BEXIMCO PHARMA

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CERTIFICATE OF ANALYSIS (WORKING STANDARD)

Name of Standard	:	Ketotifen Fumarate BP/Ph.Eur			
Mfg. Batch No.	 	0902814	Specification No.	T	RM-O 16
A.R. No.	1:	WS-04-15-016	Reference	:	N/A
Date of preparation	<u> </u>	25.04.15	Ref. Lot. No.	:	N/A
Use before	 	31.12.15	Prepared Quantity	:	15 X 200 mg
Storage condition	1:	2-8°C			

Test ,	Specification	Observation	
Description	A white, fine, crystalline powder.	Complies	
Identification			
A) By IR spectrum	The Infrared absorption spectrum of a sample match with reference spectrum of ketotifen fumarate.	Complies	
B) TLC	The spot due to fumaric acid in the chromatogram obtained with the test solution is similar in position, color and intensity to the principal spot in the chromatogram obtained with the reference solution.		
Loss on drying	NMT 0.5 %w/w	0.16 % w/w	
Assay (on dried basis)	say (on dried basis) 98.5 % to 101.0 %w/w		
Assay (as is basis)		99.5 %	

We hereby certify that, the working standard has been evaluated in accordance with the requirement of the approved SOP and specification.

4 25.04.15 Prepared By

Checked By

Approved By

FRM No.: FQC/278-01