

## QUALITY DIVISION

### CERTIFICATE OF ANALYSIS

|                                                  |                    |                  |                       |
|--------------------------------------------------|--------------------|------------------|-----------------------|
| <b>NAME OF THE PRODUCT : FUROSEMIDE Ph. Eur.</b> |                    |                  |                       |
| <b>BATCH SIZE</b>                                | <b>: 630.0 Kgs</b> | <b>BATCH No.</b> | <b>: 1059H2RI</b>     |
| <b>MFG. DATE</b>                                 | <b>: Nov. 2011</b> | <b>A. R. No.</b> | <b>: IBN – 111154</b> |
| <b>EXP. DATE</b>                                 | <b>: Oct. 2016</b> | <b>DATE</b>      | <b>: 01/12/2011</b>   |

| <u>TESTS</u>                            | <u>SPECIFICATIONS</u>                                                                                                                                                                                                                                                                                         | <u>RESULTS</u>                                                                  |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>CHARACTERS</b>                       | 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.<br><br>It melts at about 210°C, with decomposition.                  | Conforms                                                                        |
| <b>IDENTIFICATION</b>                   | 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.<br><br>B. Infrared absorption spectra of sample and standard are concordant.<br><br>C. A violet-red colour develops. | Conforms<br><br>Conforms<br><br>Conforms                                        |
| <b>RELATED SUBSTANCES<br/>(By HPLC)</b> | Impurity A : NMT 0.25%<br>Impurity B : NMT 0.25%<br>Impurity C : NMT 0.25%<br>Impurity D : NMT 0.25%<br>Impurity E : NMT 0.25%<br>Unidentified impurity : NMT 0.10%<br>Sum of Impurity : NMT 0.50%                                                                                                            | < 0.05%<br>Not Detected<br>0.10%<br>Not Detected<br>< 0.05%<br>< 0.05%<br>0.10% |
| <b>CHLORIDES</b>                        | NMT 200 ppm                                                                                                                                                                                                                                                                                                   | < 200 ppm                                                                       |
| <b>SULPHATES</b>                        | NMT 300 ppm                                                                                                                                                                                                                                                                                                   | < 300 ppm                                                                       |
| <b>HEAVY METALS</b>                     | NMT 20 ppm                                                                                                                                                                                                                                                                                                    | < 20 ppm                                                                        |
| <b>LOSS ON DRYING<br/>(at 105°C)</b>    | NMT 0.5% w/w                                                                                                                                                                                                                                                                                                  | 0.39% w/w                                                                       |
| <b>SULPHATED ASH</b>                    | NMT 0.1% w/w                                                                                                                                                                                                                                                                                                  | 0.08% w/w                                                                       |
| <b>ASSAY</b>                            | 98.5% - 101.0% of C <sub>12</sub> H <sub>11</sub> ClN <sub>2</sub> O <sub>5</sub> S<br>(on dried basis)                                                                                                                                                                                                       | 99.9% (odb)                                                                     |

**REMARKS :** The above sample **CONFORMS** as per **Ph. Eur.** Specifications.

  
**ANALYST**  
**DATE : 10/12/2011**

  
**MANAGER QUALITY CONTROL**  
**DATE OF PRINT : 10/12/2011**