

**BEXIMCO PHARMACEUTICALS LIMITED**

TONGI - 1711, GAZIPUR, BANGLADESH

Phone: 88-02-9810701-5, Fax: 88-029810711, E.mail: [info@bpl.net](mailto:info@bpl.net), Web: [www.beximcopharma.com](http://www.beximcopharma.com)**CERTIFICATE OF ANALYSIS  
(WORKING STANDARD)**

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

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.	Complies
Loss on drying	NMT 0.5 %w/w	0.16 % w/w
Assay (on dried basis)	98.5 % to 101.0 %w/w	99.70 %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.

*W*  
25.04.15  
Prepared By

*Buldm*  
25.04.15  
Checked By

*Shm*  
25.04.15  
Approved By

FRM No.: FQC/278-01

