



**UNICHEM**  
**LABORATORIES LTD.**

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**CERTIFICATE OF ANALYSIS**

(API)

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

Sr. No.	TESTS	SPECIFICATIONS	RESULTS
01	<b>Characters</b>		
	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.	<b>Identification</b>		
	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%	0.19%
05.	Sulphated Ash (%w/w)	NMT 0.1%	0.03%
06.	<b>Related substances by HPLC (% w/w)</b>		
	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 *29/06/14*

Checked By	Approved By
Name: <i>mykesh veng</i>	Name: <i>May Gion</i>
Designation: <i>Asst. Mgr - QC</i>	Designation: <i>Dr. Manoj K R</i>
Sign & Date: <i>18/10/13</i>	Sign & Date: <i>18/10/13</i>