

Certificate of Analysis

Product name: **Natrii docusas**

Batch number / Weight: **21I03-B02-225209 / 25 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **21I03-B02 / INS-21-5751**

Reference Code / No.: **V01641 / SD1012208**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, waxy mass or flakes with a characteristic odour	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Alcalinity	Conform	0,05 ml HCl		
Related non-ionic substances	$\leq 0,4$	$< 0,4$	%	
Chlorides	≤ 350	23,8	ppm	
Sodium sulphate	≤ 2	< 2	%	
Water (Karl Fischer)	$\leq 3,0$	0,89	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Docusate sodium	98,0 - 101,0	100,32	%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 Eurofins

Release:
Agnieszka Pszczółka
Qualified Person

29-11-2022

Expiration: 22-01-2024

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