

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : FUROSEMIDE Ph. Eur.			
BATCH SIZE	: 712.0 Kgs	BATCH No.	: 9024H2RI
MFG. DATE	: Jul. 2009	A. R. No.	: IBN - 090664
EXP. DATE	: Jun. 2014	DATE	: 04/08/2009

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	A white or almost white, crystalline powder, practically insoluble in water, soluble in acetone, sparingly soluble in Ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides. It melts at about 210°C, with decomposition	Conforms
IDENTIFICATION	A Examined between 220 nm and 350 nm the solution shows three absorption maxima, at 228 nm, 270 nm and 333 nm. The ratio of the absorbance at 270 nm to that at 228 nm is 0.52 to 0.57. B Infrared absorption spectra of sample and standard are concordant C A violet-red colour develops.	Conforms Conforms Conforms
RELATED SUBSTANCES (By HPLC)	Impurity A : NMT 0.25% Impurity B : NMT 0.25% Impurity C : NMT 0.25% Impurity D : NMT 0.25% Impurity E : NMT 0.25% Unidentified impurity : NMT 0.10% Sum of Impurity : NMT 0.50%	< 0.05% < 0.05% 0.17% 0.06% Not Detected 0.05% 0.28%
CHLORIDES	NMT 200 ppm	< 200 ppm
SULPHATES	NMT 300 ppm	< 300 ppm
HEAVY METALS	NMT 20 ppm	< 20 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.23% w/w
SULPHATED ASH	NMT 0.1% w/w	0.07% w/w
ASSAY	98.5% - 101.0% of $C_{12}H_{11}ClN_2O_5S$ (on dried basis)	99.6% (odb)
REMARKS : The above sample CONFORMS as per Ph. Eur. Specifications		


ANALYST

DATE : 07/08/2009


MANAGER QUALITY CONTROL

DATE OF PRINT : 07/08/2009