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Lote: 023/213

CERTIFICATE OF ANALYSIS

Product MINOXIDIL EP7/USP34 **Code N°** 17150 **Batch N°** 1110761

Manufacturing date Jun 2011 **Retesting date (where applicable)** Jun 2016 **Expiration date (where applicable)**

Analysis Number	L1PF060901		Limits	
Test	Results	M.U.	Min	Max
DESCRIPTION	white crystalline powder		white crystalline powder	off-white crystalline powder
IDENTIFICATION : IR	complies		complies	
IDENTIFICATION : UV	complies		complies	
LOSS ON DRYING	0,19	%		0,50
SULPHATED ASH	0,03	%		0,10
HEAVY METALS	<20	ppm		20
APPEARANCE OF SOLUTION	clear , not more col. than Y6		clear , not more col. than Y6	
RELATED SUBSTANCES : HPLC				
- 2,4-diamino-6-chloropyrimidine	0,01	% as Min.		0,25
- 2,4-diamino-6-chloropyrimidine-3-oxide	<0,01	% as Min.		0,25
- 2,4-diamino-6-piperidinopyrimidine	0,04	% as Min.		0,25
- largest unknown impurity	0,04	% as Min.		0,10
- total related substances	0,12	% as Min.		1,5
ASSAY : HPLC	100,0	% dr.	97,0	103,0
ASSAY : HClO4	100,3	% dr.	98,5	101,0
RESIDUAL SOLVENTS :				
- isopropanol	279	ppm		2000
- acetone	79	ppm		1000
PARTICLE SIZE : laser	on customer request		on customer request	
PACKAGING and STORAGE	preserve in well-closed cont.		preserve in well-closed cont.	

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A) .
Manufacturing site of the Active Pharmaceutical Ingredient : MULAZZANO

Date
June 15 ,2011

Q.C. Manager (Roberto Quaglia)