

## CERTIFICATE OF ANALYSIS

Product: **STREPTONAMID, pulbere orală**Batch No.: **292102**Expiry: **11.2.2023**Date of production: **12.2.2021**

## 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 | 995 239 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 %                              |                            | 2.79 %           |
| Actual acidity of aqua suspension      | 4.0 – 7.0                             |                            | 5.7              |
| Sieve residue                          | max. 5 %                              |                            | 0.6 %            |
| 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.



.....25/05/2020  
Mgr. Hana Nezvalová  
HEAD of QC, QP