

400, Tongi Industrial Area, Squibb Road, Tongi, Gazipur.
 Phone: 0088-02-9802127-8; Fax: 0088 - 02 - 9801859

QUALITY ASSURANCE
CERTIFICATE OF ANALYSIS
 Working Standard

Name of the Material		Alfuzosin Hydrochloride		
Code number	WS0005	Standardization Against	0.1 M HClO ₄	
QC Reference No.	RT131365	Reference Standard/Working Standard Batch No.	NA	
RR No.	RM-U05-13-0942	Reference Standard/Working Standard Potency:	NA	
Batch No.	PAFZP30006	RR No.	NA	
Mfg. Date	05/13	Mfg. Date	NA	
Exp. Date	29/04/18	Exp. Date	NA	
Preparation Date	22/02/14			
Valid up to	21/02/15 (Container 1 to 4)			
Valid up to	21/05/15 (Container 5)			
Sl. No.	Test	BP Specification	SK+F Specification	Result
1	Description	White or almost white, crystalline powder, slightly hygroscopic.	Same	Almost white crystalline powder, slightly hygroscopic.
2	Identification	Must meet (A & B)	Same	Positive
3	Loss on Drying	NMT 2.00 %	Same	0.21%
4	Potency	98.50 – 101.00 % on AB	Same	99.83% as it is 100.04% on AB
Remarks: Ok. Reference: Book - 262 ; Page - 194.				



22.02.14

Prepared by
 (Md. Rafiqul Islam)
 Sr. Asst. Quality Control Manager

Nusrat 22.02.14

Checked by
 (Nusrat Sultana)
 Quality Control Executive

Shafiq 22/02/14

Approved by
 (A.K.M. Shafiq-ul-Islam)
 Sr. Quality Control Manager



UNICHEM
LABORATORIES LTD.

Plot No. 197, Sector -1, Pithampur - 454 775,
Dist. - Dhar (M.P.) INDIA, Tel. No. : 07292-416600, 416601
Fax No. : 07292-416605, Website : www.unichemlabs.com

CERTIFICATE OF ANALYSIS

(API)

API Name	: ALFUZOSIN HYDROCHLORIDE Ph. Eur.	A.R. No.	: 040000068635
API Code	: 10000101	Batch size	: 30.60 KG
Batch No.	: PAFZP30006✓	Sampled by	: MT
Mfg. Date	: MAY. 2013✓	Date of sampling	: 19.06.2013
Retest Date	: APR. 2018✓	Spec. No.	: CQA/APIS/AFZ02/04
Date of Report	: 28.06.2013	STP No.	: CQA/APISTP/AFZ02/02
		Batch Qty.	: 30.400 KG

Sr. No.	TESTS	SPECIFICATIONS	RESULTS
01	Characters		
	i) Appearance	A white or almost white, crystalline powder, slightly hygroscopic.	Almost white, crystalline powder, slightly hygroscopic.
	ii) Solubility	Freely soluble in water, sparingly soluble in ethyl alcohol (96%) practically insoluble in methylene chloride.	Freely soluble in water, sparingly soluble in ethyl alcohol (96%) practically insoluble in methylene chloride.
02.	Identification		
	A) By IR	The IR spectrum of sample should be concordant with the spectrum obtained from Alfuzosin Hydrochloride working standard.	The IR spectrum of sample is concordant with the spectrum obtained from Alfuzosin Hydrochloride working standard.
	B) Chlorides	A white curdy precipitate should form, which dissolves in dilute ammonia solution.	A white curdy precipitate is formed, which dissolved in dilute ammonia solution.
03.	pH	Between 4.0 and 5.5	4.8
04.	Water by KF (%w/w)	NMT 0.5%	0.16%
05.	Sulphated Ash (%w/w)	NMT 0.1%	0.03%
06.	Related substances by HPLC (% w/w)		
	i) Impurity D	NMT 0.2%	0.02%
	ii) Unspecified impurity	NMT 0.10%	Below disregard limit
	iii) Total impurities	NMT 0.3%	Below disregard limit.
07.	Assay by Potentiometry (% w/w) (on anhydrous basis)	Between 99.0% and 101.0%	99.5%

checked by *[Signature]* 29/10/14

Checked By	Approved By
Name: <i>mykesh vram</i>	Name: <i>[Signature]</i>
Designation: <i>Asst. Mgr - QC</i>	Designation: <i>Asst. Manager QA</i>
Sign & Date: <i>[Signature]</i> 18/10/13	Sign & Date: <i>[Signature]</i> 18/10/13



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		Batch Qty.	: 30.400 KG

Sr. No.	TESTS	SPECIFICATIONS	RESULTS
	Additional tests		
A	Residual solvents by GC		
	i) Methanol	NMT 1000 ppm	Not detected
	ii) Diethyl ether	NMT 1000 ppm	Not detected
	iii) Acetone	NMT 5000 ppm	Not detected
	iv) Toluene	NMT 890 ppm	Not detected
	v) Ethanol	NMT 5000 ppm	273 ppm
	vi) Isoamyl alcohol	NMT 5000 ppm	Not detected
B	By XRPD	The XRPD pattern of the sample should be concordant with the XRPD pattern of working standard (Anhydrous form).	The XRPD pattern of the sample is concordant with the XRPD pattern of working standard (Anhydrous form).
C	Microbial Examination		
	a) Total microbial count		
	Aerobes	NMT 1000 CFU/gm	35 CFU/gm
	Fungi	NMT 100 CFU/gm	Less than 10 CFU/gm
	b) E.coli	Absent in 1 gm.	Absent in 1 gm.
D	Particle size		
	Particle size less than 100 µm	NLT 75.0%	100.0%
	Particle size less than 250 µm	NLT 95.0%	100.0%
E	Heavy metals	NMT 20 ppm	Less than 20 ppm

REMARKS: The above API Complies with the prescribed standard of quality with respect to above tests as per Specification No. CQA/APIIS/AFZ02/04 (EP-7).

Checked By	Approved By
Name: <i>Mykash Verma</i>	Name: <i>Pooja G.</i>
Designation: <i>Asst. Mgr. QC</i>	Designation: <i>Dy. Manager QA</i>
Sign & Date: <i>[Signature] 18/10/13</i>	Sign & Date: <i>[Signature] 18/10/13</i>

COA Reissued on 18.10.2013 for ESKAYEF BANGLADES LTD., BANGLADESH

ESKAYEF BANGLADESH LIMITED

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SK+F**QUALITY ASSURANCE****CERTIFICATE OF ANALYSIS
RAW MATERIAL**

Material : Alfuzosin Hydrochloride	Quantity & Container : 01 x 5kg = 5.0 kg	RM Code : RM0005
Manufacturer: Unichem Laboratories Limited, India.	Packing : Sealed in 2PE outer black in sealed alu foil in plastic drum with steel security seal.	QC. Ref. No.: RT131365
Supplier: Unichem Laboratories Limited, India.	Storage : ATC,PFL,Ambient. Date Sampled : 07.01.14	RR No. : RM-U05-13-0942
Date Received : 03.12.13	Container Sampled : 01 Quantity Sampled : 45g	Bx./Lot No. : PAFZP30006
Date RR Received by QC : 03.12.13	Sampled by : <i>JO</i> Date of Analysis : 09.01.14 to 16.01.14	Mfg. Date : 05/13
Declared Potency : 99.5 % on AB	Assigned Potency : 100.00 % as it is	Exp. Date : 29/04/18

No.	Test	BP Specification	SK+F Specification	Result
1	Description	White or almost white, crystalline powder, slightly hygroscopic.	Same	Almost white crystalline powder, slightly hygroscopic.
2	Solubility	Freely soluble in water, sparingly soluble in alcohol, practically insoluble in methylene chloride.	Same	1.05847g dissolved in 9 ml of water, 1.04475g dissolved in 99ml of ethanol(96%).
3	Identification	Must Meet (A & B)	Same	Positive (A & B)
4	pH	4.00 to 5.50	Same	4.9
5	Related substance	Impurity D : NMT 0.20% Unspecified impurity: NMT 0.10% Total Impurities: NMT 0.30%	Same	Impurity D : 0.02% Unspecified impurity: 0.02% Total Impurities: 0.09%
6	Water Content	Maximum 0.50%	Same	0.26%
7	Sulphated ash	Maximum 0.10%	Same	0.03%
8	Assay	99.00 - 101.00% on AB	Same	99.97% as it is 100.23% on AB

Additional test

9	Particle size	-	About 95 % passes through 100 mesh (< 150 micron)	99.86% passes through 100 mesh (< 150 micron).
10	Residual solvents	-	Methanol: NMT 1000ppm Diethyl ether: NMT 100ppm Acetone: NMT 5000ppm Toluene: NMT 890ppm Ethanol: NMT 5000ppm Isoamyl alcohol: NMT 5000ppm	Methanol: Not detected Diethyl ether: Not detected Acetone: Not detected Toluene: 9ppm Ethanol: 264ppm Isoamyl alcohol: Not done

Remarks : Ok.

Reference : Book- 304; Page-60.

☒ Released for use☐ Rejected

Prepared by

(Md. Rafiqul Islam)

Sr. Asst. Quality Control Manager

Checked by

(Md. Shafiqul Islam)

Sr. Quality Control Executive

Approved by

(A.K.M. Shafiq-ul-Islam)

Sr. Quality Control Manager