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OFIPHARMA LAB
 ACTIVE PHARMACEUTICAL INGREDIENTS

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 DISTRIBUIDO POR
METAPHARMACEUTICAL
 INDUSTRIAL SLU

Certificate of analysis

30 SEP 2024

Product:	Sulfadimidine sodium
Batch number:	2301016.0319
Manufacturing date:	Jan-2023
Retest date:	Jan-2027
Storage claim	N/a

Test	Method	Specification	Results
Appearance	Visual	White or creamy white crystals or powder	White crystalline powder
Identification A	BP appendix II A	Infrared spectrum conform reference	Conform reference
Identification B (2 nd identification)	BP appendix VI	Reaction on primary aromatic amines positive	N/a
Identification C (2 nd identification)	BP appendix VI	Test on sodium positive	N/a
Clarity and colour of solution	BP appendix IV B, method I	Solution of 33 % is clear and not more intensely coloured than Y ₄	Clear; ≤ Y ₄
Related substances (TLC)	Internal method	Any secondary spot not more intense than principal spot (≤ 0.5 %)	< 0.5 %
Residual solvents	Internal method	Methanol ≤ 3000 ppm	229 ppm
pH (10 % solution)	BP appendix V L	10.0 – 11.0	10.7
Loss on drying *	Internal method	≤ 2.0 %	0.3 %
Assay on dried substance (amperometric)	Internal method	98.0 % - 101.0 %	100.3 %

*A retest interval of 6 months is recommended.

This lot complies with BP2002 and company monograph based on EP.

This batch of product has been manufactured, including packaging / labelling and quality control in full compliance with the GMP requirements.

Quality Control



23 JAN 2023

R. Vree Egberts, BASc

Quality Assurance



24 JAN 2023

J. Furda, BSc

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Documentcode:	COA-0020	Version:	1.0	Page:	1 / 1