

VMP Chemiekontor GmbH
CoA
Industriestrasse 16
53721 Siegburg

Date: 22.11.2021
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Certificate of Analysis

Your order No. : 1BE21100158
Your order date : 27.10.2021

Delivery no./Item : 83149406 / 900001
Order : 92242
Material : WeylCare Allantoin EP/USP 25KG/400KG PAL
Material No. : 28196423997
Batch No. : FRBB21048
Quantity : 400 KG

From a representative sample the following values were determined:

Characteristic Method	Specification	Result	Unit
Appearance : white powder EP (Visual examination)	conforms	conforms	
Assay by potentiometric titration (EP) EP (Titrimetry)	98,5 - 101,0	99,4	%
Identification A (EP) EP2.2.24 (IR Spectrophotometry)	conforms	conforms	
Identification B (EP) EP (TLC)	conforms	conforms	
Identification C (EP) EP (Visual examination)	conforms	conforms	
Identification D (EP) EP (Visual examination)	conforms	conforms	
Acidity or alkalinity (EP) EP (Visual examination)	conforms	conforms	
Optical rotation (EP) EP2.2.7 (Polarimetry)	-0,10 - +0,10	0,00	deg

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From a representative sample the following values were determined:

Characteristic Method	Specification	Result	Unit
Reducing substances (EP) EP (Visual examination)	conforms	conforms	
Related substances (EP) EP2.2.27 (TLC)	conforms	conforms	
Loss on drying (EP) EP2.2.32 (Gravimetry)	$\leq 0,1$	0,0	%
Sulphated ash (EP) EP2.4.14 (Gravimetry)	$\leq 0,1$	0,1	%
Solubility (EP) EP (Visual examination)	conforms	conforms	
Melting point (EP) EP2.2.14 (Visual examination)	$\geq 225,0$	227,8	°C
Total aerobic microbial count (EP) EP2.6.12 Cultural technique (non-chromogenic media)	≤ 100	10	CFU/g
E.Coli (EP) EP2.6.13 Cultural technique (non-chromogenic media)	conforms	conforms	

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Characteristic Method	Specification	Result	Unit
Pseudomonas aeruginosa (EP) EP2.6.13 Cultural technique (non-chromogenic media)	conforms	conforms	
Staphylococcus aureus (EP) EP2.6.13 Cultural technique (non-chromogenic media)	conforms	conforms	
Candida albicans (EP) EP2.6.13 Cultural technique (non-chromogenic media)	conforms	conforms	
Salmonella (EP) EP2.6.13 Cultural technique (non-chromogenic media)	conforms	conforms	
Assay by potentiometric titration (USP) USP (Titrimetry)	98,5 - 101,0	99,4	%
Identification A (USP) USP197 (IR Spectrophotometry)	conforms	conforms	
Identification B (USP) USP201 (TLC)	conforms	conforms	
Acidity or alkalinity (USP) USP (Visual examination)	conforms	conforms	

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Characteristic Method	Specification	Result	Unit
Reducing substances (USP) USP (Visual examination)	conforms	conforms	
Loss on drying (USP) USP731 (Gravimetry)	<= 0,1	0,0	%
Organic impurities (USP) USP621 (TLC)	<= 0,5	0,0	%
Residue on ignition (USP) USP281 (Gravimetry)	<= 0,1	0,1	%

Date of production: 20.04.2021

Expiration date, shelf life: 19.04.2024

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The analytical results should not be construed as guaranteeing specific properties of the product or its suitability for a particular application.

The above data do not release one from carrying out an incoming goods inspection.

With regard to the analyzed parameters the tested sample material meets the respective requirements of the current EP (monograph: 1288) and the respective requirements of the current USP (monograph: Allantoin).

All parameters above refer to the current versions of EP and USP.

This report is not to be signed.