OPKO Chile S.A.

3.2.P.8.3 DATOS DEL ESTUDIO DE ESTABILIDAD

LOSARTÁN POTÁSICO
COMPRIMIDOS RECUBIERTOS 50 mg

A Subdepartamento Registros y Autorizaciones Sanitarias

EMIL
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ACCELRATED STABILITY STUDY REPORT

Name of product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8018
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and test method monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	40°C ± 2°C and 75% ± 5% RH
		Date of completion	Feb – 2019

TEST	**LIMITS**	**RESULTS OF ANALYSIS**		
		INITIAL	**3 Month**	**6 Month**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	104.5 mg	103.8 mg	105.8 mg
D.T	NMT 30 Mins.	6 mins 45 sec	7 mins	8 min
Dissolution	N.L.T. 75.0% (Q)	1]91% 2]93% 3]93% 4]95% 5]95% 6]96%	1]91% 2]90% 3]92% 4]92% 5]94% 6]94%	1]91% 2]91% 3]93% 4]94% 5]91% 6]90%
Organic Impurities				
1-H-Dimer:	N.M.T. 0.5%	0.009%	0.010%	0.012%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.002%
Total Impurity	N.M.T. 1.0%	0.009%	0.010%	0.014%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.4	-	3.1
Assay	95.0% to 105.0%	101.3%	100.45%	99.80%
Microbial Limit Test				
Total aerobic microbial count				
Bacterial Counts	NMT 1000 cfu/gm	50 cfu/gm	-	40 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	Nil
Test for specified microorganisms:				
E.coli	Absent in 1 gm	Absent	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	Absent
Stap.aureus	Absent in 1 gm	Absent	-	Absent

EMIL PHARMACEUTICALS IND. PVT. LTD. QA

SMDaptardar

Approved By
Mr. S. M. Daptardar
QA Manager

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REAL TIME STABILITY STUDY REPORT

Name of Product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8018
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and Test methods monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	30°C ± 2°C and 75% ± 5% RH
		Date of completion	Aug – 2021

TESTS	**LIMITS**	**RESULTS OF ANALYSIS**							
		INITIAL	**3 Months**	**6 Months**	**9 Months**	**12 Months**	**18 months**	**24 Months**	**36 Months**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	104.5 mg	103.2 mg	105.6 mg	104.8 mg	104.5 mg	103.7 mg	103.5 mg	105.8 mg
D.T	NMT 30 Mins.	6 mins 45 sec	7 min	7 min 15 sec	8 min	8 min	8 min 20 sec	8 min 45 sec	9 min
Dissolution	N.L.T. 75.0% (Q)	1]91% 2]93% 3]93% 4]95% 5]95% 6]96%	1]91% 2]90% 3]92% 4]94% 5]95% 6]94%	1]92% 2]91% 3]93% 4]93% 5]92% 6]94%	1]92% 2]93% 3]93% 4]91% 5]93% 6]94%	1]91% 2]93% 3]93% 4]95% 5]94% 6]91%	1]93% 2]93% 3]90% 4]94% 5]91% 6]91%	1]93% 2]92% 3]91% 4]90% 5]89% 6]90%	1]91% 2]89% 3]91% 4]92% 5]88% 6]91%

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Name of Product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8018
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and Test methods monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, M.L.T.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	30°C ± 2°C and 75% ± 5% RH
		Date of completion	Aug – 2021

TESTS	LIMITS	RESULTS OF ANALYSIS							
		INITIAL	**3 Months**	**6 Months**	**9 Months**	**12 Months**	**18 months**	**24 Months**	**36 Months**
Organic Impurities									
1-H-Dimer:	N.M.T. 0.5%	0.009%	0.010%	0.013%	0.015%	0.016%	0.018%	0.021%	0.022%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.001%	0.003%	0.005%	0.006%	0.008%	0.009%
Total Impurity	N.M.T. 1.0%	0.009%	0.010%	0.014%	0.018%	0.021%	0.024%	0.029%	0.031%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.4	-	-	-	-	-	-	2.7
Assay	95.0% to 105.0%	101.3%	100.90%	100.75%	100.50%	100.20%	99.90%	99.70%	99.45%
Microbial Limit Test									
Total aerobic microbial count									
Bacterial Counts	NMT 1000 cfu/gm	50 cfu/gm	-	-	-	-	-	-	55 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	-	-	-	-	-	Nil
Test for specified microorganisms:									
E.coli	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	-	-	-	-	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Staph aureus	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent

EMIL PHARMACEUTICALS IND PVT LTD QA

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ACCELRATED STABILITY STUDY REPORT

Name of product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8019
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and test method monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	40°C ± 2°C and 75% ± 5% RH
		Date of completion	Feb – 2019

TEST	**LIMITS**	**RESULTS OF ANALYSIS**		
		INITIAL	**3 Month**	**6 Month**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	103.7 mg	104.2 mg	104.2 mg
D.T	NMT 30 Mins.	6 min	8 min	8 min
Dissolution	N.L.T. 75.0% (Q)	1]95% 2]97% 3]95% 4]96% 5]93% 6]93%	1]92% 2]92% 3]91% 4]91% 5]95% 6]94%	1]94% 2]93% 3]91% 4]91% 5]95% 6]90%
Organic Impurities				
1-H-Dimer:	N.M.T. 0.5%	0.006%	0.008%	0.010%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.001%
Total Impurity	N.M.T. 1.0%	0.006%	0.008%	0.011%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.3	-	3.4
Assay	95.0% to 105.0%	100.2%	99.95%	99.70%
Microbial Limit Test				
Total aerobic microbial count				
Bacterial Counts	NMT 1000 cfu/gm	60 cfu/gm	-	30 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	Nil
Test for specified microorganisms:				
E.coli	Absent in 1 gm	Absent	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	Absent
Stap.aureus	Absent in 1 gm	Absent	-	Absent

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Approved By
Mr. S. M. Daptardar
QA Manager

REAL TIME STABILITY STUDY REPORT

Name of Product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8019
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and Test methods monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	30°C ± 2°C and 75% ± 5% RH
		Date of completion	Aug – 2021

TESTS	**LIMITS**	**RESULTS OF ANALYSIS**							
		INITIAL	**3 Months**	**6 Months**	**9 Months**	**12 Months**	**18 months**	**24 Months**	**36 Months**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	103.7 mg	103.8 mg	103.2 mg	105.7 mg	104.7 mg	103.5 mg	104.4 mg	104.9 mg
D.T	NMT 30 Mins.	6 min	6 min 40 sec	7 min	7 min 25 sec	8 min	8 min 10 sec	8 min 30 sec	8 min
Dissolution	N.L.T. 75.0% (Q)	1]95% 2]97% 3]95% 4]96% 5]93% 6]93%	1]95% 2]94% 3]94% 4]92% 5]93% 6]95%	1]95% 2]94% 3]93% 4]92% 5]92% 6]94%	1]93% 2]95% 3]93% 4]92% 5]91% 6]94%	1]93% 2]94% 3]92% 4]94% 5]91% 6]91%	1]91% 2]93% 3]92% 4]94% 5]90% 6]92%	1]93% 2]91% 3]90% 4]89% 5]93% 6]93%	1]91% 2]90% 3]92% 4]93% 5]89% 6]91%

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Name of Product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8019
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and Test methods monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	30°C ± 2°C and 75% ± 5% RH
		Date of completion	Aug – 2021

TESTS	LIMITS	RESULTS OF ANALYSIS							
		INITIAL	3 Months	6 Months	9 Months	12 Months	18 months	24 Months	36 Months
Organic Impurities									
1-H-Dimer:	N.M.T. 0.5%	0.006%	0.009%	0.011%	0.013%	0.015%	0.017%	0.019%	0.021%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.002%	0.004%	0.006%	0.008%	0.010%	0.011%
Total Impurity	N.M.T. 1.0%	0.006%	0.009%	0.013%	0.017%	0.021%	0.025%	0.029%	0.032%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.3	-	-	-	-	-	-	4.1
Assay	95.0% to 105.0%	100.2%	99.80%	99.65%	99.50%	99.30%	99.15%	98.80%	98.65%
Microbial Limit Test									
Total aerobic microbial count									
Bacterial Counts	NMT 1000 cfu/gm	40 cfu/gm	-	-	-	-	-	-	45 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	-	-	-	-	-	Nil
Test for specified microorganisms:									
E.coli	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	-	-	-	-	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Staph.aureus	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent

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Approved By
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ACCELRATED STABILITY STUDY REPORT

Name of product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8020
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and test method monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	40°C ± 2°C and 75% ± 5% RH
		Date of completion	Feb – 2019

TEST	**LIMITS**	**RESULTS OF ANALYSIS**		
		INITIAL	**3 Month**	**6 Month**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	106.8 mg	104.8 mg	105.8 mg
D.T	NMT 30 Mins.	7 min	7 min 20 sec	8 min 10 sec
Dissolution	N.L.T. 75.0% (Q)	1]95% 2]97% 3]94% 4]93% 5]96% 6]94%	1]95% 2]93% 3]92% 4]91% 5]93% 6]93%	1]95% 2]92% 3]91% 4]92% 5]92% 6]91%
Organic Impurities				
1-H-Dimer:	N.M.T. 0.5%	None detected	0.006%	0.009%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.002%
Total Impurity	N.M.T. 1.0%	None detected	0.006%	0.011%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.5	-	2.1
Assay	95.0% to 105.0%	101.0%	100.75%	100.40%
Microbial Limit Test				
Total aerobic microbial count				
Bacterial Counts	NMT 1000 cfu/gm	50 cfu/gm	-	55 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	Nil
Test for specified microorganisms:				
E.coli	Absent in 1 gm	Absent	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	Absent
Stap.aureus	Absent in 1 gm	Absent	-	Absent

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REAL TIME STABILITY STUDY REPORT

Name of Product	Losartan Potassium Tablet 50 mg	**Batch No**	EMD8020
Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
Parameters and Test methods monitored	Description, Identification, Avg. Wt, D.T., Dissolution, Organic Impurities, Assay, MLT.	**Expiry Date**	Jul – 2021
Date of Initiation	Aug – 2018	**Storage conditions**	30°C ± 2°C and 75% ± 5% RH
		Date of completion	Aug – 2021

TESTS	**LIMITS**	**RESULTS OF ANALYSIS**							
		INITIAL	**3 Months**	**6 Months**	**9 Months**	**12 Months**	**18 months**	**24 Months**	**36 Months**
Description	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.	Pink coloured round biconvex, film coated tablet with V2 embossing on one side & plain on other side.
Identification	The retention time of the major peak of the sample solution corresponds to that of the standard solutions obtained in assay.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Avg. Wt	95.27 mg – 110.72 mg	106.8 mg	105.9 mg	106.1 mg	104.5 mg	103.9 mg	104.7 mg	105.1 mg	103.7 mg
D.T	NMT 30 Mins.	7 min	7 min 30 sec	7 min 50 sec	8 min	8 min	8 min 20 sec	8 min 45 sec	9 min
Dissolution	N.L.T. 75.0% (Q)	1]95% 2]97% 3]94% 4]93% 5]96% 6]94%	1]95% 2]93% 3]94% 4]94% 5]93% 6]94%	1]93% 2]95% 3]94% 4]92% 5]96% 6]93%	1]94% 2]92% 3]93% 4]95% 5]93% 6]93%	1]95% 2]93% 3]94% 4]92% 5]94% 6]91%	1]93% 2]91% 3]93% 4]94% 5]93% 6]94%	1]93% 2]92% 3]94% 4]93% 5]91% 6]91%	1]93% 2]93% 3]92% 4]90% 5]89% 6]91%

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Description of the pack	10's Alu – PVC Blister pack	**Mfg. Date**	Aug – 2018
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		Storage conditions	30°C ± 2°C and 75% ± 5% RH
Date of Initiation	Aug – 2018	**Date of completion**	Aug – 2021

TESTS	**LIMITS**	**RESULTS OF ANALYSIS**							
		INITIAL	**3 Months**	**6 Months**	**9 Months**	**12 Months**	**18 months**	**24 Months**	**36 Months**
Organic Impurities									
1-H-Dimer:	N.M.T. 0.5%	None detected	0.005%	0.008%	0.009%	0.011%	0.012%	0.014%	0.016%
2-H-Dimer:	N.M.T. 0.5%	None detected	None detected	0.002%	0.005%	0.005%	0.007%	0.009%	0.010%
Total Impurity	N.M.T. 1.0%	None detected	0.005%	0.010%	0.014%	0.016%	0.019%	0.023%	0.026%
Uniformity of Content	NMT 15.0 when determined on 10 individual limits	2.5	-	-	-	-	-	-	3.5
Assay	95.0% to 105.0%	101.0%	100.89%	100.75%	100.55%	100.30%	99.99%	99.70%	99.45%
Microbial Limit Test									
Total aerobic microbial count									
Bacterial Counts	NMT 1000 cfu/gm	50 cfu/gm	-	-	-	-	-	-	45 cfu/gm
Fungi	NMT 100 cfu/gm	Nil	-	-	-	-	-	-	Nil
Test for specified microorganisms:									
E.coli	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Salmonellae	Absent in 10 gm	Absent	-	-	-	-	-	-	Absent
Pseudomonas	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent
Stap.aureus	Absent in 1 gm	Absent	-	-	-	-	-	-	Absent

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