



ESTUDIO DE ESTABILIDAD

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg

Atorvastatina Cálcica (Forma Cristalina)

Subdepartamento Registros y Autorizaciones Sanitarias

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I. PROTOCOLO

Se realizó una evaluación de la estabilidad de tres lotes de ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg fabricados por Emil Pharmaceutical Industries Pvt. Ltd., utilizando materia prima suministrada por Morepen Laboratories Ltd. El estudio se llevará a cabo a dos tiempos y condiciones ambientales.

A continuación los lotes a analizar:

Número de lote	Fecha de manufactura	Tamaño de lote
MD748	Octubre 2018	100.000 (Comp. Rec.)
MD749	Octubre 2018	100.000 (Comp. Rec.)
MD750	Octubre 2018	100.000 (Comp. Rec.)

1. Condiciones

El estudio se realizó almacenando muestras, en las siguientes condiciones de temperatura y humedad relativa:

	Estudio Acelerado	Estudio a tiempo real
Temperatura	40°C ± 2°C	30°C ± 2°C
Humedad	75 % ± 5 % H. R.	65 % ± 5 % H. R

2. Tipo de envase

Estuche de cartulina impresa que contiene Blíster ALU/PVC transparente, más folleto de información al paciente, todo debidamente rotulado y sellado.

3. Fecha de inicio y fin del estudio de estabilidad

- Fecha de inicio: El estudio se inició en Octubre 2018
- Fecha de término: El estudio aún sigue en curso.

Estudio de estabilidad

4. Análisis realizados y frecuencia de testeo:

a) Estudio acelerado

Parámetros medidos	Inicial	3 meses	6 meses
Descripción	√	√	√
Identificación	√	-	√
Peso Promedio	√	-	√
Desintegración	√	√	√
Disolución	√	√	√
Uniformidad de dosis	√	-	√
Impurezas orgánicas	√	√	√
Valoración	√	√	√
Recuento microbiano	√	√	√

b) Estudio a tiempo real

Parámetros medidos	Inicial	3 M	6 M	9 M	12 M	18 M	24 M	36 M	39 M
Descripción	√	√	√	√	√	√			
Identificación	√	-	-	-	-	-			
Peso Promedio	√	-	-	-	-	-			
Desintegración	√	√	√	√	√	√			
Disolución	√	√	√	√	√	√			
Uniformidad de dosis	√	-	-	-	-	-			
Sustancias Relacionadas	√	√	√	√	√	√			
Valoración	√	√	√	√	√	√			
Recuento microbiano	√	√	√	√	√	√			



NOTA: √ = Parámetro debe ser medido.

*** Estudio en curso, se informará actualización oportunamente.**

Cabe destacar que la metodología utilizada para la medición de los diferentes parámetros en el estudio de estabilidad del producto ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg es la misma declarada en la metodología original para el análisis del producto terminado.

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
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5. Especificaciones del producto terminado para estabilidad:





 EMIL PHARMACEUTICAL INDUSTRIES PVT. LTD. <small>Reg office: 101 Mangalim, Kurlawadi, Borivali East, Mumbai 400068, INDIA. Tel: +91-22-42090200 Email: info@emilpharma.in</small>		 <small>An ISO 9001:2008 Certified Company</small>
TITLE		Protocol No. : QA/STB/F1007-S00
Atorvastatin Tablet 20 mg		Revision No. : 00
		Page No. : 7 of 10

11. Drug product specification:

Sr. No.	Test	Specification
1	Description	White to off white biconvex film coated tablets plain on both sides.
2	Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
3	Average Weight	176.7 mg to 195.3 mg
4	Disintegration Time	N.M.T 15 minutes
5	Dissolution	N.L.T. 80% (Q) of labeled amount dissolved in 15 minutes
6	Uniformity of Dosage Units	NMT 15.0 When determined on 10 individual units
7	Organic Impurities	Atorvastatin Pymilidone Analog: NMT 0.5%
		Atorvastatin Related Compound H: NMT 1.0%
		Atorvastatin epoxy pyrroloxazin 6 hydroxy analog: NMT 0.5%
		Atorvastatin epoxy pyrroloxazin 7 hydroxy analog: NMT 0.5%
		Atorvastatin epoxy THF analog: NMT 0.25%
		Atorvastatin related compound D: NMT 0.35 to 0.5 (if Atorvastatin epoxy THF analog is integrated together)
		Any other unspecified degradation product: NMT 0.2%
8	Assay	Total degradation: NMT 4.0%
Microbial Limit Test		
Total aerobic microbial counts:		
8	Bacterial Counts	N.M.T 1000 cfu/ gm
9	Fungi	N.M.T 100 cfu/ gm
Test for Specified microorganisms		
10	Escherichia Coli	Absent in 1 gm
11	Salmonella	Absent in 10 gm
12	Pseudomonas aeruginosa	Absent in 1 gm
13	Staphylococcus aureus	Absent in 1 gm

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
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II. FÓRMULA CUALI-CUANTITATIVA

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TITLE	DOCUMENT NUMBER	BMR-T993-S01-M	
ATORVASTATIN TABLET 20 mg	ISSUE DATE	Mar 2019	
	REVISION DATE	Feb 2022	

COMPOSITION OF PRODUCT

Sr. No.	Constituent	Specification	Quantity Per Tab (mg)	USE
1	Atorvastatin Calcium*	USP	20.68	Medicament
2	Microcrystalline cellulose	BP	94.62	Diluent
3	Lactose BP(30#)	BP	60.60	Diluent
4	Croscarmellose Sodium	USP	2.10	Disintegrating agent
5	Magnesium Stearate	BP	2.00	Lubricant
BASE COATING				
6	Ready mix Moistshield**	IHS	2.00	Base Coating agent
7	Isopropyl Alcohol***	BP	-	Solvent
8	Methylene Chloride***	BP	-	Solvent
FILM COATING				
9	Ready Mix white **	IHS	4.00	Coating agent
10	Purified Water***	BP	-	Solvent

Note:

* 1.034 mg Atorvastatin Calcium — 1 mg of Atorvastatin.

Therefore, 20.68 mg Atorvastatin Calcium — 20 mg of Atorvastatin base at 100 % assay.

** About 30 % weight loss during coating

*** Does not remain in final formulation

IHS: In house

USP United state pharmacopoeia 41, NF: National Formulary 36





BP: British Pharmacopoeia 2017

Prepared by:
Mr. M. R. Patil
Production Officer
Date: 13/02/19

Checked by:
Mr. D. Damoshan
Production Manager
Date: 20/02/19

Approved by:
Mr. S. M. Daptardar
QA Manager
Date: 21/2/19

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
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TITLE	DOCUMENT NUMBER	BMR-T993-S01-M	
ATORVASTATIN TABLET 20 mg	ISSUE DATE	Mar 2019	
	REVISION DATE	Feb 2022	

Composition for Ready Mix Moistshield:

Sr. No.	Ingredients	CI number
1	Hydroxy Propyl Methyl Cellulose	-
2	Diethyl Phthalate	-
3	Ethyl Cellulose	-
4	Talc	
4	Titanium Dioxide	77891

Composition for Colour Ready Mix white:

Sr. No.	Ingredients	CI number
1	Hypromellose	-
2	Polyethylene Glycol / Macrogol	-
3	Titanium Dioxide	77891

MRP/CL
Prepared by:
Mr. M R. Patil
Production Officer
Date: 19/02/19


DM
Checked by:
Mr. D.Damoshan
Production Manager
Date: 26/02/19

SM Daptardar
Approved by:
Mr. S/M. Daptardar
QA Manager
Date: 21/2/19

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
Estudio de estabilidad

III. RESULTADOS

a) Estudio de estabilidad acelerado:



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As per ISO 9001:2015 Certified Company

ACCELERATED STABILITY STUDY REPORT

Name of Product	Atorvastatin Tablets 20 mg	Batch No.	MD748		
Description of the pack	10's Alu-PVC Blister pack	Mfg. Date	Oct 2018		
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT.	Expiry Date	Sept 2021		
		Storage Conditions	40°C ± 2°C and 75% ± 5% RH		
Date of Initiation	Oct 2018	Date of completion	Apr 2019		
TEST	LIMITS	RESULTS OF ANALYSIS			
		Initial	3 months	6 months	
Description	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	
Identification	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	-	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	
Average Weight	176.7 mg to 195.3 mg	186.12 mg	-	187.05 mg	
D.T.	NMT 15 min	1 min	1 min	1 min	
Dissolution	NLT 80% (Q) dissolved in 15 min	1] 94.65%	1] 93.54%	1] 92.90%	
		2] 93.14%	2] 91.60%	2] 92.46%	
		3] 92.49%	3] 90.74%	3] 92.68%	
		4] 90.98%	4] 94.19%	4] 90.74%	
		5] 93.14%	5] 92.25%	5] 90.96%	
		6] 93.57%	6] 92.90%	6] 91.17%	
Uniformity of dosage units	NMT 15.0 When determined on 10 individual units	1.9	-	2.1	
Organic Impurities:					
Atorvastatin Pyridone Analog	NMT 0.5%	0.077%	0.079%	0.080%	
Atorvastatin Related Compound H	NMT 1.0%	0.168%	0.170%	0.171%	
Atorvastatin epoxy pyrroleoxazin 6 hydroxy analog	NMT 0.5%	0.026%	0.025%	0.029%	
Atorvastatin epoxy pyrroleoxazin 7 hydroxy analog	NMT 0.5%	Not Detected	Not Detected	Not Detected	
Atorvastatin epoxy THF analog	NMT 0.25%	0.010%	0.013%	0.016%	

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
Estudio de estabilidad



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For POC, visit: 2008 Certified Company

ACCELERATED STABILITY STUDY REPORT

Name of Product	Atorvastatin Tablets 20 mg	Batch No.	MD748
Description of the pack	10's Alu-PVC Blister pack	Mfg. Date	Oct 2018
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT	Expiry Date	Sept 2021
		Storage Conditions	40°C ± 2°C and 75% ± 5% RH
Date of Initiation	Oct 2018	Date of completion	Apr 2019

TEST	LIMITS	RESULTS OF ANALYSIS		
		Initial	3 months	6 months
Atorvastatin related compound D	NMT 0.35 to 0.5 (if Atorvastatin epoxy THF analog is integrated together)	Not Detected	Not Detected	Not Detected
Any other unspecified degradation product	NMT 0.2%	0.083%	0.088%	0.092%
Total degradation	NMT 4.0%	0.370%	0.384%	0.411%
Assay	94.5% to 105.0%	99.87%	99.35%	98.89%

Microbial Limit Test

Total aerobic microbial count

Bacterial Counts	NMT 1000 cfu/gm	35 cfu/g	35 cfu/g	40 cfu/g
Fungi	NMT 100 cfu/gm	Absent	Absent	Absent


Test for specified microorganisms:

E. Coli	Absent in 1 gm	Absent	Absent	Absent
Absent	Absent in 10 gm	Absent	Absent	Absent
Pseudomonas	Absent in 1 gm	Absent	Absent	Absent
Stap. aureus	Absent in 1 gm	Absent	Absent	Absent




Approved By:
Mr. S. M. Daptardar
QA Manager

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
Estudio de estabilidad



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AN ISO 9001:2015 Certified Company

ACCELERATED STABILITY STUDY REPORT				
Name of Product	Atorvastatin Tablets 20 mg	Batch No.	MD749	
Description of the pack	10's Alu-PVC Blister pack	Mfg. Date	Oct 2018	
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT.	Expiry Date	Sept 2021	
		Storage Conditions:	40°C ± 2°C and 75% ± 5% RH	
Date of Initiation	Oct 2018	Date of completion	Apr 2019	
TEST	LIMITS	RESULTS OF ANALYSIS		
		Initial	3 months	6 months
Description	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.
Identification	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	-	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.
Average Weight	176.7 mg to 193.3 mg	187.15 mg	-	186.45 mg
D.T.	NMT 15 min	2 min	1 min	1 min
Dissolution	NLT 80% (Q) dissolved in 15 min	1] 93.51%	1] 92.70%	1] 93.76%
		2] 94.16%	2] 92.70%	2] 92.68%
		3] 92.65%	3] 93.12%	3] 92.25%
		4] 94.16%	4] 93.98%	4] 92.90%
		5] 94.59%	5] 94.41%	5] 90.74%
		6] 94.80%	6] 93.98%	6] 92.25%
Uniformity of dosage units	NMT 15.0 When determined on 10 individual units	1.6	-	1.9
Organic Impurities:				
Atorvastatin Pyrimidine Analog	NMT 0.5%	0.069%	0.071%	0.079%
Atorvastatin Related Compound H	NMT 1.0%	0.167%	0.166%	0.170%
Atorvastatin epoxy pyrroloxazin 6 hydroxy analog	NMT 0.5%	0.021%	0.026%	0.029%
Atorvastatin epoxy pyrroloxazin 7 hydroxy analog	NMT 0.5%	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy THF analog	NMT 0.25%	0.011%	0.013%	0.015%

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Estudio de estabilidad

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ACCELERATED STABILITY STUDY REPORT					
Name of Product	Atorvastatin Tablets 20 mg		Batch No.	MD749	
Description of the pack	10's Alu-PVC Blister pack		Mfg. Date	Oct 2018	
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT		Expiry Date	Sept 2021	
			Storage Conditions	40°C ± 2°C and 75% ± 5% RH	
Date of Initiation	Oct 2018		Date of completion	Apr 2019	
TEST	LIMITS	RESULTS OF ANALYSIS			
		Initial	3 months	6 months	
Atorvastatin related compound D	NMT 0.35 to 0.5 (if Atorvastatin epoxy THF analog is integrated together)	Not Detected	Not Detected	Not Detected	
Any other unspecified degradation product	NMT 0.2%	0.089%	0.090%	0.096%	
Total degradation	NMT 4.0%	0.360%	0.378%	0.405%	
Assay	94.5% to 105.0%	99.85%	99.22%	98.88%	
Microbial Limit Test					
Total aerobic microbial count					
Bacterial Counts	NMT 1000 cfu/gm	45 cfu/g	45 cfu/g	45 cfu/g	
Fungi	NMT 100 cfu/gm	Absent	Absent	Absent	
Test for specified microorganisms:					
E. Coli	Absent in 1 gm	Absent	Absent	Absent	
Salmonellae	Absent in 10 gm	Absent	Absent	Absent	
Pseudomonas	Absent in 1 gm	Absent	Absent	Absent	
Stap. aureus	Absent in 1 gm	Absent	Absent	Absent	

Approved By:
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 QA Manager

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
Estudio de estabilidad

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ACCELERATED STABILITY STUDY REPORT

Name of Product	Atorvastatin Tablets 20 mg	Batch No.	MD750	
Description of the pack	10's Alu-PVC Blister pack	Mfg. Date	Oct 2018	
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT.	Expiry Date	Sept 2021	
		Storage Conditions	40°C ± 2°C and 75% ± 5% RH	
Date of Initiation	Oct 2018	Date of completion	Apr 2019	
TEST	LIMITS	RESULTS OF ANALYSIS		
		Initial	3 months	6 months
Description	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.
Identification	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	-	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.
Average Weight	176.7 mg to 195.3 mg	188.01%	-	186.12%
D.T.	NMT 15 min	1 min	1 min	1 min
Dissolution	NLT 80% (Q) dissolved in 15 min	1) 94.80% 2) 95.23% 3) 92.44% 4) 93.51% 5) 94.16% 6) 93.30%	1) 92.91% 2) 91.84% 3) 92.27% 4) 92.03% 5) 93.77% 6) 92.27%	1) 92.68% 2) 92.46% 3) 92.25% 4) 92.90% 5) 90.74% 6) 90.96%
Uniformity of dosage units	NMT 15.0 When determined on 10 individual units	1.9	-	2.5
Organic Impurities:				
Atorvastatin Pyrididone Analog	NMT 0.5%	0.074%	0.077%	0.081%
Atorvastatin Related Compound H	NMT 1.0%	0.160%	0.169%	0.175%
Atorvastatin epoxy pyrroloxazin 6 hydroxy analog	NMT 0.5%	0.027%	0.021%	0.031%
Atorvastatin epoxy pyrroloxazin 7 hydroxy analog	NMT 0.5%	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy THF analog	NMT 0.25%	0.015%	0.020%	0.024%

ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg
Estudio de estabilidad



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AN ISO 9001:2015 CERTIFIED COMPANY

ACCELERATED STABILITY STUDY REPORT

Name of Product	Atorvastatin Tablets 20 mg	Batch No.	MD750	
Description of the pack	10's Alu-PVC Blister pack	Mfg. Date	Oct 2018	
Parameters and test method monitored	Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and MLT	Expiry Date	Sept 2021	
		Storage Conditions	40°C ± 2°C and 75% ± 5% RH	
Date of Initiation	Oct 2018	Date of completion	Apr 2019	

TEST	LIMITS	RESULTS OF ANALYSIS		
		Initial	3 months	6 months
Atorvastatin related compound D	NMT 0.35 to 0.5 (if Atorvastatin epoxy THF analog is integrated together)	Not Detected	Not Detected	Not Detected
Any other unspecified degradation product	NMT 0.2%	0.082%	0.086%	0.089%
Total degradation	NMT 4.0%	0.374%	0.395%	0.415%
Assay	94.5% to 105.0%	99.56%	99.11%	98.86%

Microbial Limit Test

Total aerobic microbial count

Bacterial Counts	NMT 1000 cfu/ gm	30 cfu/g	35 cfu/g	35 cfu/g
Fungi	NMT 100 cfu/ gm	Absent	Absent	Absent

Test for specified microorganisms:


E. Coli	Absent in 1 gm	Absent	Absent	Absent
Salmonellae	Absent in 10 gm	Absent	Absent	Absent
Pseudomonas	Absent in 1 gm	Absent	Absent	Absent
Stap. Aureus	Absent in 1 gm	Absent	Absent	Absent



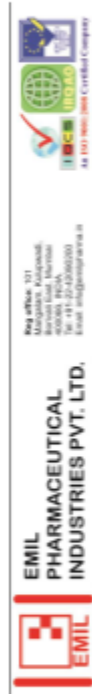
S. M. Daptardar
Approved By:
Mr. S. M. Daptardar
QA Manager

Estudio de estabilidad

b) Estudio de estabilidad a tiempo real:

 EMIL PHARMACEUTICAL INDUSTRIES PVT. LTD. Reg. office: 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000									
REAL TIME STABILITY STUDY REPORT Name of Product: Atorvastatin Tablets 20 mg Description of the pack: 10's Atorvastatin Tablets Parameters and Test methods mentioned: Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and M.T. Date of Initiation: Oct 2018 Date of completion: Dec 2022 Batch No: MD248 Mfg. Date: Oct 2018 Expiry Date: Sept 2021 Storage conditions: 30°C ± 2°C and 65% ± 5% RH									
Test		Initial	3 months	6 months	9 months	12 months	18 months	24 months	36 months
Description	Initial	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.	White to off white biconvex film coated tablets plain on both sides.
	Final	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.	The retention time of the major peak in the chromatogram of assay preparation corresponds to that of the standard preparation obtained as directed in the assay for Atorvastatin.
Average Weight		176.7 mg to 195.3 mg	-	-	-	-	-	-	-
D.T.		NMT 1.5 min	1 min	2 min	1 min	2 min	1 min	2 min	1 min


Estudio de estabilidad



REAL TIME STABILITY STUDY REPORT

Name of Product		Auro-musnam Tablets 20 mg		Batch No.		Mfg. Date					
Description of the pack		10's Alu-PVC Blister pack		Oct 2018		Sep 2021					
Parameters and Test methods monitored		Description, Identification, Average weight, D.T., Disintegration, Uniformity of Dosage Units, Organic Impurities, Assay and M.L.T.		Storage conditions		30°C ± 2°C and 65% ± 5% RH					
Date of Initiation		Oct 2018		Date of completion		Dec 2022					
Test	Limit	Initial	RESULTS OF ANALYSIS								
			3 months	6 months	9 months	12 months	18 months	24 months	36 months	39 months	
Disintegration	NLT 80% QD dissolved in 15 min	1) 94.65%	1) 93.42%	1) 93.54%	1) 93.95%	1) 90.78%	1) 92.36%				
		2) 93.14%	2) 93.64%	2) 92.68%	2) 92.37%	2) 92.29%	2) 92.13%				
		3) 92.49%	3) 94.07%	3) 92.25%	3) 91.89%	3) 91.43%	3) 90.65%				
		4) 90.98%	4) 91.05%	4) 90.74%	4) 90.60%	4) 91.64%	4) 91.28%				
		5) 93.14%	5) 90.83%	5) 90.31%	5) 90.16%	5) 91.21%	5) 90.22%				
		6) 93.57%	6) 93.64%	6) 93.33%	6) 92.79%	6) 91.64%	6) 90.65%				
Uniformity of dosage units	When determined on 10 individual units	1.9	-	-	-	-	-				
Organic Impurities											
Auro-musnam Perindolol Analog	NMT 0.5%	0.077%	0.087%	0.073%	0.082%	0.091%	0.091%	0.091%			
Auro-musnam Related Compound H	NMT 1.0%	0.166%	0.177%	0.172%	0.186%	0.196%	0.196%	0.210%			
Auro-musnam epi-9-epi-6 hydroxy analog	NMT 0.5%	0.026%	0.030%	0.035%	0.036%	0.042%	0.042%	0.046%			
Auro-musnam epi-9-epi-7 hydroxy analog	NMT 0.5%	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected			
Auro-musnam epi-9-THF analog	NMT 0.25%	0.010%	0.013%	0.019%	0.021%	0.023%	0.023%	0.023%			

Estudio de estabilidad




**EMIL
PHARMACEUTICAL
INDUSTRIES PVT. LTD.**

REAL TIME STABILITY STUDY REPORT

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Name of Product		Batch No.		Mfg. Date		Exp. Date	
Description of the pack		10% Alfa-PVC Blister pack		Oct 2018		Sept 2021	
Parameters and Test methods employed		Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and M.L.T.		Storage condition		30°C ± 2°C and 65% ± 5% RH	
Date of Initiation		Oct 2018		Date of completion		Dec 2022	
RESULTS OF ANALYSIS							
Test	Limit	Initial	3 months	6 months	9 months	12 months	18 months
NSMT 0.25 to 0.5 (if Assay is not done)	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Assay	NSMT 0.2%	0.08%	0.08%	0.09%	0.09%	0.10%	0.11%
Total degradation	NSMT 4.0%	0.37%	0.41%	0.46%	0.41%	0.42%	0.43%
Assay	98.9% to 101.0%	99.8%	99.5%	99.3%	99.1%	98.8%	98.7%
M.L.T. result 1 month							
Total Sample and Refill Count		35 c/g		40 c/g		35 c/g	
NSMT 1000 c/g		35 c/g		40 c/g		35 c/g	
NSMT 100 c/g		Absent		Absent		Absent	
Fungus		Absent		Absent		Absent	
Test for specific microorganism							
E. Coli	Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent
Salmonella	Absent in 10 g	Absent	Absent	Absent	Absent	Absent	Absent
Pseudomonas	Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent
Staph. aureus	Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent


Remark: Stability data found satisfactory up to 18 months further stability to be continue as per protocol.






QA

Approved by:
Mr. S. M. Dhanraj
QA Manager

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 ISO 9001:2015
 ISO 14001:2015
 ISO 45001:2018
 ISO 13485:2015
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Estudio de estabilidad



REAL TIME STABILITY STUDY REPORT

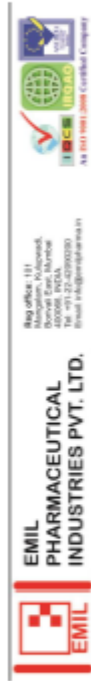
MOA, TOX, STABILITY & CLT REPORT											
Name of Product		Atorvastatin Tablets 20 mg		Batch No.		MOA		Tox		Stability	
Description of the pack		10's Alu-PVC Blister pack		Mfg. Date		Exp. Date		MOA		Tox	
Parameters and Test methods monitored		Description, Identification, Average weight, D.T., Disposition, Uniformity of Dosage Units, Organic Impurities, Assay and M.T.		Storage conditions		30°C ± 2°C and 65% ± 5% RH		MOA		Tox	
Date of Initiation		Oct 2018		Date of completion		Dec 2022		MOA		Tox	
Test		Limit	Initial	3 months	6 months	9 months	12 months	18 months	24 months	36 months	39 months
Atorvastatin related compound D		NDMT 0.35 to 0.5 (if Atorvastatin epoxy TIR analog is integrated together)	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Any other unspecified degradation product		NDMT 0.2%	0.08%	0.09%	0.09%	0.11%	0.11%	0.12%	0.12%	0.12%	0.12%
Total degradation		NDMT 4.0%	0.36%	0.40%	0.40%	0.41%	0.42%	0.43%	0.43%	0.43%	0.43%
Assay		94.5% to 105.0%	99.85%	99.44%	99.05%	98.78%	98.66%	98.59%	98.59%	98.59%	98.59%
Microbial Limit Test											
Total aerobic microbial count											
Bacterial Count		NDMT 1000 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g	45 cfu/g
Fungi		NDMT 100 cfu/g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Test for specified microorganisms:											
E. Coli		Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Salmonella		Absent in 10 g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Pseudomonas		Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Staph. Aureus		Absent in 1 g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent

Remarks: Stability data found satisfactory up to 36 months further stability to be continue as per protocol.

QA
Approved By:
Mr. S. M. Desai
QA Manager

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Estudio de estabilidad



REAL TIME STABILITY STUDY REPORT										
Name of Product		Atorvastatin Tablets 20 mg			Batch No.		MO750			
Description of the pack		10 x Atorvastatin 20 mg blister pack			Mfg. Date		Oct. 2018			
Parameters and Test methods monitored		Description, Identification, Average weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and M.L.T.			Expiry Date		Sept. 2021			
Date of Initiation		Oct. 2018			Storage conditions		30°C ± 2°C and 65% ± 5% RH			
Test		Initial	3 months	6 months	9 months	12 months	18 months	24 months	36 months	48 months
Dissolution		1) 94.30% 2) 93.23% 3) 92.44% 4) 93.51% 5) 94.16% 6) 93.30%	1) 94.19% 2) 93.77% 3) 92.70% 4) 93.12% 5) 93.98% 6) 94.19%	1) 93.76% 2) 92.90% 3) 92.68% 4) 92.28% 5) 92.46% 6) 91.82%	1) 91.35% 2) 92.20% 3) 91.76% 4) 92.85% 5) 92.40% 6) 91.98%	1) 91.35% 2) 92.65% 3) 91.35% 4) 92.45% 5) 92.00% 6) 91.56%	1) 91.19% 2) 91.62% 3) 91.62% 4) 91.84% 5) 91.19% 6) 90.97%			
Uniformity of dosage units		1.9	-	-	-	-	-			
Organic Impurities										
Atorvastatin		NSMT 0.5%	0.077%	0.034%	0.086%	0.087%	0.092%			
Pyridine/Analog		NSMT 0.5%	0.077%	0.034%	0.086%	0.087%	0.092%			
Atorvastatin Related Compound H		NSMT 1.0%	0.170%	0.170%	0.181%	0.186%	0.210%			
Atorvastatin epoxy pyridoxazin 6 hydroxymethyl		NSMT 0.5%	0.030%	0.034%	0.036%	0.042%	0.043%			
Atorvastatin epoxy pyridoxazin 7 hydroxymethyl		NSMT 0.5%	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected			
Atorvastatin epoxy THF analog		NSMT 0.25%	0.016%	0.019%	0.021%	0.026%	0.031%			



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INDUSTRIES PVT. LTD.

REAL TIME STABILITY STUDY REPORT

Name of Product		Batch No.		Mfg. Date		Exp. Date													
Description of the pack		10's Alu-PVC Blister pack		Mfg. Date		Exp. Date													
Parameters and Test methods monitored		Description, Identification, Avem. g weight, D.T., Dissolution, Uniformity of Dosage Units, Organic Impurities, Assay and M.L.T.		Storage conditions		30°C ± 2°C and 65% ± 5% RH													
Date of Initiation		Oct 2018		Date of completion		Dec 2022													
Test		Initial		3 months		6 months		9 months		12 months		18 months		24 months		36 months		39 months	
Limit		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Assay		0.082%		0.086%		0.091%		0.095%		0.099%		0.103%		0.107%		0.111%		0.115%	
Dissolution		0.374%		0.397%		0.421%		0.445%		0.469%		0.493%		0.517%		0.541%		0.565%	
Assay		94.9% to 105.0%		99.26%		99.04%		98.80%		98.56%		98.32%		98.08%		97.84%		97.60%	
Microbial Limit Test		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Total aerobic microbial count		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Bacterial Count		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Fungal		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Test for specified microorganisms:		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
E. Coli		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Salmonella		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Pseudomonas		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	
Staph. aureus		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected		Not Detected	

Remarks: Stability data found satisfactory up to 36 months further stability to be continue as per protocol.



Approved by:
Mr. S. M. Desai
QA Manager

IV. DISCUSIÓN

De acuerdo a los resultados obtenidos en el Estudio de Estabilidad, tanto Acelerado como a Tiempo Real de los lotes MD748, MD749 y MD750 se puede verificar que los lotes estudiados no muestran deterioro físico o químico en el envase utilizado (Blíster ALU/PVC transparente), no se evidencia una disminución significativa en la valoración del activo, y los parámetros analizados se mantuvieron dentro de los límites especificados, durante 6 meses en el estudio acelerado y durante al menos 18 meses en el estudio a tiempo real, el cual sigue en curso.

V. CONCLUSIÓN

Basado en los datos adquiridos de los estudios de estabilidad a tiempo real y acelerado, se concluye provisoriamente que el producto analizado es estable por un periodo de 24 meses si se almacena en su envase original cerrado, a una temperatura no mayor a $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ y una humedad ambiental de $65\% \pm 5\%$.

VI. ESPECIFICACIÓN DE LA VIDA ÚTIL

Se propone un periodo de eficacia para ATORVASTATINA COMPRIMIDOS RECUBIERTOS 20 mg de 24 meses a partir de su fecha de fabricación almacenándolo en su envase original (Blister ALU/PVC transparente), a una temperatura ambiente no mayor a $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$, protegido de la humedad y la luz.