

L10-3

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**WORKING STANDARD CERTIFICATE
(Amendment)**

QUALIFICATION OF WORKING STANDARD

ITEM		: LINEZOLID INH (FORM II)	EVALUATED WITH : USPRS/PD/L5/01
			BATCH NO.: F0L495
DATE OF QUALIFICATION	:	17.12.2014	
DIRECTION FOR STORAGE	:	Store between 2°C to 8 °C in a well closed container and protected from light. #	
DIRECTION FOR USE	:	Use as such.	
DATE OF AMENDMENT- II	:	26.11.2015	
VALIDITY OF USE	:	16.12.2016	
WORKING STANDARD No.	:	WS/C/L52/04	
A. R. No.	:	PD1516686	
SOURCE B. No.	:	LNZE0040614	
AMENDED FOR THE TEST	:	Related substances method 3 (R)-Epichlorohydrin (BY GC) test Performed as per revised Specification.	
SOURCE A.R. No.	:	PD1414073	Page 1 of 2
REFERENCE: ACL0191/02&ACL0191A/03, Protocol No.: WP/INH/WS/C/L52, Version 02.			

Sr. No.	TESTS	STANDARDS	RESULTS
1	DESCRIPTION	A white to an off white crystalline powder.	Complies
2	*IDENTIFICATION A (By IR)	The Infrared absorption spectrum of the finely ground sample in potassium bromide dispersion compressed into a disc should exhibit maxima only at the same wave numbers as that of a similar preparation of Linezolid CRS (Form II).	Complies
3	LOSS ON DRYING	Not more than 0.50 % w/w.	0.32 %
4	RESIDUE ON IGNITION	Not more than 0.10 % w/w.	0.03%
5	SPECIFIC ROTATION	Between -9.00° and -14.00° on dried basis.	-11.55°
6	*RELATED SUBSTANCES Method 1	Linezolid Impurity A : Not more than 0.08 % Linezolid Impurity B : Not more than 0.08 % Linezolid Impurity C : Not more than 0.08 % Any other Impurity : Not more than 0.08 % Total Impurities : Not more than 0.25 %	Not detected Below LOQ (0.0057%) Not detected 0.04% 0.09%
7	RELATED SUBSTANCES Method 2 (Hydrazine Content)	Not more than 1.2 ppm	0.1 ppm

HEAD QUALITY CONTROL	LAB QA HEAD
DATE : 26.11.2015	DATE : 27.11.2015

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SOURCE A.R. No.	: PD1414073		Page 2 of 2
REFERENCE: ACL0191/02&ACL0191A/03, Protocol No.: WP/INH/WS/C/L52, Version 02.			
Sr. No.	TESTS	STANDARDS	RESULTS
8	RELATED SUBSTANCES Method 3 (R)-Epichlorohydrin (BY GC)	Not more than 1.0 ppm	0.1 ppm
9	*ASSAY (By HPLC)	Linezolid contains not less than 98.5 % w/w and not more than 101.5 % w/w of C ₄₄ H ₆₉ NO ₁₂ .H ₂ O Calculated on the dried basis.	100.1%
10	@RESIDUAL SOLVENTS Method 1	Methanol: Not more than 3000 ppm Methylene Chloride: Not more than 600 ppm Ethyl Acetate : Not more than 5000 ppm	224 ppm Not detected Not detected
11	@RESIDUAL SOLVENTS Method 2	Triethylamine: Not more than 320 ppm Other class 1,2,3 Residual solvents and other organic solvents: Meets the requirements of other Class 1,2 and 3 residual solvents as per USP chapter <467> and no other organic solvents are present.	Not detected Complies
12	PURITY (By Mass Balance Method)	Not applicable.	99.5 % (As Such Basis) 99.9 % (On Dried Basis)
@ Results reported from previous analysis report.			
REMARKS: *Test Qualified with USPRS. All other test complies as per specification No. ACL0191/02&ACL0191A/03 and certified to be used as Working Standard. Note: #Third party may store as per specification.			
HEAD QUALITY CONTROL		LAB QA HEAD	
DATE : 26.11.2015		DATE : 27.11.2015	