M/S IVM PHARMACIA

Plot No. 05, Industrial Township,
Bhatoli- Kalan, Baddi (H.P.) -173205

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

QUALITY CONTROL DEPARTMENT

PRODUCT NAME	**LINEZOLID INFUSION (600 MG/ 300ML)**	**BATCH NO.**	**IV24041**
GENERIC NAME	**LINEZOLID INFUSION (600 MG/ 300ML)**	**A. R. NO.**	**QC/FP/24/1288**
MFG. DATE	**08/2024**	**PRODUCT CODE**	**V**
EXP. DATE	**07/2026**	**BATCH SIZE**	**2100 LTR**
SAMPLE SIZE	**25 X 300 ML**	**PACK SIZE**	**300 ML**
DATE TEST STARTED	**16/08/2024**	**DATE TEST COMPLETED**	**-----**
MFG. LIC. NO.	**LVP/18/09**	**SPECIFICATION NO.**	**FPS/F044-02**

S.NO.	TEST	OBSERVATION	SPECIFICATION
1	Description	Clear colorless solution	Clear, colorless solution
2	Identification	The retention time of major peak in the sample solution is corresponds to that in standard preparation.	The retention time of major peak in the chromatogram of sample preparation corresponds to that in standard preparation as obtained in the assay.
3	pH	4.88	Between 4.5 to 5.5
4	Extracted Volume	300 ml	Not less than nominal volume
5	Related Substances Max. individual impurity Total impurity	 0.35% 0.47%	 Not more than 0.5% Not more than 1.0%
6	Bacterial Endotoxins	Less than 1.75 EU/mg	Not more than 1.75 EU/ mg of Linezolid
7	Sterility	Under test	No growth observed during incubation period of 14 days.
8	Particulate Contamination	2.07 particles/ml Nil	≥ 10 µm particles Not more than 25 per ml ≥ 25 µm particles Not more than 3 per ml
9	Assay Each 100ml contains Linezolid IP.....200.0mg Dextrose Anhydrous IP 5.0gm	 195.892 mg/100ml (97.95%) 4.85 gm (96.9%)	 Not less than 180.0 mg (90.0%) and Not more than 220.0 mg (110.0%) of stated amount of Linezolid. Not less than 4.5 gm (90.0%) & Not more than 5.5 gm (110.0%) of the Stated amount of dextrose).

Remark: The above sample complies / ~~does not comply~~ as per IH/ ~~IP/BP/USP~~ specification or external lab analysis report.

	ANALYSED BY	CHECKED BY	APPROVED BY
Signature/ Date	Rakhi 28/08/24	28/08/24	28/08/24
	Officer-QC	**Executive–QC**	**Quality Head**