

CERTIFICATE OF ANALYSIS

Product: **SULFADIMIDIN BIOVETA, pulbere orală, 20 g/plic**

Batch No.: **15 19 A01**

Expiry: **14.10.2022**

Date of production: **15.10.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White to yellowish microcrystalline powder.		complies
Mass uniformity	20 g		complies
Microbiological quality	Must comply. TAMC (CFU/g): 10^3 TYMC (CFU/g): 10^2 <i>Escherichia Coli</i> (in 1 ml): absent		complies <10 CFU/g <10 CFU/g absent
Sulfadimidine assay	98.0 – 101.0 %		100.1 %
Sulfadimidine identity	Must comply.		complies
Sulfadimidine impurities			
- Sulfanilamide	max 0.5 %		0.009 %
- Any individual known impurity	max 0.1 %		<0.1 %
- Any individual undefined impurity	max 0.1 %		<0.1 %
- Sum of impurities	max 1.0 %		0.257 %
Loss on drying	max. 7 %		0.6 %
pH	10.0 – 11.0		10.5
Appearance and colour of solution	Must comply.		complies
Related substances	max. 0.5 %		<0.5 %

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 442.



04/11/2019
Mgr. Hana Nezvalová
HEAD of QC, QP