



Bal Pharma Limited

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

(Quality Control Department) CERTIFICATE OF ANALYSIS

Product : AMILORIDE HYDROCHLORIDE EP
Batch No : 2001022001002
Mfg. Date : Jan-2020
Retest/Expiry Date : Dec-2024
Customer Name : Meta Pharmaceutical Ind S.L



CAS No : 17440-83-4
Batch Qty : 31.590Kgs
A.R.No. : FP/0134/20
Release Date : 04-03-2020
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) Infrared absorption spectrum of sample should be concordant with the Infrared absorption spectrum of Amiloride HCl working standard.	Complies
	b) TLC	Complies
	c) Chlorides test should be positive	Positive
	d) Water test should be confirms	Complies
Free acid	Not more than 0.3ml of 0.1M sodium hydroxide is required to neutralize 1.0gm of sample.	NII
Related substances (By HPLC)	Unspecified impurities(each) :Not more than 0.10%	0.07%
	Total impurities : Not more than 0.4%	<0.4%(0.07%)
	Impurity C :Not more than 0.2%	*BDL
water	Between 11.0 and 13.0% w/w	11.06%
Sulphated ash	Not more than 0.1%	<0.1%(0.06%)
Assay (On anhydrous basis)	98.0 - 101.0 %	100.3%
Residual solvents	Methanol : Not more than 1000ppm	14ppm
	Acetonitrile : Not more than 200ppm	BDL
	Dimethylformamide : Not more than 500ppm	BDL

Remarks: *BDL=Below Detectable Limit. The product complies with respect to EP-9.7 specification.

Compiled by: Ranjitha V.P	Checked by: Amaranatha. R	Approved by: Sivaraman. V
Date: 07-03-2020	Date: 07-03-2020	Date: 07-03-2020

Prepared by: Perumal. P
Date: 07-03-2020

Verified by: V. Sundarachari
Date: 07-03-2020

Authorized by: Venkatesh S Rao
Date: 07-03-2020

P. — R
07/03/2020

V. Sundarachari
07/03/2020

Venkatesh S Rao
07/03/2020