

STUDIES ON THE LIGHT STABILITY OF FLORDIPINE TABLETS IN  
AMBER BLISTER PACKAGING MATERIAL

Arvind N. Narurkar, Pai-Chang Sheen, David F. Bernstein,\*  
and Matthew A. Augustine  
Pharmacy R&D Department, Revlon Health Care Research  
1 Scarsdale Road, Tuckahoe, NY 10707  
and \*Chelsea Laboratories, Inc., West Hempstead, NY 11552

ABSTRACT

Accelerated light conditions have been used in the evaluation of light stability of flordipine tablets. The tablets were subjected to exaggerated light exposure in a fadeometer and to 150 foot candles of fluorescent light in a light cabinet. A comparative study was conducted between the tablets exposed directly to light and to those covered with amber vinyl sheeting. The color change was evaluated by a tristimulus colorimeter using the Hunter L, a, b scale. The b coordinate was selected for the final evaluation of light stability since it corresponded closely to the visual increase in yellowness with time. The data demonstrated that the amber colored vinyl sheeting had an excellent protective effect on the discoloration of flordipine tablets. Data obtained in the fadeometer in six hours as well as results from exposure in the light cabinet for twenty-nine days, facilitate the comparative evaluation of light stability of flordipine tablets. One hour's exposure to fadeometer was found to be equal to 480 hours in fluorescent light.

## INTRODUCTION

Exposure of dosage forms to accelerated light conditions in a fadeometer followed by color measurements in a tristimulus colorimeter has been utilized for the evaluation of the light stability of white tablets<sup>1-4</sup>. Many drugs are sensitive to light and change color when exposed to natural or artificial light. Official compendia often state that drugs should be stored protected from light. Light stability studies have been performed under exaggerated light in stability cabinets<sup>5</sup> and in a fadeometer<sup>6-9</sup>. Fadeometer exposure was found to be a rapid screening technique for light stability studies of pharmaceutical formulations.

Flordipine is very sensitive to light and changes from a white to a yellow color when exposed to natural or artificial light. In the present study, the fadeometer was used as the principal tool to obtain accelerated color stability data of flordipine tablets. The accelerated stability data from tristimulus values was compared with the stability under more realistic shelf life conditions. A comparative study was conducted between the tablets covered with amber vinyl sheeting and those exposed directly to light radiation. The purpose of this study was to evaluate the light protecting properties of the amber vinyl sheeting to be used in blister packaging.

## MATERIALS AND METHODS

### Materials

Flordipine tablets (REV 2906), 50 mg, were used for light stability studies.

Clear amber colored vinyl sheeting, Genotherm® US3002, 10 mil thickness, was used as a light-protective packaging material.

### Equipment

The Weatherometer, model type XW with carbon arc lamp (Atlas Electric Devices Co.), giving 3000 foot candle, was used. The samples were exposed at a distance of 46 cm from the arc.

A light cabinet with six General Electric 20 W fluorescent light tubes at a distance of 90 cm, giving 150 foot candle, was used. The temperature of the cabinet was  $26 \pm 2^{\circ}\text{C}$ .

Hunterlab tristimulus colorimeter model 25-9 was used for measuring color change.

### Methods

Preparation of samples for light exposure study:

#### a) Exposure in the Fadeometer

Twenty-four tablets were covered with amber colored vinyl sheeting in such a way that the surface of the tablet was exposed to the fadeometer. Four tablets were removed hourly up to six hours. Twenty-four uncovered tablets were also treated in the same manner.

#### b) Exposure in the light cabinet

Fifty tablets were covered with amber sheeting in such a way that the same surface of the tablets was exposed to fluorescent light radiation. Two tablets were removed periodically up to 30 days. Fifty uncovered tablets were also treated in the same manner.

#### c) Reference standard

Reference tablets were stored in complete darkness at  $25^{\circ}\text{C}$ .

#### d) Measurement of Color

The tristimulus reflectance values were used to assess the color change. The b coordinate was selected for the final

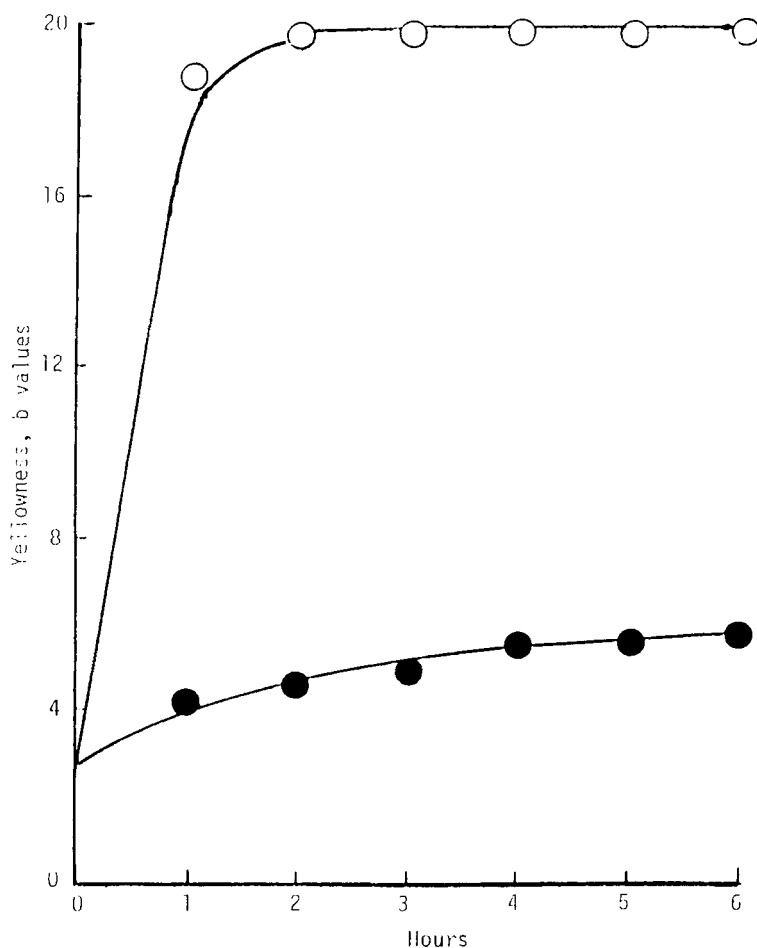


Figure 1 Plots of yellowness (b values) vs. exposure time in the fadeometer for flordipine tablets. Key: O, tablets directly exposed; ●, tablets covered with clear amber colored vinyl sheeting Genotherm® US3002.

evaluation of light stability because the visual appearance showed an increase in yellowness with time. The surface of the tablets was measured using the sample port with measuring area of  $25.5 \text{ mm}^2$ .

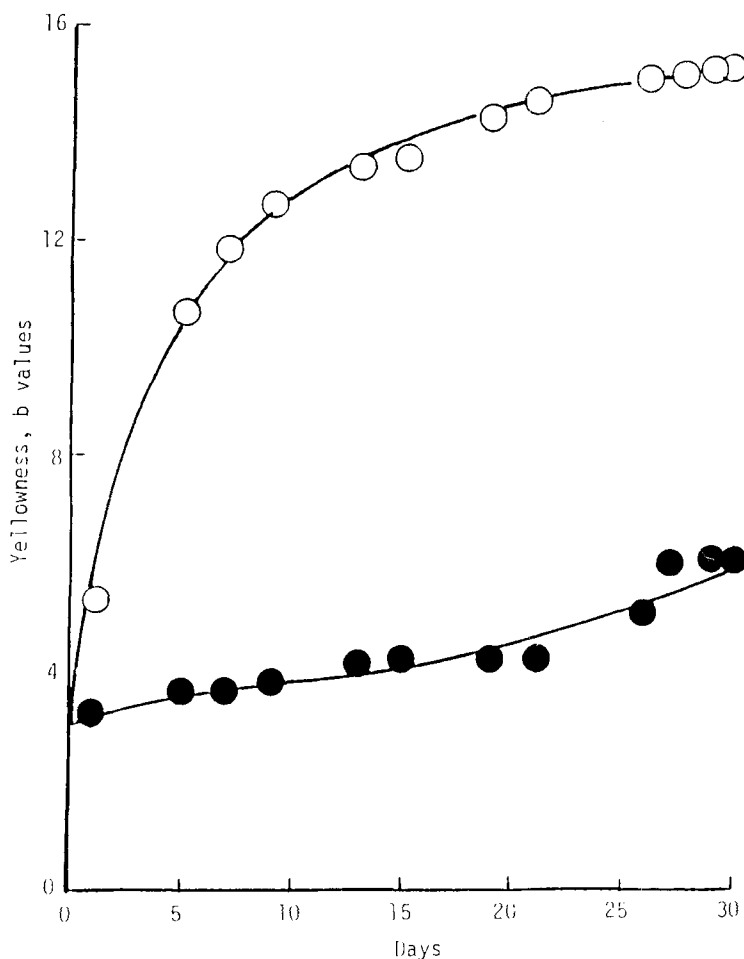


Figure 2 Plots of yellowness (b values) vs. exposure time in the light cabinet for flordipine tablets. Key: O, tablets directly exposed; ●, tablets covered with clear amber colored vinyl sheeting Genotherm® US3002.

### RESULTS AND DISCUSSION

The results as presented in Figure 1 indicate that there is a significant difference in b values between the tablets covered with amber vinyl sheeting and those exposed directly to fadeometer radiation. There is no further change in b values after one hour

for the tablets exposed directly to fadeometer radiation and no significant change after one hour for tablets covered with amber vinyl sheeting. Similar findings were earlier reported by Nyqvist and co-workers<sup>2</sup>.

The results as presented in Figure 2 also indicate that there is a significant difference in b values between the tablets covered with amber vinyl sheeting and those exposed directly to 150 foot candle light.

When comparing the b values from the fadeometer data with those obtained from exposure in the light cabinet, an acceleration of approximately 480 times was obtained. The b values at plateau were 20 for the fadeometer samples and 15 for the light cabinet samples. This may be due to a sizable portion of carbon arc radiation's lying in the UV region and giving a higher radiation energy than does fluorescent light<sup>10</sup>.

### CONCLUSION

The accelerated fadeometer radiation exposure study may be a rapid guideline for selecting a proper packaging material. It was demonstrated that the amber colored vinyl sheeting had an excellent protective effect on the discoloration of flordipine tablets.

### ACKNOWLEDGEMENT

The authors thank Ms. L. Schneider, Ms. J. Santiago, and Mr. A. Dixon for their technical assistance in the fadeometer experiments.

### REFERENCES

- (1) P. Turi, R. A. Tausendfreund, A. F. Michaelis and C. Steren, J. Pharm. Sci. 63, 1309 (1974).

- (2) H. Nyqvist, P. Lundgren and I. Jansson, Acta Pharm. Suec. 17, 148 (1980).
- (3) H. Nyqvist, M. Nicklasson, P. Lundgren, A. Fyhr and U. Stjernfelt, Acta Pharm. Suec. 19, 91 (1982).
- (4) P. Turi, D. Brusco, H. V. Maulding, R. A. Tausendfreund and A. F. Michaelis, J. Pharm. Sci., 61, 1811 (1972).
- (5) L. Lachman, C. J. Swartz and J. Cooper, J. Pharm. Sci. 49, 213 (1960).
- (6) Y. Matsuda and Y. Minamida, J. Pharm. Soc. Jpn 96, 425 (1976).
- (7) Y. Matsuda and Y. Minamida, Chem. Pharm. Bull. 24, 2229 (1976).
- (8) Y. Matsuda, H. Inouye and R. Nakanishi, J. Pharm. Sci. 67, 196 (1978).
- (9) Y. Matsuda and M. Mihara, Chem. Pharm. Bull. 26, 2649 (1978).
- (10) R. A. Kinmonth and J. L. Scott "Playing the numbers and intercomparison of radiant exposure among lamps and daylight" Atlas Sunspots, Volume 14, issue 32, 1984.