

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML  
Gysz: 2119251 Lej: 2025-08-22  
Kisz: 10 ML Me: Darab  
ALPHA-VET KFT BUDAPEST részére

Szállító:  
Medimpex Gy. Zrt.  
1158 Budapest  
Rákospalotaihatárút2  
Tel: +36-1-414-6476  
e-mail: qa@mpx.hu



CERTIFICATE OF ANALYSIS

Page 1 of 1

ANTISEDAN 5 mg/ml Solution for injection 10 ml

Product Number: 133981  
Origin Batch Number: 2119251  
Date of Manufacture: 22.08.2022  
Date of Expiration: 08.2025  
Strength/Potency: 5 mg/ml  
Dosage form: Solution for injection  
Package size: 10 ml  
Package type: Vial  
Storage: +15..25 °C  
Country of destination: Bulgaria,Croatia,Hungary,Serbia,Slovenia

TESTS	METHOD	REQUIREMENTS	RESULTS
Colour of solution	100494-2	colourless	colourless
Average volume in container	100229-2	nlt 10,0 ml	10,5 ml
Volume in cont.	100229-2	10,0 - 11,0 ml	10,5 ml
Partic.matter, presence of visib. partic	100473-2	practically no particles	practically no particles
Clarity of solution	100493-2	clear	clear
pH	100432-2	4,0 - 6,0	4,4
Ident., atipamezole HCl, HPLC	100643-4	positive	positive
Ident., methyl parahydroxybenzoate, HPLC	100643-4	positive	positive
Assay, atipamezole HCl, %	100643-4	95,0 - 105,0 %	101,1 %
Assay, methyl parahydroxybenzoate, %	100643-4	90,0 - 110,0 %	99,8 %
Related substances	100643-4	nmt 1,0 %	<0,1 %
Test for sterility	113205-1	sterile	sterile
Bacterial endotoxins.	120383-1	nmt 10 EU/ml	nmt 10 EU/ml

Quality control site : Orion Corporation, Espoo plant Orionintie 1 FI-02200 ESPOO  
Certificate of GMP Compliance: FIMEA/2022/002459  
Authorisation number: FIMEA/2019/000732

Electronically approved 05.10.2022 16:38:31 by a Qualified Person Sampo Kurvonen

133981\_2119251\_COA\_05.10.2022\_16:39:50\_SAMPKURV

Orion Corporation

Manufacturing license number FIMEA/2019/000732

ORION PHARMA

Orionintie 1, 02200 ESPOO  
P.O.Box 65, 02101 ESPOO  
Tel. +358 10 4261  
Fax +358 10 426 3815

Tengstrominkatu 8, 20360 TUSKLI  
P.O.Box 425, 20101 TURKU  
Tel. +358 10 42692  
Fax +358 10 426 7777

Voitinkatu 8, 70700 KUOPIO  
P.O.Box 1780, 70701 KUOPIO  
Tel. +358 10 428 611  
Fax +358 10 428 6444

Jouensuunkatu 7, 74100 SALO  
Tel. +358 10 4261

Orion Corporation. Registered office and domicile: Orionintie 1, FI-02200 Espoo, Finland.