FIS - FABBRICA ITALIANA SINTETICI S.p.A.
Viale Milano, 26 - 36075 Montecchio Maggiore - Vicenza (Italy)
FAX +39-0444-698094 PHONE +39-0444-708011 e-mail mkt@fisvi.com

QUALITY CONTROL

Fabbrica Italiana Sintetici

CERTIFICATE OF ANALYSIS

CoA # 17749

Product: **FUROSEMIDE**

Chemical Name (IUPAC): 4-chloro-2-[(furan-2-ylmethyl)amino]-5-sulfamoylbenzoic acid

CAS NBR: **54-31-9**

Lot Number: **201412170079** **Code:** **0644**

Manufacturing date: Oct-2014 Expiration Date Oct-2019

Test Item:	*Test Results:*	*Specifications:*
APPEARANCE (EP)	Practically white crystalline powder odorless	**Must be practically white crystalline powder odorless**
TEST "C" USP	positive	**positive**
IDENTIFICATION BY IR SPECTROPHOTOMETRY	conform	**must exibit maxima at same wavelenghts as USP RS and EP CRS**
IDENTIFICATION BY UV SPECTROPHOTOMETRY	according to USP and EP	**according to USP and EP**
1ST MAX ABSORPTION (UV SPECT.)	229nm	**226nm - 230nm**
2ND MAX ABSORPTION (UV SPECT.)	272nm	**269nm - 273nm**
3RD MAX ABSORPTION (UV SPECT.)	333nm	**331nm - 335nm**
ABSORBANCE RATIO 271/228 nm	0.55	**0.52 - 0.57**
A (1%, 1 cm) abt 271 nm	585	-
RESIDUE ON IGNITION (EP, USP)	0.0%	**NMT 0.1%**
LOSS ON DRYING (EP, USP)	0.1%	**NMT 0.5%**
ASSAY (by NaOH 0.1N) (EP, USP) (calc. on dried subst.)	100.7%	**98.5% - 101.0%**
APPEARANCE OF SOLUTION (in NaOH) (EP)	clear	**Must be clear**
COLOR OF SOLUTION (in NaOH) (EP)	less than BY5	**Must be less than BY5**
CHLORIDES (EP)	less than 0.02%	**NMT 0.02%**
SULPHATES (EP)	less than 0.03%	**NMT 0.03%**
HEAVY METALS (EP)	less than 10 ppm	**NMT 10 ppm**
HEAVY METALS (USP)	less than 10 ppm	**NMT 10 ppm**
CSAA, RELATED COMP. B (HPLC) (USP)	<0.05%	**NMT 0.20%**
BIS-FUROSEMIDE (HPLC) (USP)	0.08%	**NMT 0.15%**

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Test Item:	*Test Results:*	*Specifications:*
SINGLE LARGEST UNSPECIFIED IMPURITY AT 254 nm (USP)	<0.05%	NMT 0.10%
SINGLE LARGEST UNSPECIFIED IMPURITY AT 272 nm (USP)	<0.05%	NMT 0.10%
TOTAL IMPURITIES AT 254 nm (HPLC) (USP)	0.0%	NMT 0.5%
TOTAL IMPURITIES AT 272 nm (HPLC) (USP)	0.1%	NMT 0.5%
EP IMPURITY C (HPLC)	<0.05%	NMT 0.20%
EP IMPURITY D (HPLC)	<0.05%	NMT 0.15%
SINGLE LARGEST UNSPECIFIED IMPURITY (HPLC) (EP)	<0.05%	NMT 0.10%
TOTAL IMPURITIES (HPLC) (EP)	0.0%	NMT 0.5%
RESIDUAL CHLOROFORM	<10ppm	NMT 60ppm

The product complies with specifications of USP 38 and EP 8.3.

Preserve in well-closed, light resistant container

Lot Approval Date: 23-January-2015

Control and manufacturing records have been reviewed according to FIS internal SOP and found to be in accordance with cGMPs, applicable laws and with all current documentation submitted by FIS to regulatory authorities or to the customer, in connection with marketing authorization.

Lot Released Date: 23-January-2015

Certificate of Analysis was e-signed on 27-Jan-2015 by Federica Panarotto, Quality Control Manager

Certificate of Analysis was e-signed on 27-Jan-2015 by Dr.ssa A.Bortoli, Qualified Person