

Product/sample name : Dikalii clorazepas monohydricus; 500172  
 Client-code : 129  
 Project-code : 0115178  
 Batch number : 19C06-B03 *19C06-F50* *na 280122*  
 Analysis : Ph. Eur. 04/2019:0898  
 Version : 4

Test	Test method	Specification	Result	Complies
Characters	Appearance	White or light yellow, crystalline powder	Light yellow, crystalline powder	Yes
Identification B	2.2.24	Compared to reference	Conform	Yes
Identification E	2.3.1	Reaction of potassium (b)	Conform	Yes
Appearance of solution	2.2.1 *	Clear	Clear	Yes
	2.2.2 (II)	≤ GY5	< GY5	Yes
Karl Fisher	2.5.12	3.5 - 5.5%	4.9 %	Yes
Assay	2.2.20	99.0 - 101.0 %	100.2 %	Yes
Related substances	2.2.27	Limits A: Impurity B: ≤ 0.2 % Any other impurity: ≤ 0.1 % Limits B: Impurity A: ≤ 0.1 %	No results obtained	

SPECIFICATIET  
 GECONTROLEERD  
 EN CONFORM  
 DATUM: 29-11-21  
 PARAAF: YS

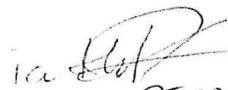
\* Remark: Performed at 37 ° C. Solution was turbid at room temperature.

**QA-statement:**

This study met the criteria for a valid test and was performed in compliance with 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

*100*  
  
 25 NOV 21

This certificate is approved by Manager QA on 25 November 2021

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