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CERTIFICATE OF ANALYSIS

Product FUROSEMIDE EP7/USP34 **Code N°** 10705 **Batch N°** 1111164

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

Analysis Number	L1PF092001		Limits	
Test	Results	M.U.	Min	Max
Description	White, crysalline powder		White, crysalline powder	Almost white
Identification				
- IR	Conforms to Standard		Conforms to Standard	
- UV	Conforms to Standard		Conforms to Standard	
Loss on drying	0,1	%		0,5
Water (K.F.)	0,3	%		0,5
Residue on ignition	<0,05	%		0,1
Heavy metals	<20	ppm		20
Sulphates	<300	ppm		300
Chlorides	<200	ppm		200
Assay (NaOH)	100,3	%dried	98,5	101,0
Related Substances HPLC :				
- EP Impurity A/USP Impurity A	<0,025	%	< 0,025(disgregard area value)	0,25
- EP Impurity B	<0,025	%	< 0,025(disgregard area value)	0,25
- EP Impurity C/USP Impurity B	0,11	%	< 0,025(disgregard area value)	0,25
- EP Impurity D	<0,025	%	< 0,025(disgregard area value)	0,25
- EP Impurity E	<0,025	%	< 0,025(disgregard area value)	0,25
- Any other unknown Impurity	0,02	%	< 0,025(disgregard area value)	0,10
- Total Impurities	0,16	%	< 0,025(disgregard area value)	0,50
OVI (USP) : Not used	Not tested		Not tested	
Particle size	for information	micron	for information	
Packaging and Storage	Preserve in well closed,		Preserve in well closed,	light resistant containers

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
September 22 ,2011

Q.C. Manager (Roberto Quaglia)