

Certificate of Analysis

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Code:	069-03	DSM Code:	5039364
Product:	Prionex® 10%		
Lot:	42044901	Manufacturing date:	02/2017
Analysis No.:	7442044901	Re-test date:	02/2022

Tests, Parameters:	Specification:	Results:
Appearance	clear, pale yellow to amber colored liquid	corresponds
pH	6.0 - 7.5	7.0
Residue on drying	9.0 - 11.0 % m/V	9.8 % m/V
Total nitrogen	1.50 - 1.90 % m/V	1.65 % m/V
Polypeptid content, calculated from total nitrogen	8.2 - 10.5 % m/V	9.1 % m/V
Relative density d20/20	1.030 - 1.045	1.035
Sodium chloride	0.55 - 0.70 % m/V	0.63 % m/V
Heavy metals	< 20 ppm	corresponds
Arsenic	< 1 ppm	corresponds
Endotoxin testing (LAL)	< 10 EU / ml	corresponds
Sterility	sterile	corresponds

Remarks: Intermediate product is heat treated for 1 hour at 145°C.

Final product in primary packing container (1-lt bottles) is sterilized by heat treatment for 30 minutes at 121°C.

This lot was analysed and released by our authorized Quality Assurance Department and was found to meet the specifications as given above.

Basle/Switzerland: 25.07.2017 / ags

Frédéric Crevoisier / QA

On behalf of the responsible department:

