



MICRO LABS LIMITED
API, BOMMASANDRA (ML-15)

Factory: Plot No. 43-45, KIADB, Jigani-Bommasandra Link Road, Anekal Taluk, Bengaluru - 560 105, India.

Phone : 08110 - 415647/48, Fax: 08110- 415647-131

Regd. Office: 31, Race course Road, Bengaluru-560001, Karnataka, India.

CIN: U24232KA1973PLC002401

Website: www.microlabsltd.com E-mail Address: info@microlabs.in

CERTIFICATE OF ANALYSIS

Product Name	: Besifloxacin Hydrochloride	Mfg. Date	: April-2021
Batch No.	:	Retest/ Expiry date	: March-2026
AR No.	:	Analysis completed on	: 10/05/2021
Batch Quantity	: 3.906 Kg	Specification No.	:
COA Number	:		

S. No.	Test	Results	Specification Limit
1	Description	Pale yellow powder.	White to pale yellow powder.
2	Identification		
	a) By IR	The IR spectrum of the sample is concordant with the IR spectrum of the BES working standard.	The IR spectrum of the sample should be concordant with the IR spectrum of the BES reference/working standard.
	b) By HPLC	The retention time of the principle peak in the chromatogram of the sample solution is corresponding to that in the chromatogram of the standard solution as obtained in the test for assay by HPLC.	The retention time of the principle peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution as obtained in the test for assay by HPLC.
	c) Test for Chloride	Complies	Sample should respond to the test for chloride.
3	Solubility	Slightly soluble in methanol and slightly soluble in water.	Slightly soluble in methanol and slightly soluble in water.
4	Water content by KF Titrator	0.22% w/w	Not more than 1.0% w/w
5	Residue on ignition	0.03% w/w	Not more than 0.1% w/w
6	Related substances by HPLC		
	Method-1		
	a) BES-1	Not detected	Not more than 0.10 %
	b) BES Impurity B	0.03%	Not more than 0.15 %
	c) BES Impurity C	Not detected	Not more than 0.15 %
	▶ Any other individual impurity	0.03%	Not more than 0.10 %
	Method-2		
	BES-S2 content	Below detection limit (0.01%)	Not more than 0.10% w/w
	Total impurities (Method-1 + Method-2)	0.09% w/w	Not more than 0.50% w/w
7	BES impurity A content by chiral HPLC	0.25% w/w	Not more than 0.5% w/w
8	Assay by HPLC (On anhydrous and solvent free basis)	100.1%w/w	Not less than 98.0%w/w and Not more than 102.0%w/w
9	HCl content by titrimetry (on anhydrous basis)	8.8%w/w	Between 8.0%w/w and 9.0%w/w
10	Residual solvents by GC		
	Method-1		
	a) Methanol	119 ppm	Not more than 3000 ppm
	b) Isopropyl alcohol	Not detected	Not more than 5000 ppm
	c) Acetonitrile	Not detected	Not more than 410 ppm
	d) Acetone	Not detected	Not more than 5000 ppm
	e) Dichloromethane	Not detected	Not more than 600 ppm
	f) Tetrahydrofuran	Not detected	Not more than 720 ppm
	Method-2		
	a) Benzene content	Not detected	Not more than 2 ppm
	b) Mesityl oxide content	Not detected	Not more than 100 ppm

Prepared by (QC): <i>SLC</i>	Reviewed by (QC): <i>B. Srinivas</i>	Approved by (QA): <i>[Signature]</i>
Date : 10/05/21	Date : 10/05/21	Date : 10/05/2021

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 AR No. : Analysis completed on : 10/05/2021
 Batch Quantity : 3.906 Kg Specification No. :
 COA Number :

S. No.	Test	Results	Specification Limit
11*	Microbial Limit Test		
	a) Total Aerobic Microbial Count (TAMC)	Less than 10 CFU/g	Not more than 100 CFU/g
	b) Total Yeasts and Molds (TYMC)	Less than 10 CFU/g	Not more than 10 CFU/g
	c) Pathogens:		
	i) <i>Escherichia coli</i>	Absent	Should be absent/g
	ii) <i>Pseudomonas aeruginosa</i>	Absent	Should be absent/g
	iii) <i>Staphylococcus aureus</i>	Absent	Should be absent/g
	iv) <i>Salmonella species</i>	Absent	Should be absent/10g
	v) <i>Enterobacteria</i>	Absent	Should be absent/g
	vi) <i>Clostridia</i>	Absent	Should be absent/g
	vii) <i>Candida albicans</i>	Absent	Should be absent/g
12*	Bacterial Endotoxins test (BET)	Less than 10 EU/mg	Not more than 10 EU/mg
13*	Particle size distribution by laser diffraction		
	a) d(0.1)	4 µm	For information only
	b) d(0.5)	15 µm	
	c) d(0.9)	33 µm	
	d) d(1.0)	60 µm	
14*	Bulk Density		
	a. Untapped density	0.26 g/mL	For information only
	b. Tapped density	0.53 g/mL	

Remarks: The Product is Complies with the above specification. *Customer requirement

Prepared by (QC): <i>fllo</i>	Reviewed by (QC): <i>B. Srinivas</i>	Approved by (QA): <i>Deero</i>
Date : 10/05/21	Date : 10/05/21	Date : 10/05/2021

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Product Details:

Storage condition: Preserve in air-tight container and protected from light. Store at controlled temperature at 25 °C, excursion permitted between 15 °C and 30 °C.

Packing condition: Pack the sample in transparent LDPE bag, twist and tie with tag, followed by black LDPE bag, twist and tie with tag, followed by triple laminated aluminum bag, seal the bag with heat sealer and then place in HDPE drum.

Chemical Names :

BES impurity A: 7-[(3S)-3-amino-6-fluoro-8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid hydrochloride

BES impurity B : 7-[(3R)-azepin-3-ylamino]-8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

BES-1 : 7-[(3R)-3-aminoazepin-1-yl]-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid hemimandelate

BES impurity C : 7-{3-[7-(8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid)amino] azepan-1-yl} 8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid

BES-S2 : (3R)-azepan-3-amine mandelate.

Prepared by (QC): <i>glo</i>	Reviewed by (QC): <i>B. Srinivas</i>	Approved by (QA): <i>Deena</i>
Date : 10/05/21	Date : 10/05/21	Date : 10/05/2021

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