ajanta pharma limited

Ajanta House,
Charkop, Kandivli West,
Mumbai 400 067
India

T +91 22 6606 1000
F +91 22 6606 1200
E info@ajantapharma.com
W www.ajantapharma.com

NQCL
WRS
B21-1

CERTIFICATE OF ANALYSIS
(Working Standard)

Name of the sample	BROMFENAC SODIUM SESQUIHYDRATE		
Lot Number	WS/B-04.12		
Date of analysis	Apr 24, 2015	**Retest Date**	Apr 23, 2016

Sr. No.	Test(s)	Specification(s)	Result(s)
1.0	Description	Yellow or orange, crystalline powder, odourless.	Yellow crystalline powder, odourless. Complies
2.0	Solubility	Soluble in water and in 0.1N sodium hydroxide; slightly soluble in methanol, insoluble in chloroform and 0.1N hydrochloric acid.	Complies
3.0	Identification A. Ultraviolet and visible absorption spectrophotometry B. Infrared absorption C. Test for Sodium	The maximum absorption is at about 268 nm and 379 nm. The infrared absorption spectrum of the sample is concordant with the spectrum of Bromfenac Sodium working standard. A dense white precipitate is formed.	Maximum absorption is at 374.80 nm Positive Positive Positive
4.0	pH (5.0% solution in water)	8.5 to 10.5	9.37
5.0	Water content (By KF)	6.0% to 8.0%	6.79%
6.0	Related substances i) Individual impurity ii) Total impurities	 Not more than 0.5% Not more than 1.0%	 0.137% 0.362%
7.0	Assay Bromfenac Sodium (On anhydrous basis)	Not less than 98.0 % and not more than 102.0%	99.6%

Remarks: The working standard of Bromfenac Sodium Sesquihydrate WS/B-04.12, complies as per In-house specification.

Prepared By	Checked By	Approved By
Jayashree Ghatkar Analyst Date: Apr 24, 2015	Nitin Gonjare Executive Date: Apr 24, 2015	Dr. Dhanraj Amin Associate Vice President Date:

AJANTA PHARMA LIMITED
MUMBAI
AUTHORISED C. O. A.
Sign :-
Date :- May 18, 2015

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
02 JUL 2015
TEL: 2726963 / 3544525/30
FAX: 2718073
P. O. Box 29726 – 00202, NAIROBI