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Certificate of Analysis

Product/sample name : Midazolami hydrochloridum; 502530
Client-code : 129
Project-code : 0106502
Batch number : 18B28-B05
Analysis : DAC/NRF 2015/1
Version : 1

Test	Test method	Specification	Result	Complies
Characters	Appearance	White or almost white, crystalline powder	Almost white, crystalline powder	Yes
Solubility	Client spec.	Sparingly soluble, clear after 2 days	Conform	Yes
Identity B	2.2.24	Compared to reference*	Conform	Yes
Identity D	2.3.1	Reaction of chloride (a)	Conform	Yes
Appearance	2.2.1	Clear	Clear	Yes
of solution	2.2.2 (II)	≤ Y6	< Y6	Yes
pH	2.2.3	3.7 – 4.7	4.4	Yes
Related substances	2.2.29	Impurity B: ≤ 0.2 %	Not detected	Yes
		Impurity A: ≤ 0.1 %	< 0.1 %	Yes
		Impurity G: ≤ 0.1 %	Not detected	Yes
		Any other imp.: ≤ 0.10 %	0.08 %	Yes
		Sum: ≤ 0.3 %	0.1 %	Yes
Impurity C	2.2.27 (TLC)	≤ 0.1 %	< 0.1 %	Yes
Loss on drying	2.2.32	≤ 0.5 %	0.1 %	Yes
Sulphated ash	2.4.14	≤ 0.1 %	< 0.1 %	Yes
Assay	Monograph	98.5 - 101.5 %	99.6 %	Yes
Endotoxin	2.6.14	≤ 0.25 EU / mg	< 0.24 EU / mg	Yes

** Remark: compared torefernce spectrum in DAC/NRF 2015/1 (ATR)*

QA-statement:
This study met the criteria for a valid test and was performed in compliance with the Good control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community.
The reported results adequately reflect the raw data of the study.

Conclusion:
The results do comply with the specifications

This certificate is approved by Manager QA on 9 April 2018

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