

Certificate of Analysis

Product name: Kalii sulfoguaiacolas

Batch number / Weight: 22K26-B13-225281 / 1 KG

Analysed according to: USP

Number of analysis / Inspection Code 22K26-B13 / INS-22-10124

Reference Code / No.: V01676 / 21PG12093

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Water (Karl Fischer)	3,0 - 6,0	4,50	%	
Sulphates	Conform	Conform	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Potassium guaiacolsulfon	98,0 - 102,0	99,85	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska Qualified Person

24-01-2023

Expiration: 18-12-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl Fagron Sp. z o.o.

ul. Armii Krajowej 3 32-540 Trzebinia, Poland e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.

ul. Pasternik 26, 31-354 Kraków, Poland

tel.: +48 12 3343 512 e-mail: biuro@fagron.pl