CLOXACILINA CÁPSULAS 500 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 **:** BB22003; BB22006 Y BB22009
Fechas de Fabricación **:** Abril 2012
Fecha de inicio del estudio **:** Abril 2012
Fecha de término del estudio : Octubre 2012
Tipo y Tamaño de lotes : Lotes pilotos de 100.000 cápsulas
Tipo de material de envase : Lámina de Aluminio - Polietileno de baja densidad (PBD) cubierta con tono brillante por un lado.(plain aluminium strip foil) impresa

Fabricante de API empleado en Estudio:
DSM Sinochem Pharmaceuticals India Private Limited # Bhai Mohan Singh Nagar, Toansa, Distt. Nawanshahr, Punjab
Fabricante y dirección del sitio de Fabricación:
Laboratorios Baroque Pharmaceuticals PVT LTD., 192/3, Sokada, Khambhat, India
Laboratorio que desarrolla el Estudio de Estabilidad:
Laboratorios Baroque Pharmaceuticals PVT LTD., 192/3, Sokada, Khambhat, India

	Tiempo(meses) →	**Inicial 0**	**3**	**6**
Test ↓	**Especificación ↓**			
Descripción	Cápsula de gelatina dura N°0, tapa y cuerpo de color naranja. Contiene polvo granular de color blanco.	**x**	**x**	**x**
Peso promedio del contenido de la cápsula	580,0 mg ± 7,5% (536,5 – 623,5 mg)	**x**	**x**	**x**
Tiempo de desintegración	No más de 30,0 minutos	**x**	**x**	**x**
Agua	No más de 5,0%	**x**	**x**	**x**
Disolución: **Medio:** 900 mL de Buffer fosfato de potasio 0,05 M pH6,8; **Aparato** Canastillo; **Velocidad:** 100 rpm; **Tiempo:** 30 minutos y **Temperatura:** 37 °C ± 0,5 °C	No menos de 80% (Q) [Q + 5% = 85%]de lo declarado se disuelve a los 30 minutos	**x**	**x**	**x**
Valoración de Cloxacilina sódica (equivalente a Cloxacilina Base)	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.	**x**	**x**	**x**
Control Microbiológico	Recuento total de bacterias aerobias: < 1000 UFC/g	**x**	**x**	**x**
	Recuento total de hongos y levaduras : < 100 UFC/g	**x**	**x**	**x**
	Patógenos . E.coli : Ausencia	**x**	**x**	**x**

En donde se indica con una **"x= equis",** significa que se hará (Hizo) la determinación analítica indicada.;
NA : No aplica

ESTABILIDAD A TIEMPO REAL (NATURAL)

Temperatura **:** 30ºC ± 2ºC y Humedad Residual: 65% ± 5% (Zona Climática IVA)
Lotes analizados **:** BB22003; BB22006 y BB22009
Fechas de Fabricación **:** Abril 2012
Fecha de inicio del estudio **:** Abril 2012
Fecha de término del estudio : Abril 2014
Tipo y Tamaño de lotes : Lotes pilotos 100.000 cápsulas
Tipo de material de envase : Lámina de Aluminio - Polietileno de baja densidad (PBD) cubierta con tono brillante por un lado (plain aluminium strip foil) impresa
Fabricante de API empleado en Estudio:
DSM Sinochem Pharmaceuticals India Private Limited # Bhai Mohan Singh Nagar, Toansa, Distt. Nawanshahr, Punjab
Fabricante y dirección del sitio de Fabricación:
Laboratorios Baroque Pharmaceuticals PVT LTD., 192/3, Sokada, Khambhat, India
Laboratorio que desarrolla el Estudio de Estabilidad:
Laboratorios Baroque Pharmaceuticals PVT LTD., 192/3, Sokada, Khambhat, India

Tiempo(meses) →		Inicial 0	3	6	9	12	18	24
Test ↓	**Especificación ↓**							
Descripción	Cápsula de gelatina dura N°0, tapa y cuerpo de color naranja. Contiene polvo granular de color blanco.	x	x	x	x	x	x	x
Peso promedio del contenido de la cápsula	580,0 mg ± 7,5% (536,5 – 623,5 mg)	x	x	x	x	x	x	x
Tiempo de desintegración	No más de 30,0 minutos	x	x	x	x	x	x	x
Agua	No más de 5,0%	x	x	x	x	x	x	x
Disolución: **Medio:** 900 mL de Buffer fosfato de potasio 0,05 M pH6,8; **Aparato** Canastillo; **Velocidad:** 100 rpm; **Tiempo:** 30 minutos y **Temperatura:** 37 °C ± 0,5 °C	No menos de 80% (Q) [Q + 5% = 85%]de lo declarado se disuelve a los 30 minutos	x	x	x	x	x	x	x
Valoración de Cloxacilina sódica (equivalente a Cloxacilina Base)	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.	x	x	x	x	x	x	x
Control Microbiológico	Recuento total de bacterias aerobias: < 1000 UFC/g	x	x	x	x	x	x	x
	Recuento total de hongos y levaduras : < 100 UFC/g	x	x	x	x	x	x	x
	Patógenos . E.coli : Ausencia	x	x	x	x	x	x	x

En donde se indica con una **"x= equis",** significa que se hará (Hizo) la determinación analítica indicada.; **NA :** No aplica

2.- FÓRMULA CUALICUANTITATIVA

7.2 **Composition:**

Reference number of Batch Manufacturing Record: BQE/BMR/698

SR. NO.	L. C. per Capsule (mg)	Ove %	INGREDIENTS	SPECIFI-CATION	ITEM CODE
MIXING					
1.	556.55 Eq. to 500.00	-	CLOXACILLIN SODIUM USP EQ. TO. CLOXACILLIN (B)*	USP	100032U
2.	80.00	-	PURIFIED TALC (D)$	BP	B101028B
FILLING					
3.	-----	2.0	EHG CAP SIZE "0" Orange/Orange	IHS	107004

Where,
(B)* = Quantity to be calculated on the basis of its potency
(D)$ = Quantity to be compensated on increasing quantity of active material and its L.O.D.
(Potency: 89.84%)
A.Q.R/B = Actual Quantity Required Per Batch
Ove % = Overages in %.
L.C. per Capsule = Label Claim per Capsule
IHS = In House Specification
BP = British Pharmacopoeia

Authorized by [QA]:

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	Cápsula de gelatina dura N°0, tapa y cuerpo de color naranja. Contiene polvo granular de color blanco.
Peso promedio del contenido de la cápsula	580,0 mg ± 7,5% (536,5 – 623,5 mg)
Tiempo de desintegración	No más de 30,0 minutos
Agua	No más de 5,0%
Disolución: **Medio:** 900 mL de Buffer fosfato de potasio 0,05 M pH6,8; **Aparato** Canastillo; **Velocidad:** 100 rpm; **Tiempo:** 30 minutos y **Temperatura:** 37 °C ± 0,5 °C	No menos de 80% (Q) [Q + 5% = 85%]de lo declarado se disuelve a los 30 minutos
Valoración de Cloxacilina sódica (equivalente a Cloxacilina Base)	No menos de 90,0% y no más de 120,0% de la cantidad declarada en la etiqueta del producto terminado.
Control Microbiológico	Recuento total de bacterias aerobias: < 1000 UFC/g
	Recuento total de hongos y levaduras : < 100 UFC/g
	Patógenos . E.coli : Ausencia

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, 1,3, Y 6 MESES) completo y a Tiempo real (NATURAL) en condiciones de temperatura y humedad (Temperatura 30°C ± 2° C; Humedad relativa 65% ± 5% [ZONA CLIMÁTICA IVA]), del cual se presentan los puntos 0,3,6, 9,12,18 y 24 meses, para los Lotes BB22003;BB22006 Y BB22009. Se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase estudiado. No se evidencia una disminución significativa en la valoración del activo y los parámetros analizados se mantuvieron dentro de los límites especificados.

6.- CONCLUSIONES:

Con los resultados obtenidos permiten proponer, para el producto **CLOXACILINA SÓDICA CÁPSULAS 500 mg**, un período de eficacia de 24 meses, almacenado en su envase original en un lugar fresco a una temperatura no mayor a 30 ºC, 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 BB22003; BB22006 Y BB22009. En las condiciones de temperatura y humedad señaladas.

ESTUDIO

DE

ESTABILIDAD ACELERADO

TABLAS RESUMEN DE RESULTADOS

CLOXACILINA CÁPSULAS 500 mg

ESTUDIO DE ESTABILIDAD

Diseño- Estudio – Tabla Resumen

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BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
		Page	1 of 12
TITLE	STABILITY STUDY REPORT FORMAT		

ACCELERATED STABILITY STUDY

Name of Product:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains: Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
		Sample Qty.:	11 Strips of 10 Capsules	**Date of incubation**	08/04/2012
Batch No. :	**BB22003**	**API Source:**	Cloxacillin Sodium USP : DSM Sinochem (I) Pvt Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	581.2 mg	579.4 mg	580.3 mg
Disintegration Test	Not more than 30.0 minutes	7 min 10 sec	6 min 50 sec	6 min 10 sec
Water	NMT 5.0%	3.25%	3.29%	3.35%
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.25% to 104.47%	97.99% to 103.18%	96.10% to 101.47%

Authorized By QA: Reviewed

CLOXACILINA CÁPSULAS 500 mg

ESTUDIO DE ESTABILIDAD

Diseño- Estudio – Tabla Resumen

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
	QUALITY CONTROL	Revision	00
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Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.90%	98.67%	97.02%
Test	Specification	Initial	3 Month	6 Month
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 38 CFU/g B) Nil C) Absent	A) 41 CFU/g B) Nil C) Absent	A) 45 CFU/g B) Nil C) Absent
Protocol No.	SP/BQE698			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Prepared By : DARSHAN S SHAH (Q.C OFFICER) 15/10/2012	Checked By :HARSHAD B PATEL (Q.C EXECUTIVE) 15/10/2012		Approved By :VINOD A PATEL (Q.C MANAGER) 15/10/2012	

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		Supersedes	NEW
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ACCELERATED STABILITY STUDY

Name of Product:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains: Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
		Sample Qty.:	11 Strips of 10 Capsules	**Date of incubation**	16/04/2012
Batch No. :	**BB22006**	**API Source:**	Cloxacillin Sodium USP : DSM Sinochem (I) Pvt Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	582.4 mg	580.1 mg	579.6 mg
Disintegration Test	Not more than 30.0 minutes	6 min 55 sec	6 min 35 sec	7 min 20 sec
Water	NMT 5.0%	3.27%	3.33%	3.38%
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.18% to 104.18%	97.74% to 103.02%	96.38% to 101.68%

Authorized By QA: Approved

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
	QUALITY CONTROL	Revision	00
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TITLE	STABILITY STUDY REPORT FORMAT		

Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.48%	98.13%	97.14%
Test	**Specification**	**Initial**	**3 Month**	**6 Month**
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 37 CFU/g B) Nil C) Absent	A) 42 CFU/g B) Nil C) Absent	A) 46 CFU/g B) Nil C) Absent
Protocol No.	SP/BQE698			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			

Prepared By : DARSHAN S SHAH	Checked By :HARSHAD B PATEL	Approved By :VINOD A PATEL
(Q.C OFFICER)	(Q.C EXECUTIVE)	(Q.C MANAGER)
23/10/2012	23/10/2012	23/10/2012

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ACCELERATED STABILITY STUDY

Name of Product:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition**	40°C± 2°C /75% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains: Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
		Sample Qty.:	11 Strips of 10 Capsules	**Date of incubation**	25/04/2012
Batch No. :	**BB22009**	**API Source:**	Cloxacillin Sodium USP : DSM Sinochem (I) Pvt Ltd.	**Period**	6 Months

Test	Specification	Initial	3 Month	6 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	580.1 mg	579.3 mg	580.9 mg
Disintegration Test	Not more than 30.0 minutes	6 min 40 sec	7 min 10 sec	7 min 35 sec
Water	NMT 5.0%	3.22%	3.27%	3.34%
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.37% to 104.01%	97.74% to 103.02%	96.38% to 101.68%

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Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.02%	98.13%	97.14%
Test	**Specification**	**Initial**	**3 Month**	**6 Month**
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 36 CFU/g B) Nil C) Absent	A) 40 CFU/g B) Nil C) Absent	A) 44 CFU/g B) Nil C) Absent
Protocol No.	**SP/BQE698**			
Conclusion:	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Remark	The product is found stable for 6 Months at storage condition 40°C± 2°C/75% RH ± 5% RH.			
Prepared By : DARSHAN S SHAH (Q.C OFFICER) 01/11/2012	Checked By :HARSHAD B PATEL (Q.C EXECUTIVE) 01/11/2012		Approved By :VINOD A PATEL (Q.C MANAGER) 01/11/2012	

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ESTABILIDAD A TIEMPO REAL

[Natural]

TABLAS RESUMEN DE RESULTADOS

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BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
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		Supersedes	NEW
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LONG TERM STABILITY STUDY					
Name of Product:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition:**	30°C± 2°C /65% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains:	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
	Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S			**Date of incubation**	08/04/2012
		Sample Qty.:	25 Strips of 10 Capsules		
Batch No. :	**BB22003**	**API Source:**	Cloxacillin Sodium USP: DSM Sinochem (I) Pvt Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	581.2 mg	580.4 mg	579.8 mg	582.4mg	580.9 mg	578.2 mg	578.3 mg
Disintegration Test	Not more than 30.0 minutes	7 min 10 sec	6 min 25 sec	7 min 15 sec	6 min 30 sec	6 min 35 sec	6 min 40 sec	6 min 50 sec
Water	NMT 5.0%	3.25%	3.26%	3.28%	3.27%	3.29%	3.32%	3.34%

Authorized By QA: Sanjeet

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
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Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.25% to 104.47%	99.01% to 104.02%	98.64% to 103.74%	98.22% to 103.31%	97.82% to 102.63%	97.27% to 101.98%	96.88% to 101.34%
Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.90%	100.14%	99.62%	99.07%	98.92%	98.01%	97.25%
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 38 CFU/g B) Nil C) Absent	A) 39 CFU/g B) Nil C) Absent	A) 41CFU/g B) Nil C) Absent	A) 40 CFU/g B) Nil C) Absent	A) 42 CFU/g B) Nil C) Absent	A) 44 CFU/g B) Nil C) Absent	A) 46 CFU/g B) Nil C) Absent
Protocol No.	SP/BQE698							
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 : DARSHAN S SHAH	Checked By :HARSHAD B PATEL	Approved By :VINOD A PATEL
(Q.C OFFICER)	(Q.C EXECUTIVE)	(Q.C MANAGER)
Date : 15/04/2014	Date : 15/04/2014	Date : 15/04/2014

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Authorized By QA: Received

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	QUALITY CONTROL	Revision	00
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LONG TERM STABILITY STUDY					
Name of Produet:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition:**	30°C± 2°C /65% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains: Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
		Sample Qty.:	25 Strips of 10 Capsules	**Date of incubation**	16/04/2012
Batch No. :	**BB22006**	**API Source:**	Cloxacillin Sodium USP: DSM Sinochem (I) Pvt Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	582.4 mg	581.6 mg	580.3 mg	580.5 mg	578.3 mg	579.6 mg	579.1 mg
Disintegration Test	Not more than 30.0 minutes	6 min 55 sec	6 min 30 sec	6 min 15 sec	7 min 15 sec	7 min 25 sec	6 min 55 sec	5 min 50 sec
Water	NMT 5.0%	3.27%	3.28%	3.30%	3.31%	3.33%	3.34%	3.36%

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
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TITLE	STABILITY STUDY REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.18% to 104.18%	98.88% to 104.00%	98.42% to 103.55%	98.02% to 103.22%	97.77% to 102.85%	97.20% to 102.33%	96.73% to 101.68%
Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.48%	100.01%	99.51%	99.03%	98.63%	98.13%	97.55%
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 37 CFU/g B) Nil C) Absent	A) 38 CFU/g B) Nil C) Absent	A) 40CFU/g B) Nil C) Absent	A) 42 CFU/g B) Nil C) Absent	A) 43 CFU/g B) Nil C) Absent	A) 45CFU/g B) Nil C) Absent	A) 47 CFU/g B) Nil C) Absent
Protocol No.	SP/BQE698							
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 : DARSHAN S SHAH	Checked By :HARSHAD B PATEL	Approved By :VINOD A PATEL
(Q.C OFFICER)	(Q.C EXECUTIVE)	(Q.C MANAGER)
Date : 22/04/2014	Date : 23/04/2014	Date : 23/04/2014

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BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
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TITLE	STABILITY STUDY REPORT FORMAT		

LONG TERM STABILITY STUDY					
Name of Product:	**CLOXACILLIN SODIUM CAPSULES USP 500MG**	**Storage Condition:**	30°C± 2°C /65% RH ± 5% RH.	**Mfg. Date**	APR. 2012
				Exp. Date	MAR. 2014
Label Claim	Each hard gelatin capsule contains: Cloxacillin Sodium USP Eq. to Cloxacillin 500mg Excipients Q.S	**Packing details:**	Strip Packing	**Batch size**	100000 capsules
				Date of incubation	25/04/2012
		Sample Qty.:	25 Strips of 10 Capsules		
Batch No. :	**BB22009**	**API Source:**	Cloxacillin Sodium USP: DSM Sinochem (I) Pvt Ltd.	**Period**	24 Months

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Description	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder.	Orange cap and Orange body size "0", hard gelatin capsule containing white coloured granular powder
Average Weight of Powder in each Capsule	580.0 mg ± 7.5%	580.1 mg	581.5 mg	580.3 mg	579.4 mg	578.9 mg	578.3 mg	579.6 mg
Disintegration Test	Not more than 30.0 minutes	6 min 40 sec	6 min 20 sec	7 min 25 sec	5 min 55 sec	6 min 30 sec	7 min 25 sec	7 min 15 sec
Water	NMT 5.0%	3.22%	3.24%	3.27%	3.30%	3.32%	3.35%	3.37%

Authorized By QA: Sanjiva

CLOXACILINA CÁPSULAS 500 mg

ESTUDIO DE ESTABILIDAD

Diseño- Estudio – Tabla Resumen

BAROQUE PHARMACEUTICALS PVT. LTD. 192/3, SOKHADA-388620, KHAMBHAT, DT: ANAND (GUJ.)	DEPARTMENT	Doc. No.	SR/BQE698
	QUALITY CONTROL	Revision	00
		Supersedes	NEW
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TITLE	STABILITY STUDY REPORT FORMAT		

Test	Specification	Initial	3 Month	6 Month	9 Month	12 Month	18 Month	24 Month
Dissolution	NLT 80% (Q) [Q+5% = 85%] of the labeled stated amount of Cloxacillin	99.37% to 104.01%	98.86% to 103.64 %	98.30% to 103.21%	97.86% to 102.80 %	97.40% to 102.38%	97.01% to 101.99%	96.66% to 101.58%
Assay (Cloxacillin sodium eq. to Cloxacillin)	NLT 90.0% & NMT 120.0% of the stated amount of Cloxacillin	100.02%	99.72%	99.24%	98.79%	98.36%	97.92%	97.58%
Microbial Contamination	A) TAMC: NMT 10^3 CFU/g B) TYMC: NMT 10^2 CFU/g C) E.Coli: Should be Absent	A) 36 CFU/g B) Nil C) Absent	A) 37 CFU/g B) Nil C) Absent	A) 38 CFU/g B) Nil C) Absent	A) 40 CFU/g B) Nil C) Absent	A) 41 CFU/g B) Nil C) Absent	A) 42 CFU/g B) Nil C) Absent	A) 46 CFU/g B) Nil C) Absent
Protocol No.	SP/BQE698							
Conclusion:	The product is found stable for 24 Months at storage condition 30°C± 2^0C/65% RH ± 5% RH.							
Remark	The product is found stable for 24 Months at storage condition 30°C± 2^0C/65% RH ± 5% RH.							

Prepared By : DARSHAN S SHAH (Q.C OFFICER)	Checked By :HARSHAD B PATEL (Q.C EXECUTIVE)	Approved By :VINOD A PATEL (Q.C MANAGER)
Date : 01/05/2014	Date : 01/05/2014	Date : 01/05/2014

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