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SUN PHARMACEUTICAL INDUSTRIES LTD.

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	: Careprost sterile Eye drops, 3ml	**Mfg. Date**	: 10/2012
Generic Name	: Bimatoprost ophthalmic solution , 0.03% w/v		
Batch No.	: HKL1234	**Exp. Date**	: 09/2014
A.R. No.	: F121279	**Release Date**	: 20/10/2012

Sr. No.	Test	Result	Specification
1.	Description	Clear, colourless solution filled in 5ml opaque plastic bottle.	Clear, colourless solution filled in 5ml opaque plastic bottle.
2.	Identification- By HPLC	Meets the requirement	The retention time of the major peak in the chromatogram in assay preparation is corresponds to that of the standard preparation as obtain in assay.
3.	pH	7.1	Between 6.0 and 8.0
4.	Volume in container	3.45 ml	Not less than 3.0 ml
5.	Volume variation	Min.: 3.37 ml Max. : 3.51 ml	Between 3.00 ml and 3.75 ml
6.	Sterility	Sterile	Should comply the test.
7.	% Transmittance at 650 nm.	99.1 %	Not less than 95.0%
8.	Absorbance of solution at 420 nm.	0.006	Not more than 0.1
9.	Assay -of Benzalkonium chloride solution	0.1012 mg/ml 101.2 %	Between 0.08 mg/ml and 0.12 mg/ml (Between 80.0% and 120.0% of the label claim)
10.	Degradation product- by HPLC.	Individual : 0.144 % Total : 0.196 %	Individual impurity : Not more than 4.0% Total impurity : Not more than 8.0%
11.	Assay- of Bimatoprost	0.3081 mg/ml 102.7 %	Between 0.27 mg/ml and 0.33 mg/ml Between 90.0% and 110.0% of label claim.

Opinion: The above Batch complies as per In-house specification.

Generated By :	**Authorized By :**
Date : 03/12/12	**Date :** 03/12/12

SUN PHARMACEUTICAL INDUSTRIES LIMITED CHECKED Q.C.