. Excipients Q.S.	Sample Qty.:	49 blisters of 10 Tablets	Date of incubation	07-10-2011		
Batch No. :	BB21031	API Source:	Amoxicillin USP: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Diluted Potassium Clavulanate BP: Shandong New Time Pharmaceutical Co. Ltd.	Period	24 Months		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White coloured oval shape film coated tablet with on both sides plain.	White coloured oval shape film coated tablet with on both side plain	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.
Average weight	1060.0 mg ± 5.0%	1061.0 mg	1059.2 mg	1060.7 mg	1058,3 mg	1062.3 mg	1061.9 mg	1060.8 mg
Disintegration test	Not more than 30.0 minutes	10 min 35 sec	10 min 55 sec	11 min 10 sec	11 min 30 sec	11 min 55 sec	12 min 15 sec	12 min 45 sec
Hardness	Not less than 3.0 Kp	Minimum: 12.0 Kp Maximum: 15.0 Kp	Minimum: 12.0 Kp Maximum : 14.0 Kp	Minimum: 11.0 Kp Maximum: 14.0 Kp	Minimum: 11.0 Kp Maximum: 13.0 Kp	Minimum: 11.0 Kp Maximum : 13.0 Kp	Minimum: 10.0 Kp Maximum: 13.0 Kp	Minimum: 10.0 Kp Maximum: 12.0 Kp

BAROQUE		DEPARTMENT		SR/BQE441
DAIZOGUE				00 NEW
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620,		QUALITY CONTROL	Supersedes	
KHAMBHAT, DT: ANA			Page	4 of 15
TITLE	STABILITY STUDY	REPORT FORMAT	398	

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Dissolution test	1) N.L.T 85.0% (Q) Amoxicillin USP in 30 min,	1) Minimum: 103.27% Maximum: 105.92%	1) Minimum: 103.08% Maximum: 105.61%	1) Minimum: 102.90% Maximum: 105.30%	1) Minimum: 102.73% Maximum: 105:04%	1) Minimum: 102.38% Maximum: 104.72%	1) Minimum: 102.07% Maximum: 104.28%	1) Minimum: 101.34% Maximum: 104.03%
	2) N.L.T 80.0% (Q) Clavulanic acid BP in 30 min.	2) Minimum; 108.15% Maximum : 110.81%	2) Minimum: 108.01% Maximum: 110.53%	2) Minimum: 107.71% Maximum : 110.21%	2) Minimum: 107.43% Maximum: 109.86%	2) Minimum: 107.13% Maximum: 109.42%	2) Minimum: 106.82% Maximum: 109.03%	2) Minimum: 106.51% Maximum: 108.81%
Water	Not more than 10.0 %	7.40 %	7.42 %	7.49 %	7.53 %	7.59 %	7.65 %	7.71 %
UNIFORMITY OF DOSAGE UNIT (a) Amoxicillin (By Weight variation) (b) Clavulanic acid (By Content Uniformity)	Acceptance value should be ≤ 15 Acceptance value should be ≤ 15	3.14 2.16	3.19 2.18	3.25 2.21	3.31 2.25	3,36 2,31	3.42 2.35	3.46 2.39
Assay of 1) Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 500 mg	1. NLT 90.0% and NMT 120.0%	1) 104.92 %	1) 104.63 %	1) 104.47 %	1) 104.18 %	1) 103.95 %	1) 103.68 %	1) 103.32 %
2) Diluted Potassium Clavulanate B.P. Eq. To Clavulanic Acid 125 mg	2. NLT 90.0% and NMT 120.0%	2) 107.29 %	2) 107.19 %	2) 106,98 %	2) 106.77 %	2) 106.43 %	2) 106.02 %	2) 105.92 %

UNCONT	ROLL	ED C	One

Authorized By QA: Salaiged

PA DOOLIE	9	DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE			Revision	00 NEW
PHARMACEUTICALS 192/2 & 3, SOKHADA-38		QUALITY CONTROL	Supersedes	
KHAMBHAT, DT: ANA			Page	5 of 15
TITLE	STABILITY STUDY	REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month	
Microbial purity	1) TAMC: 10 ¹ CFU/g 2) TYMC: 10 ² CFU/g	1) 21 CFU/g 2) Nil	1) 22 CFU/g 2) Nil	1) 23 CFU/g 2) Nil	1) 24 CFU/g 2) NiI	1) 24 CFU/g 2) Nil	1) 25 CFU/g 2) Nil	1) 26CFU/g 2) Nil	
Protocol No.	SP/BQE441								
Conclusion:	The product is found	product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.							
Remark	The product is found								
Prepared By : DARSI (Q.C OI	IAN S SHAH	Checked By	:HARSHAD BP	atel .		ved By :VINOD /	A PATEL ANAGER) 17	Molle	
Date :		Date :			Date :				

UNCONTROLLED COPY

Authorized By QA: Assayed

PN DOOLE	DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE		Revision	00
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620,	QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANAND (GUJ.)		Page	8 of 15

		LONG TERM STAE	BILITY STUDY		
Name of Product:	AMOXICILLIN AND CLAVULANA POTASSIUM TABLETS USP 625 M			Mfg. Date Exp. Date	OCT-2011 SEP-2013
Lubul Chim	Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin Anhydrous 500 Mg Diluted Potassium Clavulanate B.P.	Packing details :	Alu/Alu packing	Batch size	150000 Tablets
Label Claim	Eq. to Clavulanic Acid 125 Mg Excipients Q.S. Colour: Titanium Dioxide BP	Sample Qty.:	49 blisters of 10 Tablets	Date of incubation	16-10-2011
Batch No. ;	BB21032	API Source:	Amoxicillin USP: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Diluted Potassium Clavulanate BP: Shandong New Time Pharmaceutical Co. Ltd.	Period	24 Months -

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White coloured oval shape film coated tablet with on both sides plain.	White coloured oval shape film coated tablet with on both side plain	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.
Average weight	1060.0 mg ± 5.0%	1060.6 mg	1060.7 mg	1059.0 mg	1058.3 mg	1061.1 mg	1059.0 mg	1058.6 mg
Disintegration test	Not more than 30.0 minutes	10 min 10 sec	10 min 30 sec	10 min 55sec	11 min 30 sec	11 min 45 sec	12 min 10 sec	12 min 40 sec
Hardness	Not less than 3.0 Kp	Minimum: 13.0 Kp Maximum: 16.0 Kp	Minimum: 13.0 Kp Maximum: 16.0 Kp	Minimum: 12.0 Kp Maximum: 15.0 Kp	Minimum: 11.0 Kp Maximum: 15.0 Kp	Minimum; 11.0 Kp Maximum; 13.0 Kp	Minimum: 10.0 Kp Maximum: 14.0 Kp	Minimum: 9.0 Kp Maximum: 12.0 Kp

UNCONTROLLED COPY

Authorized By QA: Sharyed

PA DOOLIE		DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE			Revision	00
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620,		QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANA			Page	9 of 15
TITLE STABILITY STU		REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	-18 Month	24 Month
	1) N.L.T 85.0% (Q) Amoxicillin USP in 30 min.	1) Minimum: 103.87% Maximum: 106.05%	1) Minimum: 103,38% Maximum: 105,82%	1) Minimum: 103.09% Maximum: 105.34%	1) Minimum: 102.73% Maximum: 104.98%	1) Minimum: 102.18% Maximum: 104.48%	1) Minimum: 101.89% Maximum: 104.10%	1) Minimum: 101.67% Maximum: 103.66%
Dissolution test	2) N.L.T 80.0% (Q) Clavulanic acid BP in 30 min.	2) Minimum: 108.69% Maximum: 111.63%	2) Minimum: 108.37% Maximum: 111.30%	2) Minimum: 108.03% Maximum: 111.01%	2) Minimum: 107.62% Maximum: 110.68%	2) Minimum: 107.19% Maximum: 110.31%	2) Minimum: 106.96% Maximum: 110.04%	2) Minimum: 106.64% Maximum: 109.63%
Water	Not more than 10.0 %	7.49 %	7.55 %	7.60 %	7.67 %	7.72 %	7.77%	7.83 %
UNIFORMITY OF DOSAGE UNIT (a) Amoxicillin (By Weight variation) (b) Clavulanic acid (By Content Uniformity)	Acceptance value should be ≤ 15 Acceptance value should be ≤ 15	3.18 2.25	3.20 2.28	3.25 2.33	3.30 2.35	3.34 2.40	3.39 2.47	3.45 2.50
Assay of 1) Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 500 mg 2) Diluted Potassium Clavulanate B.P. Eq. To Clavulanic Acid 125 mg	1. NLT 90.0% and NMT 120.0% 2. NLT 90.0% and NMT 120.0%	1) 105.39 % 2) 107.98 %	1) 105.18 %	1) 104.84 %	1) 104.62 % 2) 106.60 %	1) 104.24 %	1) 103.94 % 2) 105.76 %	1) 103.62 %

UNCONTROLLED COPY

Authorized By QA: Grayad

BN DOOLIE		DEPARTMENT	Doc. No.	SR/BQE441
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620,			Revision	00
		QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANAND (GUJ.)			Page	10 of 15
TITLE	STABILITY STUDY	REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Microbial purity	1) TAMC: 10 ³ CFU/g 2) TYMC: 10 ² CFU/g		1) 21 CFU/g 2) NiI	1) 22 CFU/g 2) Nil	1) 22 CFU/g 2) Nil	1) 23 CFU/g 2) Nil	1) 23 CFU/g 2) Nil	1) 25CFU/g 2) Nil
Protocol.No.	SP/BQE441		-	4	London		1	1.00
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH,							
Remark		The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.						
Prepared By: DARSI (Q.C OI		Checked By :H	ARSHAD B PA	TEL	Approve	d By :VINOD A	Ques	hulsen
Date :		Date:			Date:		600	1

UNCONTROLLED COPY

Authorized By QA: Assaysel

MONOGRAFÍA ANALÍTICA DE PRINCIPIO ACTIVO

PN DOOLIE		DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE			Revision	00
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)		QUALITY CONTROL	Supersedes	NEW
			Page	13 of 15
TITLE STABILITY STUDY		REPORT FORMAT		

	LON	G TERM STAE	BILITY STUDY		
Name of Product:	AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP 625 MG			Mfg. Date Exp. Date	OCT-2011 SEP-2013
Label Claim Eq. 1 Eq. t Exci	Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin Anhydrous 500 Mg. Diluted Potassium Clavulanate B.P.	Packing details :	Alu/Alu packing	Batch size	150000 Tablet
	Eq. to Clavulanic Acid 125 Mg. Excipients Q.S. Colour: Titanium Dioxide BP	Sample Qty.:	49 blisters of 10 Tablets	Date of incubation	23-10-2011
Batch No. ;	BB21033	API Source:	Amoxicillin USP: DSM Sinochem Pharmaceuticals India Pvt. Ltd. Diluted Potassium Clavulanate BP: Shandong New Time Pharmaceutical Co. Ltd.	Period	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	White coloured oval shape film coated tablet with on both sides plain.	White coloured oval shape film coated tablet with on both side plain	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.
Average weight	1060.0 mg ± 5.0%	1061.0 mg	1060.8 mg	1060.1 mg	1059.6 mg	1062.3 mg	1059.7 mg	1060.4 mg
Disintegration test	Not more than 30.0 minutes	10 min 30 sec	10 min 45 sec	11 min	11 min 25 sec	11 min 55 sec	12 min 20 sec	12 min 50 sec
Hardness .	Not less than 3.0 Kp	Minimum: 12.0 Kp Maximum : 15.0 Kp	Minimum: 12.0 Kp Maximum: 14.0 Kp	Minimum: 11.0 Kp Maximum: 14.0 Kp	Minimum: 10.0 Kp Maximum: 13.0 Kp	Minimum: 10.0 Kp Maximum: 12.0 Kp	Minimum: 9.0 Kp Maximum: 12.0 Kp	Minimum: 9.0 Kp Maximum: 11.0 Kp

UNCONTROLLED COPY

Authorized By QA: Lewyed

PN POOLIE	DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE		Revision	00
PHARMACEUTICALS PVT. L 192/2 & 3, SOKHADA-388620,	TD. QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANAND (GI	J.)	Page	14 of 15

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
	1) N.L.T 85.0% (Q) Amoxicillin USP in 30 min.	1) Minimum: 103.99% Maximum: 106.18%	1) Minimum: 103.62% Maximum: 105.83%	1) Minimum: 103.13% Maximum: 105.28%	1) Minimum: 102.92% Maximum : 104.92%	1) Minimum: 102.52% Maximum: 104.50%	1) Minimum: 102.08% Maximum: . 104.13%	1) Minimum: 101.72% Maximum: 103.63%
Dissolution test	2) N.L.T 80.0% (Q) Clavulanie acid BP in 30 min.	2) Minimum: 109.04% Maximum: 111.84%	2) Minimum: 108.69% Maximum: 111.49%	2) Minimum: 108.24% Maximum: 111,10%	2) Minimum: 107.72% Maximum: 110.69%	2) Minimum: 107.35% Maximum: 110.21%	2) Minimum: 106,99% Maximum: 110,01%	2) Minimum: 106,57% Maximum: 109,57%
Water	Not more than 10,0 %	7.52 %	7.56 %	7.62 %	7.66 %	7.70 %	7.74%	7.80 %
UNIFORMITY OF DOSAGE UNIT (a) Amoxicillin (By Weight variation) (b) Clavulanic acid (By Content Uniformity)	Acceptance value should be ≤ 15 Acceptance value should be ≤ 15	3.07 2.19	3.13 2.24	3.18 2.30	3.24 2.34	3.29 2.41	3.36 2.46	3.41 2.53
Assay of 1) Amoxicillin USP (As Trihydrate) Eq. to Amoxicillin 500 mg	1. NLT 90.0% and NMT 120.0%	3) 105.81%	1) 105.42 %	1) 105.08 %	1) 104.71 %	1) 104.28%	1) 103.86 %	1) 103.41 %
2) Diluted Potassium Clavulanate B.P. Eq. To Clavulanic Acid 125 mg	2. NLT 90.0% and NMT 120.0%	4) 108.26%	2) 107.83 %	2) 107.52 %	2) 107.09 %	2) 106.59 %	2) 105.16 %	2) 104.84 %

UNCONTRULLED COPY

Authorized By QA: Resurged

Dr. DOOLIE	DEPARTMENT	Doc. No.	SR/BQE441
BAROQUE		Revision	00
PHARMACEUTICALS PVT. LTD. 192/2 & 3, SOKHADA-388620,	QUALITY CONTROL	Supersedes	NEW
KHAMBHAT, DT: ANAND (GUJ.)		Page	15 of 15

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Microbial purity	1) TAMC: 10 ³ CFU/g 2) TYMC: 10 ² CFU/g		1) 22CFU/g 2) Nil	1) 23 CFU/g 2) Nil	1) 24 CFU/g 2) Nil	1) 24 CFU/g 2) Nil	1) 25 CFU/g 2) Nil	1) 26CFU/g 2) Nil
Protocol No.	SP/BQE441							
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.							
Remark	The product is found st	product is found stable for 24 Months at storage condition 30°C± 2°C/65% RH ± 5% RH.						
Prepared By : DARSI (Q.C.OF	03/10/2013		ARSHADBPA SCENECUTIV		1356	d By :VINOD A (Q.C MA	PATEL QUAN NAGER LO	ros
Date: Date:				Date:				

UNCONTROLLED COPY

Authorized By QA: _ assaiyed