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Lote: 0020313

CERTIFICATE OF ANALYSIS

Product **FUROSEMIDE EP6/USP32** Code N° **10705** Batch N° **0911188**

Manufacturing date **Nov 2009** Retesting date (where applicable) **Nov 2014** Expiration date (where applicable)

Analysis Number	H1PF112501		Limits	
Test	Results	M.U.	Min	Max
Description	White, crystalline powder		White, crystalline powder	Almost white
Identification				
- IR	Conforms to Standard		Conforms to Standard	
- UV	Conforms to Standard		Conforms to Standard	
Loss on drying	0,2	%		0,5
Water (K.F.)	0,1	%		0,5
Residue on ignition	<0,05	%		0,1
Heavy metals	<20	ppm		20
Sulphates	<300	ppm		300
Chlorides	<200	ppm		200
Assay (NaOH)	100,5	%dried	98,5	101,0
Related Substances HPLC :				
- EP Impurity A/USP Impurity A	<0,025	%	< 0,025(disregard area value)	0,25
- EP Impurity B	<0,025	%	< 0,025(disregard area value)	0,25
- EP Impurity C/USP Impurity B	0,05	%	< 0,025(disregard area value)	0,25
- EP Impurity D	<0,025	%	< 0,025(disregard area value)	0,25
- EP Impurity E	<0,025	%	< 0,025(disregard area value)	0,25
- Any other unknown Impurity	0,08	%	< 0,025(disregard area value)	0,10
- Total Impurities	0,12	%	< 0,025(disregard area value)	0,50
OVI (USP) : Not used	Not tested		Not tested	
Particle size	see enclosed	micron	for information	
Packaging and Storage	Preserve in well closed, light resistant containers		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

December 01 ,2009

Q.C. Manager (Roberto Quaglia)

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