

Certificate of Analysis

Name of the product : Sedator

Product number : 91095220 Packaging : 10ml
Batch number : 097856 Date of analysis : 13-07-2017
Manufacturing date : 06-2017 CoA version : SC-LAB91095220.3.0
Expiry date : 06-2020 Destination : Hungary

DETERMINATIONS	SPECIFICATIONS	RESULTS
CHARACTERS	A clear, colourless solution practically free from particles	A clear, colourless solution practically free from particles
CLARITY	As water	As water
IDENTITY	Positive	Positive
pH	3.8 – 5.8	4.9
DENSITY (g/ml)	1.00 - 1.01	1.01
VOLUME (ml)	Minimum 10.0	10.1
STERILITY	Passes the test	Passes the test
ASSAY OF		
Medetomidine hydrochloride (mg/ml)	0.95 – 1.05	1.01
Methyl parahydroxybenzoate (mg/ml)	0.90 – 1.10	1.00
Propyl parahydroxybenzoate (mg/ml)	0.18 – 0.22	0.20

Jeroen Van den Brande



07 SEP 2017

Qualified Person

Conclusion : Conform specifications.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.