LUPIN

QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	:	**LINEZOLID TABLETS 600MG GDF 10X10**			
Batch No.	:	**J303750**	**Q.C.Ref.No**	:	**40001643224**
Mfg. Date	:	**04.2023**	**Exp. Date**	:	**03.2026**
Date of Release	:	**12.05.2023**	**Batch Size**	:	**1,271.00 BOX**
Specification No.	:	**FPS 316367-06**			

TESTS	OBSERVATIONS	SPECIFICATIONS
Description	White coloured, oval shaped, beveled edges,biconvex, film coated tablet having score line on one side and plain on other side.	White to off white coloured, oval shaped, beveled edges, biconvex, film coated tablet having score line on one side and plain on other side.
Identification(By HPLC)	The retention time of the Linezolid peak in the chromatogram of the test preparation corresponds to that of the standard preparation as obtained in the assay.	The retention time of the Linezolid peak in the chromatogram of the test preparation corresponds to that of the standard preparation as obtained in the assay.
Identification (By UV)	The test preparation exhibit the maxima at same wavelength as that obtained in the standard preparation.	The test preparation should exhibit the maxima at same wavelength as that obtained in the standard preparation.
Color identification test for Titanium dioxide	An orange red colour is produced in the test preparation.	An orange red colour is produced in the test preparation.
Average weight (mg)	873.96mg	875.50 mg ±3% (849.24 to 901.77mg)
Uniformity of dosage units by massvariation	103%	Content of each unit should be between 510.0mg to 690.0mg (85% - 115% of the label claim)
Content Minimum	101%	Content of each unit should be between 510.0mg to 690.0mg (85% -

Remarks : Approved as per above specification.

COMPILED BY
Bhupesh Kumar

APPROVED BY
Jitender Singh Patial

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Registered Office :Kalpataru Inspire,3rd FLR,Santacruz (E), Mumbai-400055.(Maharashtra) India. Tel.: (91-22) 6640 2222, (91-22) 6640 2323. Fax : (91-22) 6640 2299. Website : www.lupin.com

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Specification No.	:	**FPS 316367-06**			

TESTS	OBSERVATIONS	SPECIFICATIONS
		115% of the label claim)
Content Maximum	104%	Content of each unit should be between 510.0mg to 690.0mg (85% - 115% of the label claim)
RSD	0.7%	Not more than 6.0%
Acceptance value	2.9%	Less than or equal to 15.0
Water Content (% w/w) (By KF Method A)	1.1%	Not more than 5.0 (Shelf life Limit) Not more than 2.5 (Release Limit)
Dissolution (%)Dissolution medium: 0.05 M Phosphate Buffer, Paddle, pH 6.8, 900 ml,50RPM, Temp. 37° C ± 0.5° C"	99%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
Dissolution minimum	98%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
Dissolution maximum	100%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
elated Substances	Complies	Should Comply
Linezolid impurity A	Not Detected	Not more than 0.2 (Shelf life Limit) Not more than 0.15 (Release Limit)
Any individual impurity	Below detection Limit	Not more than 0.17(Shelf life

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Specification No.	:	**FPS 316367-06**			

TESTS	OBSERVATIONS	SPECIFICATIONS
		Limit) Not more than 0.10(Release Limit)
Total impurity	Below detection Limit	Not more than 1.0 (Shelf life Limit) Not more than 1.0 (Release Limit)
Assay	Complies	Each film coated tablet contain Linezolid 600mg
Linezolid	615.6mg	(540.0-660.0) mg Shelf life Limit (570.0-630.0) mg Release Limit
% Linezolid	102.6%	(90.0 - 110.0)% Shelf life Limit (95.0 - 105.0)% Release Limit
Microbial Limits	Not Applicable	Should comply
Total aerobic microbial count (CFU/g)	Not Applicable	Not more than 10^3
Total combined yeast/ mould count	Not Applicable	Not more than 10^2
Escherichia Coli (in 1 g)	Not Applicable	Absent
Tablet divisibility by average mass%	Complies	Each split portion has not less than 85.0 to 115.0 of the expected weight of the split tablet portion.

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Product	:	**LINEZOLID TABLETS 600MG GDF 10X10**			
Batch No.	:	**J303752**	**Q.C.Ref.No**	:	**40001643501**
Mfg. Date	:	**04.2023**	**Exp. Date**	:	**03.2026**
Date of Release	:	**13.05.2023**	**Batch Size**	:	**1,269.00 BOX**
Specification No.	:	**FPS 316367-06**			

TESTS	OBSERVATIONS	SPECIFICATIONS
Description	White coloured, oval shaped, beveled edges,biconvex, film coated tablet having score line on one side and plain on other side.	White to off white coloured, oval shaped, beveled edges, biconvex, film coated tablet having score line on one side and plain on other side.
Identification(By HPLC)	The retention time of the Linezolid peak in the chromatogram of the test preparation corresponds to that of the standard preparation as obtained in the assay.	The retention time of the Linezolid peak in the chromatogram of the test preparation corresponds to that of the standard preparation as obtained in the assay.
Identification (By UV)	The test preparation exhibit the maxima at same wavelength as that obtained in the standard preparation.	The test preparation should exhibit the maxima at same wavelength as that obtained in the standard preparation.
Color identification test for Titanium dioxide	An orange red colour is produced in the test preparation.	An orange red colour is produced in the test preparation.
Average weight (mg)	874.99mg	875.50 mg ±3% (849.24 to 901.77mg)
Uniformity of dosage units by massvariation	103%	Content of each unit should be between 510.0mg to 690.0mg (85% - 115% of the label claim)
Content Minimum	102%	Content of each unit should be between 510.0mg to 690.0mg (85% -

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Product	:	**LINEZOLID TABLETS 600MG GDF 10X10**			
Batch No.	:	**J303752**	**Q.C.Ref.No**	:	**40001643501**
Mfg. Date	:	**04.2023**	**Exp. Date**	:	**03.2026**
Date of Release	:	**13.05.2023**	**Batch Size**	:	**1,269.00 BOX**
Specification No.	:	**FPS 316367-06**			

TESTS	OBSERVATIONS	SPECIFICATIONS
		115% of the label claim)
Content Maximum	105%	Content of each unit should be between 510.0mg to 690.0mg (85% - 115% of the label claim)
RSD	1.0%	Not more than 6.0%
Acceptance value	3.8%	Less than or equal to 15.0
Water Content (% w/w) (By KF Method A)	1.2%	Not more than 5.0 (Shelf life Limit) Not more than 2.5 (Release Limit)
Dissolution (%)Dissolution medium: 0.05 M Phosphate Buffer, Paddle, pH 6.8, 900 ml,50RPM, Temp. 37° C ± 0.5° C"	98%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
Dissolution minimum	97%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
Dissolution maximum	99%	NLT 80% (Q) of the labeled amount of Linezolid dissolved in 30 minutes.
Related Substances	Complies	Should Comply
Linezolid impurity A	Not Detected	Not more than 0.2 (Shelf life Limit) Not more than 0.15 (Release Limit)
Any individual impurity	Below detection Limit	Not more than 0.17(Shelf life

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TESTS	OBSERVATIONS	SPECIFICATIONS
		Limit) Not more than 0.10(Release Limit)
Total impurity	Below detection Limit	Not more than 1.0 (Shelf life Limit) Not more than 1.0 (Release Limit)
Assay	Complies	Each film coated tablet contain Linezolid 600mg
Linezolid	616.0mg	(540.0-660.0) mg Shelf life Limit (570.0-630.0) mg Release Limit
% Linezolid	102.7%	(90.0 - 110.0)% Shelf life Limit (95.0 - 105.0)% Release Limit
Microbial Limits	Not Applicable	Should comply
Total aerobic microbial count (CFU/g)	Not Applicable	Not more than 10^3
Total combined yeast/ mould count	Not Applicable	Not more than 10^2
Escherichia Coli (in 1 g)	Not Applicable	Absent
Tablet divisibility by average mass%	Complies	Each split portion has not less than 85.0 to 115.0 of the expected weight of the split tablet portion.

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