




POPULAR PHARMACEUTICALS LTD
QUALITY CONTROL DEPARTMENT
INDUSTRIAL OPERATIONS
TONGI

Certificate of Analysis for Working Standard

Material Name	Tobramycin	Expiry Date :10.02.2017
Material Code No.	PORA0013	
Batch No. (In House)	WS/16/029	

Raw material details		Reference Standard details	
Manufacturer	Iffect Chemphar Co. Ltd, China	Name of the RS	Tobramycin
Manufacturer's Batch No.	IF-TO-150416	RS Batch No.	WS/15/029
GRN No.	PR-1215-0132	RS Vial No.	'04
Manufacturing date	16.04.2015	RS Potency (AS Such)	902.85 ug/mg
Expiry date	15.04.2018	Opening Date	10.11.2015
Analysis date	05.01.2016	Valid up to	10.02.2016
		Testing Instruction	BP-2015
		Analyst's log book reference	LB/JEF/07 (Page# 185)

Tests	Specifications	Results
Appearance	White or almost white powder.	Almost white powder.
Water	Not more than 8.0%	7.29%
Assay	Not less than 900 µg/mg , calculated on the anhydrous basis.	975.03 µg/mg
Assay (As such)	N/A	903.95 µg/mg
Conclusion : <i>Material complies with in-house specification. Released to use as working standard.</i>		
Authorized person : Md. Feroz Alam, Sr. Manager-Quality control.		signature :  10.02.16.

Certificate issued on 10/02/2016 by
 Popular Pharmaceuticals Limited

End of report



Handwritten signature

T37-1
SPECIFICATION

POPULAR PHARMACEUTICALS LTD.

Product Name : TOBRABAC EYE DROPS

Product Code : 51117

Document No

SPC/FDF/108/00

Ref : USP + In - House

Page

1 of 1

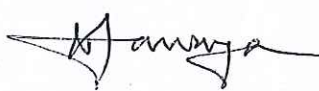
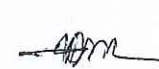

Version No

00

Effective Date


21st Nov 2006

Sl. No.	Test	Specification
1	Description	Clear colorless sterile solution free from any foreign particles.
2	Identification of Tobramycin by TLC	The distances from origin to the pink spots for both the standard and test solution must correspond.
3	pH	7.0 to 8.0
4	Content / ml Tobramycin 3.00 mg	(2.70 to 3.60) mg (90.0 to 120.0) % of the stated amount.
5	Sterility	Sterile.

Prepared By :  Sr. Officer, Quality Control Date : 21.11.06	Checked By :  Asst. Manager, Quality Control Date : 21.11.06	Approved By :  Asst. Manager, Quality Compliance Date : 21.11.06
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Popular Pharmaceuticals Limited		STANDARD TEST PROCEDURE
Product Name: TOBRABAC EYE DROPS	Document No:	STP/FDF/108/00
Product Code: 51117	Page	1 of 4
Ref: USP + In-House	Version No	00
	Effective Date	21 st Nov 2006

1 General Guiding Principles

Valid for all the test methods:	
Reagents	Analytical grade, if reagents of other quality are only available, their applicability must be examined. Secondary reagents to be prepared as per updated version of QC/SOP/008.
Water	Unless stated otherwise, either distilled or demineralised water must be used.
Equipment and Apparatus	After examining their suitability, equipment and apparatus would be used.
Handling precautions	1. Solutions should be protected from light and heat during analysis.

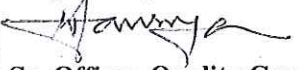
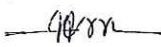

2 List of Working Standards

Name of working standards	Used for
Tobramycin	Assay.


3 Test Procedures

3.1 Description

Procedure
Check physical appearance of the solution. Take about 10 ml of the test sample in a test tube and observe visually.
Specification
Clear colorless sterile solution free from any foreign particles.

Prepared By:  Sr. Officer, Quality Control Date: 21.11.06	Checked By:  Asst. Manager, Quality Control Date: 21-11-06	Approved By:  Asst. Manager, Quality Compliance Date: 21.11.06
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Popular Pharmaceuticals Limited		STANDARD TEST PROCEDURE
Product Name: TOBRABAC EYE DROPS	Document No:	STP/FDF/108/00
Product Code: 51117	Page	2 of 4
Ref : USP + In-House	Version No	00
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3.2 Identification By TLC

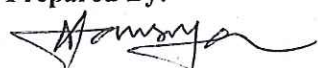
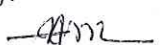
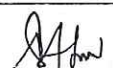
Procedure
Prepare a Standard solution of USP Tobramycin RS containing 3 mg per mL. Separately apply 6 µL of the Ophthalmic solution, 6 µL of the Standard solution, and 6 µL of a mixture of equal volumes of the two solutions to a thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture. Place the plate in a suitable chromatographic chamber, and develop the chromatogram in a solvent system consisting of a mixture of methanol, ammonium hydroxide, and chloroform (60:30:25) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, allow the solvent to evaporate, and heat the plate at 110° for 15 minutes. Immediately locate the spots on the plate by spraying with a 1 in 100 solution in Ninhydrin in a mixture of butyl alcohol and pyridine (100:1).
Specification
The distance from origin to the pink spot for both the standard and the test solutions must correspond.

3.3 pH

Procedure
As per USP
Specification
7.0 to 8.0

3.4 Weight/ml (g/ml)

Procedure
Weigh a dry calibrated pycnometer and then fill it with the optacarpine solution, remove any excess of the sample and weigh.
Calculation
$\text{Weight per ml (g/ml)} = \frac{W_f - W_p}{V_v} \text{ g/ml}$ <div style="display: flex; justify-content: space-between;"> <div> <p>Where:</p> <p>W_p = Weight of Empty Pycnometer, g</p> <p>W_f = Weight of Filled Pycnometer, g</p> <p>V_v = Volume of Pycnometer, ml</p> </div> </div>

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STANDARD TEST PROCEDURE

Product Name: TOBRABAC EYE DROPS

Document No: STP/FDF/108/00

Product Code: 51117

Page 3 of 4

Ref : USP + In-House

Version No 00

Effective Date 21st Nov 2006

3.5 Biological Assay Of Tobramycin

Requirements

1. Media : Antibiotic Media 1
2. Organism : Staphylococcus aureus (ATCC 29737)
3. Diluting fluid : Purified Water

Standard Preparation

Standard to be taken-30 mg

If potency is x %, standard is to be taken (30 X 100/x) mg

Standard high solution (Std/H): Weigh (30 X 100/x) mg of standard in 50 ml volumetric flask and volume up to the mark with purified water. Shake to dissolve. (600µg/ml)

Standard low solution (Std/L): Transfer 2 ml of Std/H solution in test tube containing 6 ml purified water (1: 4 dilution). Mix the solution by vortex. (150µg/ml)

Sample Preparation

Sample to be taken-10 ml

Sample high solution (T/H): Transfer 10 ml of sample in 50 ml volumetric flask and volume up to the mark with purified water. Shake to dissolve. (600µg/ml)

Sample low solution (T/L): Transfer 2 ml of T/H solution in test tube containing 6 ml purified water (1: 4 dilution). Mix the solution by vortex. (150µg/ml)

Prepared By:

Sr. Officer, Quality Control

Checked By:

Asst. Manager, Quality Control

Approved By:

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Date: 21.11.06

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Popular Pharmaceuticals Limited

**STANDARD TEST
PROCEDURE**

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Page 4 of 4

Ref : USP + In-House

Version No 00

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Procedure

- Fill the petridish or rectangular tray to a depth of 3-4 mm with Antibiotic Media 1.
- Allow the plate to dry for 30 minute before use.
- Swab the surface of the media with Staphylococcus aureus (ATCC 29737).
- Make holes of 8 mm diameter in the inoculated media with a sterile stainless steel borer.
- By means of a constant delivery dropping pipette fill 140 µL of each dose of sample and standard in to the holes of plates
- Allow the plate for some time to diffuse the solutions into the media.
- Then incubate the plate at 35°C overnight.
- After incubation measure the zone of inhibition.

Calculation:

$$E = \frac{1}{2} \{(T_H - T_L) + (Std_H - Std_L)\}$$

$$F = \frac{1}{2} \{(T_H + T_L) - (Std_H + Std_L)\}$$

$$b = E/I, \text{ where } I = \log 4$$

$$M = F/b$$

$$\text{Potency of Product} = (\text{Anti log of } M) \times (\text{Claim})$$

Where,

T_H = Diameter of Inhibition zone of Sample high dose, mm.

T_L = Diameter of Inhibition zone of Sample low dose, mm.

S_H = Diameter of Inhibition zone of Standard high dose, mm

S_L = Diameter of Inhibition zone of Standard low dose, mm.

Specification

(2.70 to 3.60) mg

(90.0 to 120.0) % of the stated amount.

3.6 Sterility

Procedure

As per BP

Specification

Sterile

Prepared By:

Sr. Officer, Quality Control

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Asst. Manager, Quality Control

Approved By:

Asst. Manager, Quality Compliance

Date: 21.11.06

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