

ANALYSENZERTIFIKAT/ CERTIFICATE OF ANALYSIS

Datum/Date: 20.08.2012
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Produkt/Product: Dapsone EP/BP
 Denk Art.-Nr./art. no: 900645

Charge-Nr./Batch no: 12/015	Herstelldatum/Manufacturing date: 23.04.2012	Verfalldatum/Expiry date: 03/2017
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Sr. No.	Test	Result unit	Requirement	Result
1.0	<u>Pharmacopoeial tests</u>			
1.1	Description	--	a white or slightly yellowish-white Crystalline powder	White crystalline powder
1.2	Solubility	--	Insoluble in water, freely soluble in acetone, sparingly soluble in alcohol and freely dissolves in chute mineral acids.	Passes
1.3	<u>Identification Test</u>			
1.3.1.	Melting point	°C	175 - 181	178
1.3.2.	Light absorption			
	- at 260 nm	A	700-760	741
	- at 295 nm	A	1150 - 1250	1198
1.3.3.	TLC	--	Similar to reference standard	Passes
1.4.	Related substances by TLC	--	To comply with the test mentioned in EP/BP	Passes
1.5.	Loss on Drying	%	Max. 0.30	0.07
1.6.	Sulphated ash	%	Max. 0.10	0.03
1.7	Assay (by titration)	%	99.0 - 101.0	99.9
2.0	<u>Additional tests</u>			
2.1	Assay by HPLC	%W/W	NLT 98.0 - NMT 102.0	99.9
2.2	Related substances by HPLC			
2.2.1.	4 Amino 4' Hydroxy DPS	%W/W	NMT 0.4	0.1
2.2.2.	2,4' Diamino DPS	%W/W	NMT 0.1	ND
2.2.3.	4 Amino DPS	%W/W	NMT 0.4	0.3
2.2.4.	4 Amino 4 Chloro DPS	%W/W	NMT 0.1	ND
2.2.5	O-Dimer of Dapsone	%W/W	NMT 0.3	0.2
2.2.6.	4 Chloro DPS	%W/W	NMT 0.1	ND
2.2.7.	Individual Unidentified Impurities	%W/W	NMT 0.10	0.04
2.2.8.	Total impurities	%W/W	NMT 1.5	0.8
2.3.	Residual Solvent (Mehtanol)	ppm	Max. 3000	ND

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2.4.	<u>Particle size</u>			
2.4.1.	Less than 50µ	%	Minimum 10	17
2.4.2.	Less than 150µ	%	Minimum 50	74
2.4.3.	Less than 250µ	%	Minimum 90	97
2.5.	Heavy metals	ppm	Maximum 10	< 10

Remarks: The above product **PASSES** as per specification SP/FP/DAP-EP (GEN)/01

Wir bestätigen die korrekte Abschrift des Original Analysenzertifikats. Voranstehende Angaben entsprechen unseren besten Erfahrungen und Kenntnissen und dienen ausschließlich der Information. Eine Eigenschaftszusicherung oder rechtliche Verbindlichkeit, gleich welcher Art, kann nicht abgeleistet werden.

We confirm the true and correct transcription of the original certificate of analysis. This information is based on our present state and knowledge and is intended to provide general notes on our products and their uses. It should not therefore be construed as guaranteeing specific properties of the product described or their suitability for a particular application.

Denk Ingredients GmbH

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