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QUALITY ASSURANCE * BAL PHARMA LTD. B'LORE * Dt. 09/06/2020

Quality Control Department
CERTIFICATE OF ANALYSIS

PRODUCT	: BENZYDAMINE HCl EP	CAS NO	: *132-69-4*
Batch No	: 300111911068	Batch qty	: 76.750Kgs
Mfg. Date	: November-2019	A.R.No.	: FP/0340/20
Expiry Date	: October-2024	Release date	: 11.05.2020
Customer Name	: -----	Customer spec. No.:	------

Tests	Specifications	Results
Appearance	A white or almost white, hygroscopic, crystalline powder.	A white crystalline powder
Solubility	Very soluble in water; Freely soluble in Ethanol96%) and in methylene chloride, slightly soluble in acetone, Practically insoluble in heptane.	Complies
Identification	a) Infrared spectrum should be concordant with that of the reference spectrum of benzydamine hydrochloride b) Should be positive to reaction chlorides	Complies Positive
Related substances (by HPLC)	1. Impurity B NMT 0.5% 2. Impurity A NMT 0.2% 3. Impurity D NMT 0.15% 4. Unspecified impurity NMT 0.10% 5. Total impurities NMT 1.0%	*BDL BDL BDL BDL BDL
Loss on drying	Not more than 1.0%	<1.0%(0.15%)
Sulphated ash	Not mote than 0.1%	<0.1%(0.06%)
Assay (On dried basis)	NLT 99.0 to NMT 101.0%	100.6%
Impurity G(CPDMA) (by GC)	Not more than 5ppm	1.7ppm
Residual solvents	Methanol :NMT 1000ppm Isopropyl alcohol :NMT 2500ppm Toluene :NMT 200ppm Chlorobenzene :NMT 100ppm Dimethyl sulphoxide :NMT 2000ppm	BDL 292ppm BDL BDL BDL

Remarks: *BDL=Below Detectable Limit.The product complies with respect to EP-10.0 specification.

Compiled by: Sanjaya (Officer Q.C)	Checked by:Kishor (Asst,Manager Q.C)	Approved by:Mahesh C.M (Sr, Manager Q.C)
Date: 11.05.2020	Date: 11.05.2020	Date: 11.05.2020

Prepared by
Date 09/06/2020

Verified by
Date 09/06/2020

Authorized by
(Quality Assurance)
9/6/2020