

Certificate of Analysis

Product name: Fagron Advanced Derma Pack MDT

Batch number: 26A28-H05-72104

Analysed according to: IHS

Analytical records Minoxidil 25I09-H04-00025

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Solubility	Slightly soluble in water, soluble in methanol and in propylene glycol	Conform		
Identification B	Conform	Conform		IR
Appearance of solution	Clear and $\leq$ Ref.Sol Y6	Conform		
Optical density	$\leq 0,02A$	0,002A		450nm
Related substances	Conform	Conform		HPLC
Impurity E	$\leq 0,2$	$<0,05$	%	
Impurity B	$\leq 0,15$	$<0,05$	%	
Unspecified impurities	$\leq 0,10$	$<0,05$	%	
Total	$\leq 0,3$	$<0,05$	%	
Loss on drying	$\leq 0,5$	0,1	%	
Sulfated ash	$\leq 0,1$	$<0,1$	%	
Assay Minoxidil	99,0 - 101,0	100,3	%	Dried substance
Particle size	<100	95	μm	PSD d90
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab.

Meets the requirements of the PH.EUR 11.8

Analytical records Dutasteride 25E23-B15-014003

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder	Conform		
Identification	A, B	Conform		
Specific optical rotation	$(+33,0) - (+39,0)$	+35,28	°	
Related substances	Conform	Conform		
Test A		Conform		
Impurity A	$\leq 0,2$	0,00	%	
Impurity B	$\leq 0,15$	0,000	%	
Impurity C	$\leq 0,2$	0,00	%	
Impurity E	$\leq 0,3$	0,00	%	
Impurity F	$\leq 0,4$	0,05	%	

Impurity G	<= 0,3	<0,05	%	
Unspecified impurities	<= 0,10	<0,05	%	
Test B		Conform		
Impurity I	<= 0,5	0,00	%	
Impurity H	<= 0,3	0,00	%	
Unspecified impurities	<= 0,10	0,07		
Total impurities	test A + test B <=1,5	0,12	%	
Water	<= 0,2	0,1	%	
Sulfated ash	<= 0,1	0,04	%	
Assay	97,0 - 102,0	98,57	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		DP

Analysis performed by the authorized lab FSNE

Meets the requirements of the PH.EUR 11.8

Analytical records Macrogolglycerol hydroxystearate 40 26A23-H19-00491

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish semi-liquid or pasty mass	Conform		
Solubility	Freely soluble in water, in acetone and in ethanol (96%), practically insoluble in light petroleum	Conform		
Identification A	Conform	Conform		Iodine value
Identification B	Conform	Conform		Saponification value
Identification C	Conform	Conform		TLC
Identification D	Conform	Conform		Black precipitate
Appearance of solution	<= III / <= BY6	Conform		
Alkalinity	Conform	Conform		Not blue
Acid value	<= 2,0	0,41	mg KOH/g	
Hydroxyl value	57 - 80	71	mg KOH/g	
Iodine value	<= 5,0	1,8	gI2/100g	
Saponification value	45 - 69	51,1	mg KOH/g	
Ethylene oxide and dioxan	Conform	Conform		
Ethylene oxide	<= 1	<1	ppm	
Dioxan	<= 10	<2	ppm	
Diethylene glycol	<=620	<100	mg/kg	
Ethylene glycol	<=620	<100	mg/kg	
Acetic acid	<=5000	1300	mg/kg	
Heavy metals	<=10	Conform	mg/kg	
Nickel	<=20	<2	mg/kg	
Water	<= 3,0	1,4	%	
Total ash	<= 0,3	Conform	%	
Total Aerobic Microbial Count (TAMC)	<=100	<10	CFU/g	
Total Yeasts and Moulds Count (TYMC)	<=10	<10	CFU/g	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab.

Meets the requirements of the PH.EUR 11.8

Analytical records Trichofoam™ 26A05-H02-00694

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear to slightly turbid liquid	Conform		
Colour	Slightly yellowish	Conform		
Odour	Characteristic	Conform		
Density	0,990 - 1,030	1,020	g/ml	25°C
pH	1,50-2,50	1,76		
Impurities	Exempt	Conform		
TSE/BSE-statement	No contamination with BSE/TSE-no risk materials	Conform		

Analysis performed by the authorized internal lab.

Meets the requirements of the IHS

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

29/01/2026

Expiration: 14/05/2027

Conclusion: APPROVED

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