

CERTIFICATE OF ANALYSIS

Product: **STREPTONAMID, pulbere orală**

Batch No.: **15 19 01**

Expiry: **03.03.2021**

Date of production: **04.03.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White till low greyish powder.		complies
Mass uniformity	2.8 g		complies
Microbiological quality	Must comply with Ph. Eur., art.5.1.4.		complies
Streptomycin assay	950 000–1 050 000 IU/2.8 g	900 000–1 100 000 IU/2.8 g	1 047 370.0 IU/2.8 g
Phthalylsulfathiazole assay	0.95 – 1.05 g/2.8 g	0.9 – 1.1 g/2.8 g	1.04 g/2.8 g
Identity test of streptomycin	Must be proved.		complies
Identity test of phthalylsulfathiazole	Must be proved.		complies
Humidity	max. 7 %		4.09 %
Actual acidity of aqua suspension	4.0 – 7.0		5.5
Sieve residue	max. 5 %		3.7 %
Uniformity of mass	Must comply.		complies

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. 441.




22/03/2019
Mgr. Hana Nezvalová
HEAD of QC, QP