

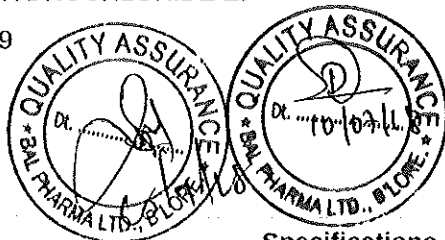


# Bal Pharma Limited

(Quality Control Department)  
**CERTIFICATE OF ANALYSIS**

Unit - II :  
61-B, Bommasandra Industrial Area  
Bangalore - 560 099, INDIA  
Tel : +91-80-41570814 / 815 / 816 / 817  
Fax : +91-80-41570812  
Email : unit2@balpharma.com / balpharma@yahoo.com

|                    |                              |                    |              |
|--------------------|------------------------------|--------------------|--------------|
| Product            | : AMILORIDE HYDROCHLORIDE EP | CAS No             | : 17440-83-4 |
| Batch No           | : 200111805009               | Batch Qty          | : 35.180Kgs  |
| Mfg. Date          | : May-2018                   | A.R.No.            | : FP081018   |
| Retest/Expiry Date | : Apr-2023                   | Release Date       | : 23-06-2018 |
| Customer Name      | : --                         | Customer Spec. No. | : --         |



| Tests                        | Specifications                                                                          | Results              |
|------------------------------|-----------------------------------------------------------------------------------------|----------------------|
| Description                  | A pale-yellow or greenish-yellow powder.                                                | A pale yellow powder |
| Solubility                   | Slightly soluble in water and in anhydrous ethanol.practically insoluble in heptane     | Complies             |
| Identification               | a) IR spectrum                                                                          | Complies             |
|                              | b) TLC                                                                                  | Complies             |
|                              | c) Cetrimide test                                                                       | Positive             |
|                              | d) Chlorides                                                                            | Positive             |
|                              | e) Water test should be confirms                                                        | Conforms             |
| Free acid                    | Not more than 0.3ml of 0.1M sodium hydroxide is required to neutralize 1.0gm of sample. | Complies             |
| Related substances (by HPLC) | Impurity C :Not more than 0.2%                                                          | <0.2%(0.11%)         |
|                              | Unspecified impurities(each) :Not more than 0.10%                                       | *BDL                 |
|                              | Total impurities : Not more than 0.4%                                                   | <0.4%(0.11%)         |
|                              | Between 11.0 and 13.0% w/w                                                              | 11.12%               |
| water                        |                                                                                         |                      |
| Sulphated ash                | Not more than 0.1%                                                                      | <0.1%(0.05%)         |
| Assay (On anhydrous basis)   | 98.0 - 101.0 %                                                                          | 98.8%                |
| Residual solvents            | Methanol : Not more than 1000ppm                                                        | BDL                  |
|                              | Acetonitrile : Not more than 200ppm                                                     | BDL                  |
|                              | Dimethylformamide : Not more than 500ppm                                                | BDL                  |

**Remarks:** \*BDL=Below Detectable Limit. The material complies with respect to Ph.Eur-9.2 specifications.

Complied by: Sandhya. M.N

Checked by: Shanthala. S

Approved by: Raghunatha T.H

Date: 10-07-2018

Date: 10-07-2018

Date: 10-07-2018

Prepared by: Kamala. P

Verified by: Rajasekhar

Authorized by: Venkatesh S Rao

Date: 10-07-2018

Date: 10-07-2018

Date: 10-07-2018