



TRIFARMA S.p.A.

Manufacturing Site:
Ceriano Laghetto (formerly Alchymars)
Via delle Industrie, 6
20816 - Ceriano Laghetto (MB) - ITALY
Tel. +39 (0)2 9690018
Fax. +39 (0)2 9690643

MINOXIDIL USP / EP

Analysis No: PF/12/0123

Source of specification:

◇ = USP ◇◇ = EP ◇◇◇ = In house

Batch No. : **01010**

Manufacturing date : July 2012

Retest date : July 2017

Test	Specification	Result
Description ◇	White or off-white, crystalline powder	Complies
Identification		
1. Infrared ◇◇	Positive	Complies
2. UV ◇◇	E ₁ % 230 nm : 1015 – 1120	1070
	E ₁ % 281 nm : 1060 – 1170	1103
	E ₁ % 230 nm : 1525 – 1685	1553
	E ₁ % 262 nm : 485 – 535	503
	E ₁ % 288 nm : 555 – 605	577
Appearance of solution ◇◇	Clear and not more than Y6	Complies
Melting point ◇	248 °C – 268 °C (dec)	255 - 256 °C (dec)
Loss on drying ◇ ◇◇		
Eur.Ph.	≤ 0.5%	< 0.05 %
USP	≤ 0.5%	< 0.05 %
Sulphated ashes ◇	≤ 0.1%	< 0.03 %
Heavy metals ◇	≤ 20 ppm	< 20 ppm
Related substances HPLC ◇◇◇		
• Purity	≥ 99.0 %	100.0 %
• 2,4-pyrimidinediamino-6 chloro-3-oxide	≤ 0.2 %	0 %
• 2,4-pyrimidinediamino-6 piperidino	≤ 0.2 %	0 %
• 2,4-pyrimidinediamino-6 chloro	≤ 0.2 %	0 %
• Each unknown impurity	≤ 0.1 %	0 %
• Total impurities	≤ 1.0 %	0 %
Assay (HClO ₄ 0.1 N) ◇◇	98.5 – 101.0 % o.d.b.	99.4 %
Powder fineness ◇◇◇		
	< 125 µm : not less than 100.0%	100.0 %
	< 100 µm : not less than 90.0%	95.2 %
Bulk density ◇◇◇	0.4 – 0.6 g/mL	0.45 g/mL
Residual Solvents ◇◇◇		
• Methanol	≤ 500 ppm	113 ppm
Class 1 solvents	NOT USED	—

Spec: ALC0159

Date: July 31, 2012	Approved by: Dr. L. Fasoli - Quality Control Manager 	Released by: Dr. P. Volante - Qualified Person
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