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IDENTIFICATION STUDY
FOR THE
RACEMIC (-) FORM
OF
PHENYLEPHRINE HYDROCHLORIDE
IN
PHENYLEPHRINE HYDROCHLORIDE
OPHTHALMIC SOLUTION, USP, 2.5% AND 10%

(STU0328)

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TABLE OF CONTENTS

1.00	INTRODUCTION.....	Page 3
2.00	SCOPE.....	Page 3
3.00	EQUIPMENT.....	Page 3
4.00	PRODUCT.....	Page 3
5.00	STANDARD.....	Page 3
6.00	REAGENTS.....	Page 4
7.00	PREPARATION.....	Page 4
8.00	PROCEDURE.....	Page 5
9.00	RESULTS.....	Page 5
10.00	CONCLUSION.....	Page 9

1.0 INTRODUCTION:

This study is being performed in response to a request by the FDA to add an identification test to determine if Phenylephrine Hydrochloride R (-) form is present in the finished product NDA submission 203510.

The test being performed is an identification test by Polarimetry adapted from the raw material monograph for Phenylephrine Hydrochloride in the USP to determine if the material is in the R (-) form or S (+) form. The limit for the test is -42° to -47.5° which will confirm that that the material being used is in the R (-) form.

The finished product was prepared so that the working concentration of Phenylephrine Hydrochloride Ophthalmic Solution 2.5% formula A0358 is 25mg/mL and Phenylephrine Hydrochloride Ophthalmic Solution 10% formula A0359 is 50mg/mL. These solutions were then compared to that of Sigma Aldrich Phenylephrine Hydrochloride R (-) form as a control.

2.0 SCOPE:

This report is applicable to Phenylephrine Hydrochloride Ophthalmic Solution 2.5% and 10% formulas A0358 and A0359 as finished product test method TMQC-205 used at Altaire Pharmaceuticals Inc.

3.0 EQUIPMENT:

Dr. Steeg & Reuter Optical Polarimeter model SR-6.

4.0 PRODUCT:

4.01 Phenylephrine HCl Ophthalmic Solution, USP 2.5% formula A0358.

4.01.01 Finished Product Lot 11578

4.01.02 Placebo (without Phenylephrine Hydrochloride) batch 061611C.
Reference book 301 p 80-82

4.02 Phenylephrine HCl Ophthalmic Solution, USP 10% formula A0359.

4.02.01 Finished Product Lot 11582

4.02.02 Placebo (without Phenylephrine Hydrochloride) batch 061611A.
Reference book 301 p 80-82

5.0 STANDARD:

5.01 Phenylephrine Hydrochloride R (-) Sigma Aldrich lot P6126. Purity factor is 1.00

6.0 REAGENTS:

6.01 Deionized water

7.0 PREPARATION

7.01 Phenylephrine HCl Ophthalmic Solution, USP 2.5% formula A0358

7.01.01 Sample Preparation: As is. The concentration is 25mg/mL (2.5g/100mL).

7.01.02 Placebo Preparation: As is.

7.02 Phenylephrine HCl Ophthalmic Solution, USP 10% formula A0359

7.02.01 Sample Preparation: Pipet 25mL of sample into a 50mL volumetric flask and then dilute to volume with water and mix well. The concentration is 50mg/mL (5g/100mL).

7.02.02 Placebo Preparation: Pipet 25mL of placebo into a 50mL volumetric flask and then dilute to volume with water and mix well.

7.03 Phenylephrine Hydrochloride Controls

7.03.01 10mg/mL Solution: 1.01714g of Phenylephrine Hydrochloride Sigma lot P6126 was weighed into a 100mL volumetric flask, and then diluted to volume with water. The concentration is 10.1714mg/mL (1.01714g/100mL)

7.03.02 25mg/mL Solution: 2.50666g of Phenylephrine Hydrochloride Sigma lot P6126 was weighed into a 100mL volumetric flask, and then diluted to volume with water. The concentration is 25.06666mg/mL (2.50666g/100mL)

7.03.03 37mg/mL Solution: 3.70214g of Phenylephrine Hydrochloride Sigma lot P6126 was weighed into a 100mL volumetric flask, and then diluted to volume with water. The concentration is 37.0214mg/mL (3.70214g/100mL).

7.03.04 50mg/mL Solution: 2.50611g of Phenylephrine Hydrochloride Sigma lot P6126 was weighed into a 50mL volumetric flask, and then diluted to volume with water. The concentration is 50.1222mg/mL (5.01222g/100mL).

7.03.05 75mg/mL Solution: 3.75165g of Phenylephrine Hydrochloride Sigma lot P6126 was weighed into a 50mL volumetric flask, and then diluted to volume with water. The concentration is 75.0330mg/mL (3.75165g/50mL).

then diluted to volume with water. The concentration is 75.033mg/mL (7.5033g/100mL).

8.0 PROCEDURE

8.01 Using an Optical Polarimeter determine the rotation of the blank, placebo, sample and control solutions. Make 5 readings of each solution and determine the average.

9.0 RESULTS

Table 1 Blank Readings

Reading	Blank (degrees)
1	0°
2	0°
3	0°
4	0°
5	0°
Average =	0°

Table 2 Sigma Aldrich Control Readings

Reading	10mg/mL	25mg/mL	37mg/mL	50mg/mL	75mg/mL
1	-0.9°	-2.3°	-3.4°	-4.6°	-6.5°
2	-0.9°	-2.3°	-3.5°	-4.7°	-6.5°
3	-0.9°	-2.4°	-3.4°	-4.6°	-6.5°
4	-0.9°	-2.3°	-3.4°	-4.7°	-6.5°
5	-0.9°	-2.3°	-3.4°	-4.7°	-6.5°
Average =	-0.9°	-2.32°	-3.42°	-4.66°	-6.5°

Table 3 Placebo Readings

Reading	Placebo formula A0358	Placebo formula A0359
1	0°	0°
2	0°	0°
3	0°	0°
4	0°	0°
5	0°	0°
Average =	0°	0°

Table 4 Sample Readings

Reading	Placebo formula A0358	Placebo formula A0359
1	-2.4°	-4.5°
2	-2.4°	-4.5°
3	-2.4°	-4.6°
4	-2.5°	-4.6°
5	-2.4°	-4.5°
Average =	-2.42°	-4.54°

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