

ANTISEDAN 5MG/ML OLDATOS INJEKCIÓ 10ML
Gysz: 2078061 Lej: 2024-09-07
Kisz: 10 ML Me: Darab
ALPHA-VET KFT SZÉKESFEHÉR részére

Szállító:
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CERTIFICATE OF ANALYSIS

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ANTISEDAN 5 mg/ml Solution for injection 10 ml

Product Number: 133981
Orion Batch Number: 2078061 ✓
Date of Manufacture: 07.09.2021
Date of Expiration: 09.2024 ✓
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,Malta,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 %	103,5 %
Assay, methyl parahydroxybenzoate, %	100643-4	90,0 - 110,0 %	99,9 %
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/2020/001590
Authorisation number: FIMEA/2019/000732

Electronically approved 05.12.2021 12:43:59 by a Qualified Person Salla Puhakka

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Orion Corporation

Manufacturing license number FIMEA/2019/000732

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