

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white coloured, elongated, biconvex, one side scored & film coated tablets. 6 tablets packed in an alu-alu blister of printed aluminium foil & base aluminium foil.	Off white coloured, elongated, biconvex, one side scored & film coated tablets. 6 tablets packed in an alu-alu blister of printed aluminium foil & base aluminium foil.
2	Identification	As below	As below

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
2.a	By HPLC	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution.(one peak due to Amoxycillin & other due to Potassium Clavulanate).	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution.(one peak due to Amoxycillin & other due to Potassium Clavulanate).
2.b	By Lactic Acid Bacillus	Gram positive rods with terminal spores should be observed.	Complies
3	Dimension	As below	As below
3.a	Length	19.9 mm $\pm$ 0.2 mm	20.00 mm

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
3.b	Width	8.9 mm $\pm$ 0.2 mm	8.94 mm
3.c	Thickness	6.4 mm $\pm$ 0.4 mm	6.32 mm
4	Average weight	1127.0 mg $\pm$ 5.0%	1093.59 mg
5	Uniformity of weight	Within $\pm$ 5.0 % of average weight.	-1.7% to +2.4%
6	Disintegration Time	Not more than 30 minutes	Passes (05 Minutes 29 Seconds)
7	Water	Not more than 10.0% w/w	6.85 %w/w
8	Dissolution .	As below	As below

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
8.a	For Amoxycillin .	S1- Each tablet is not less than 90% of the labeled amount dissolved in 30 minutes. If the results do not conform to the requirements at the stage S1, continue testing with additional tablets through stages S2 and S3 unless the result conforms at stage S2. S2- Average of 12 tablets (S1+S2) is equal to or greater than 85%, and no tablet is less than 70%. S3- Average of 24 tablets (S1+S2+S3) is equal to or greater than 85%, not more than 2 tablets are less than 70%, and no tablet is less than 60%.	1=101.35%, 2=99.83%, 3=98.79%, 4=96.73%, 5=94.30%, 6=94.18%, Min.94.18%, Max.101.35%, Mean 97.53%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
8.b	For Clavulanic Acid .	S1- Each tablet is not less than 85% of the labeled amount dissolved in 30 minutes. If the results do not conform to the requirements at the stage S1, continue testing with additional tablets through stages S2 and S3 unless the result conforms at stage S2. S2- Average of 12 tablets (S1+S2) is equal to or greater than 80%, and no tablet is less than 65%. S3- Average of 24 tablets (S1+S2+S3) is equal to or greater than 80%, not more than 2 tablets are less than 65%, and no tablet is less than 55%.	1=102.64%, 2=101.77%, 3=101.64%, 4=100.95%, 5=101.26%, 6=101.15%, Min.100.95%, Max.102.64%, Mean 101.57%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
9	Uniformity Content of Clavulanic Acid .	85% to 115% of Average value		1=99.28%, 2=98.89%, 3=99.47%, 4=100.30%, 5=99.83%, 6=100.63%, 7=100.33%, 8=100.19%, 9=101.07%, 10=100.84%, Min.98.81%, Max.100.98%, Mean 100.08%
10	Assay - Each film coated tablet contains:	Shelf Life Limit	Release Limit	

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
10.a	Amoxycillin Trihydrate IP eq. to Amoxycillin - 500 mg/Tab	NLT 450.00mg/Tab to NMT 600.00mg/Tab (NLT 90.00% to NMT120.00% of label claimed)	NLT 475.00mg/Tab to NMT 600.00mg/Tab (NLT 95.00% to NMT120.00% of label claimed)	501.77mg 100.35%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
10.b	Potassium Clavulanate Diluted IP eq. to Clavulanic Acid - 125 mg/Tab	NLT 112.50mg/Tab to NMT 150.00mg/Tab (NLT 90.00% to NMT120.00% of label claimed)	NLT 118.75mg/Tab to NMT 150.00mg/Tab (NLT 95.00% to NMT120.00% of label claimed)	126.09mg 100.87%

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)**

Product Name :	HEALCLAV LB 625 TABLETS		
Generic Name :	Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AD09	A. R. No.:	F20240226008
Mfg. Date :	Feb. 2024	Pack Size:	1x6 Tablets
Expiry date:	Jan. 2026	Pack Type:	Alu-Alu Blister
Batch Size :	156000 Tablets	Sampled On:	26/02/24
Product Code :	40045519	Sample Quantity:	6 Tablets
Specification No, Ver No.:	STS/FP/40045519-00	Sampled By:	MUKESH LALMAN VISHWAKARMA
Ref. STP No. , Ver No.:	STP/FP/0072-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	26/02/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	27/02/24

S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
10.c	Lactic Acid Bacillus - 60 million spores/tab	Not less than 54.00million spores/tab (Not less than 90.00% of label claimed)	Not less than 57.00million spores/tab (Not less than 95.00% of label claimed)	67.17million spores 111.95%

CONCLUSION : The Finished Product complies as per IH Specifications.

	Prepared By QC	Reviewed By QC	Approved By QC
Date	27/02/24	27/02/24	27/02/24
Name	Gaurav Kumar	Jai Prakash Singh	Sudhir Sharma
Designation	EXECUTIVE	MANAGER	SR. MANAGER

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

Name : Shivam Chauhan ; Date : 28/02/2024