

Centaur

We impart Health to Life

CENTAUR PHARMACEUTICALS PVT. LTD.

API DIVISION

Centaur House, Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E).
 Mumbai - 400 055, INDIA. Tel: +91 22 66499100 • Fax: +91 22 66499108/112
 Email: export@centaurchem.com • Website: http://www.centaurpharma.com/api

Formulations • API • Contract Manufacturing • Contract Research

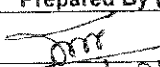
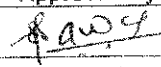
CERTIFICATE OF ANALYSIS

Name of the Drug	BRIMONIDINE TARTRATE	AR NO.: FP/042/14/0019
Batch No.	201404202P	Mfg. Date January'2014
Batch Size	6.350 Kg	Exp. Date December'2018 ✓
Lot Size	---	Analysis Date 19/01/2014

Results of the analysis and protocols of the tests applied

S. No.	Test	Specification	Result
1	Description	White to slightly yellowish powder.	Slightly yellowish powder.
2	Solubility	Soluble in water and slightly soluble in methanol	Soluble in water and slightly soluble in methanol
3	Identification Infrared absorption Spectrophotometry	The IR spectrum of sample should be concordant with IR spectrum of Ref/working Standard of Brimonidine tartrate.	Complies
4	pH of solution (1 % w/v solution)	Between 3.0 to 4.5	3.91
5	Appearance of solution	Solution Should be clear and not more intensely coloured than reference solution Y ₇ .	Solution is clear and less intensely coloured than reference solution Y ₇ .
6	Specific optical rotation	+ 9.0° to + 10.5°	+ 10.0°
7	Loss on drying (105 °C for 3 h)	Not more than 0.5 %	0.33 %
8	Sulphated ash	Not more than 0.1 %	0.04 %
9	Heavy Metals	Not more than 20 ppm	Less than 20 ppm
10	Related Substances By HPLC	i) Individual Impurities: Acetyl Brimonidine: NMT 0.10 % Bromo compound: NMT 0.10 % Desbromobrimonidine: NMT 0.10 % ii) Unknown impurity: NMT 0.10 % iii) Total impurities: NMT 0.50 %	Less than 0.01 % (LOD) Less than 0.01 % (LOD) Less than 0.01 % (LOD) Less than 0.01 % (LOD) Less than 0.01 %
11	Assay (By HPLC)	99.0 % - 101.0 % of C ₁₁ H ₁₀ BrN ₅ .C ₄ H ₆ O ₆ on the dried basis.	99.9 %
12	Residual solvent By GC	Acetone: NMT 5000 ppm Ethyl acetate: NMT 5000 ppm Methanol: NMT 3000 ppm Monochloro Benzene: NMT 360 ppm Methylene chloride (MDC): NMT 600 ppm Benzene: NMT 2 ppm	1319 ppm Less than 24 ppm (LOD) 133 ppm Less than 2.88 ppm (LOD) Less than 4.8 ppm (LOD) Less than 0.19 ppm (LOD)
13	Tartrate content by Titration	33.2 % - 34.4 %	33.4 %
14	Acetic acid content by GC	NMT 5000 ppm	Less than 60 ppm (LOD)

The sample complies with the prescribed above Inhouse specification.

	Prepared By (Analyst)	Approved By (QC Manager)
Signature		
Date	08/03/2014	08/03/2014