

Product/sample name : Midazolami Hydrochloridum; DAC 2015/1; 502530
 Client-code : 129
 Project-code : 0108949
 Batch number : 18F19-B02
 Analysis : DAC/NRF 2015/1
 Version : 1

240718 RW

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 of solution	2.2.1	Clear	Clear	Yes
	2.2.2 (II)	≤ Y6	< Y6	Yes
pH	2.2.3	3.7 – 4.7	4.3	Yes
Related substances	2.2.29	Impurity B: ≤ 0.2 %	Not detected	Yes
		Impurity A: ≤ 0.1 %	Not detected	Yes
		Impurity G: ≤ 0.1 %	Not detected	Yes
		Unspecified imp.: ≤ 0.10 %	Not detected	Yes
		Sum: ≤ 0.3 %	0.2 %	Yes
Impurity C	2.2.27 (TLC)	≤ 0.1 %	< 0.1 %	Yes
Loss on drying	2.2.32	≤ 0.5 %	0.5 %	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	< 0.03 EU/mg	Yes

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 23 July 2018

Both 23 July 2018