

Certificate of Analysis

Product name: Fagron Advanced Derma Pack CAF 50 G
Batch number: 22E17-H06-72095
Analysed according to: IHS

Analytical records Clindamycin hydrochloride 20J12-H08-00060

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		Slightly hygroscopic
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chlorides
pH	3,0 - 5,0	4,4		10% <i>m/V</i>
Specific optical rotation	+135 - +150	+144		Anhydrous, 4% <i>m/V</i> ; DP
Related substances	Conform	Conform		HPLC; DP
Impurity C	<= 4,0	0,77	%	
Impurity B	<= 2,0	0,50	%	
Any other impurity	<= 0,5	Conform	%	
Total	<= 6,0	1,9	%	
Water	3,0 - 6,0	5,01	%	Karl-Fischer
Sulfated ash	<= 0,5	0,03	%	DP
Assay Clindamycin hydrochloride	92,0 - 102,0	97,8	% <i>m/m</i>	HPLC, anhydrous; DP
Residual solvents	Conform	Conform		DP
Ethanol	<= 5000	Not detected	ppm	
Acetone	<= 5000	164	ppm	
Chloroform	<= 60	Not detected	ppm	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		DP

Analysis performed by the authorized internal lab

Meets the requirements of the PH.EUR 10.2

Analytical records Alpha bisabolol 22D05-H03-00562

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear, colourless to light yellow liquid	Conform		
Identification B	Conform	Conform		IR-spectrum
Relative density	0,9240 - 0,9320	0,9291		20°C; DP
Relative density	0,9220 - 0,9310	0,9275		25°C; DP
Refractive index	1,4910 - 1,4990	1,4959		20°C
Refractive index	1,4890 - 1,4970	1,4938		25°C
Content	>= 95,0	96,7	%	GC; DP
Quantification of Farnesol	<= 1000	282	mg/kg	DP

Flashpoint > 100 Conform °C DP

Analysis performed by the authorized internal lab

Meets the requirements of the IHS

Analytical records Fitalite™ 20I25-H11-00455

Tests	Requirement	Result	Unit	Standard remark
Appearance	Off white to light yellow, semi-viscous gel cream	Conform		
Odour	Specific, not perfumed	Conform		
Identification	Conform	Conform		Sorbic acid; DP
Identification	Conform	Conform		Benzoic acid; DP
Density	0,99 - 1,02	0,99	g/ml	DP
Agglomerates	Absent	Conform		DP
Viscosity	75000 - 200000	113600	mPa*s	DP
pH	3,5 - 5,5	5,0		
Assay	0,070 - 0,140	0,103	%	Sorbic acid; DP
Assay	0,130 - 0,260	0,206	%	Benzoic acid; DP
Microbial contamination	Conform	Conform		DP
Total Aerobic Microbial Count (TAMC)	< 100	< 10	CFU/g	
Total Yeasts and Moulds Count (TYMC)	< 10	< 10	CFU/g	
Pseudomonas aeruginosa	Absent	Conform		DP
Staphylococcus aureus	Absent	Conform		DP

Analysis performed by the authorized internal lab

Meets the requirements of the IHS

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

17/05/2022

Expiration: 31-05-2023

Conclusion: APPROVED

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