



BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAK81539

Eurofins Batch Number JJ20AA2541

Version: 1

Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: IOQ6PH19016843

General Method Reference: DAC Midazolami hydrochloridum + current Ph. Eur.

Eurofins Sample Number JJ20AA2541-1	
Original Received Date:	06-Oct-2020
Description:	Midazolami hydrochloridum; 502530
Lot Number:	20I24-F01
Containers Submitted:	1 Container

Eurofins Sample Number JJ20AA2541-2	
Original Received Date:	06-Oct-2020
Description:	Midazolami hydrochloridum; 502530
Lot Number:	20I24-F01
Containers Submitted:	1 Container


Analysis/Sample	Specification	Result	Unit
Characters Appearance			
JJ20AA2541-1	White or almost white, crystalline powder	Meets Requirements-White crystalline powder	----
Method: Current Ph Eur			
Analysis Date 20-Oct-2020 to 20-Oct-2020 for JJ20AA2541-1			
Identity B by IR			
JJ20AA2541-1	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those of the reference.	Meets Requirements	----
Method: Current Ph Eur (2.2.24)			
Analysis Date 23-Oct-2020 to 23-Oct-2020 for JJ20AA2541-1			
Identity D Reaction of chloride (a)			
JJ20AA2541-1	Reaction of chloride A	Meets Requirements	----
Method: Current Ph Eur (2.3.1)			
Analysis Date 23-Oct-2020 to 23-Oct-2020 for JJ20AA2541-1			



Analysis/Sample	Specification	Result	Unit
Clarity and degree of opalescence of liquids			
JJ20AA2541-1	Clear solution	Meets Requirements	----
Method: Current Ph Eur (2.2.1)			
Analysis Date 23-Oct-2020 to 23-Oct-2020 for JJ20AA2541-1			
Degree of coloration of liquids			
JJ20AA2541-1	≤ Y6	< Y6	----
Method: Current Ph Eur (2.2.2 Method II)			
Analysis Date 26-Oct-2020 to 26-Oct-2020 for JJ20AA2541-1			
pH			
JJ20AA2541-1	3.7-4.7	4.5	----
Method: Current Ph Eur (2.2.3)			
Analysis Date 23-Oct-2020 to 23-Oct-2020 for JJ20AA2541-1			
Related Substances by HPLC 1p/1i			
JJ20AA2541-1			
Impurity B	NMT 0.2	Not Detected	%
Impurity A	NMT 0.1	Not Detected	%
Impurity G	NMT 0.1	Not Detected	%
Unspecified impurities	NMT 0.10	0.08	%
Sum	NMT 0.3	0.1	%
Method: Current Ph Eur (2.2.29)(2.2.25)(2.2.46)			
Analysis Date 22-Oct-2020 to 27-Oct-2020 for JJ20AA2541-1			
Impurity C by TLC			
JJ20AA2541-1	≤ 0.1	< 0.1	%
Method: Current Ph Eur (2.2.27)			
Analysis Date 21-Oct-2020 to 30-Oct-2020 for JJ20AA2541-1			
Loss on drying			
JJ20AA2541-1	NMT 0.5	0.0	%
Method: Current Ph Eur (2.2.32)			
Analysis Date 20-Oct-2020 to 30-Oct-2020 for JJ20AA2541-1			
Sulfated ash			
JJ20AA2541-1	NMT 0.1	< 0.1	%
Method: Current Ph Eur (2.4.14)			
Analysis Date 02-Nov-2020 to 03-Nov-2020 for JJ20AA2541-1			

SPECIFICATIES
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DATUM
06-11-20

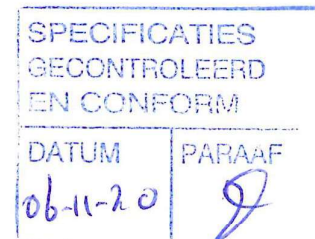
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Analysis/Sample	Specification	Result	Unit
Assay Potentiometric			
JJ20AA2541-1	98.5 - 101.5	98.9	%
Method: DAC 2015			
Analysis Date 26-Oct-2020 to 26-Oct-2020 for JJ20AA2541-1			
Bacterial Endotoxin-Gel Clot:Limit test			
JJ20AA2541-2	≤ 0.25	<0.24	EU/mg
Method: Current Ph Eur (2.6.14, Method A); Current USP/NF <85>			
Sample Compliance Assessment			
Samples JJ20AA2541-1, JJ20AA2541-2 meet the requirement(s) for all listed test(s) where specifications were applied.			

Eurofins BPT Testing Facility	Test
Eurofins PROXY Laboratories B.V. Archimedesweg 25 2333 CM, Leiden, THE NETHERLANDS	Assay Potentiometric Characters Appearance Clarity and degree of opalescence of liquids Degree of coloration of liquids Identity B by IR Identity D Reaction of chloride (a) Impurity C by TLC Loss on drying pH Related Substances by HPLC 1p/1i Sulfated ash
Eurofins Bactimm B.V. Middenkampweg 19 Nijmegen, 6545 CH THE NETHERLANDS	Bacterial Endotoxin-Gel Clot:Limit test

Contracted Company: PROXY Laboratories Chemistry and Biochemistry
Archimedesweg 25, 2333 CM, Leiden, The Netherlands PROXYcustomer@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.



Reviewed and electronically signed for Quality Assurance Approval by
Gonnie den Dekker, Analytical Review Officer
for Eurofins PROXY Laboratories B.V., on 05-Nov-2020 14:10:37 UTC+01:00