

CERTIFICATE OF ANALYSIS

Product name	Lenalidomide	Batch No.	LDM20240402
Manuf. Date	2024-04-12	Expiry Date	2027-04-11
Batch Quantity	9.5kg	Test Standard	QC-D-087 (EP)

TEST	SPECIFICATIONS	RESULTS
Appearance	Off-white to pale-yellow powder	Conform
Identification	A,B,C,D : Conform to standard	Conforms to standard
Related substances	LNB-C1 : $\leq 0.10\%$ LNB-C2 : $\leq 0.10\%$ LNB-B : $\leq 0.10\%$ Any unknown impurity : $\leq 0.10\%$ Total impurities: $\leq 0.5\%$	Not detected Not detected Not detected Not detected Not detected
LNB-2	$\leq 60\text{PPM}$	Conform
LNB-3	$\leq 60\text{PPM}$	Conform
LNB-5	$\leq 60\text{PPM}$	Conform
Residual solvents	Acetone $\leq 5000\text{ppm}$ Isopropanol $\leq 5000\text{ppm}$ Hexane $\leq 290\text{ppm}$ Ethyl acetate $\leq 5000\text{ppm}$	Not detected Not detected Not detected Not detected
Chloroform	$\leq 60\text{ppm}$	Not detected
Loss on drying	$\leq 0.5\%$	0.04%
Sulfated ash	$\leq 0.1\%$	0.4%
Benzene	$\leq 2\text{ppm}$	Not detected
Palladium	$\leq 10\text{ppm}$	Not detected
Assay	98.0 – 102.0%	100.1%

Conclusion: The product complies with the requirements of QC-D-087 (EP) standard

Add:No. 138 YuWu Road, XinMin Town, DianJiang 408302, chongqing,china

Quality Manager:

朱永

Rechecker:

易洪斌

Analyst:

刘英

Add:No. 138 YuWu Road, XinMin Town, DianJiang 408302, chongqing,china