



SPECIFICATION

Product : Streptokinase - Streptodornase powder
Product No. : 5417005900

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Version : 1
valid from : 01/10

Synonym : Streptochinasi-Streptodornasi

CAS-No. : 8048-16-6 (SK: 9002-01-1, SD: 37340-82-2)

Formula : -

ABDATA : SK: 828000, SD: 827800

Mol.-weight : -

ASK- No. : SK: 02143, SD: 02144

| Controls | Specification | Method |
|------------------------------|---|---------------|
| Appearance | white powder | visual |
| Identification Streptokinase | positive | PrQ-0024 |
| Streptokinase activity | 8.000 – 12.000 I.U./mg confidence limits (<i>P</i> =95 %) 80-125 % | PrQ-0023 |
| Streptodornase activity | 2.500 – 10.000 I.U./mg | PrQ-0060 |
| Loss on drying | ≤ 3 % | PrQ-0028 |
| pH | 6,8 – 8,5 (5.000 I.U. SK/ml) ¹⁾ | PrQ-0066 |
| TAMC | ≤ 2.000 CFU/g | FeQ-0044 |
| Abnormal toxicity | non toxic at 50.000 I.U. SK/mouse | Ph.Eur. 2.6.9 |

¹⁾ dissolved in 0,9 % NaCl aq.

| | |
|------------------------|--------------------------|
| Primary packing | : sterile plastic bottle |
| Storage | : 2° to 8° C |
| Shelf life | : 2 years |