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INFLUENCE OF THIOUREA ON THE PHOTOSTABILITY OF FD & C RED NO. 3 SOLUTIONS

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ABSTRACT

The effect of thiourea as a photostabilizing agent for FD & C Red No. 3 solutions was investigated. Thiourea was found to enhance the stability of the dye solutions prepared in phosphate buffers of pH values of 7 and 7.9 and exposed to long-wave or short-wave ultraviolet light sources. Thiourea also demonstrated a photoprotective action for the dye solution in phosphate buffer of pH 7 on exposure to fluorescent light. However, thiourea was detrimental to the photostability of the dye solutions prepared in distilled water, acetate, phophate or citrate buffer of pH 4.5 and exposed to long-wave or short-wave ultraviolet light sources. The pH of the solution, its buffer species and the concentration of thiourea appeared to influence the photostability of FD & C Red No. 3.

INTRODUCTION

The stability of certified dyes in various dosage forms has been studied in several reports (1-4). Uric acid was reported by Asker and his associates (5,6) to enhance the photostability of FD & C Blue No. 2 Solutions. In another report (7), dimethyl sulfoxide was found to act as a photoprotective agent for FD & C Red No. 3 solutions. Thiourea Which has been used as an antioxidant was found by Asker and co-workers

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to stabilize reserpine solutions on exposure to ultraviolet light (8). Therefore, it appeared worthwhile to investigate the effect of thiourea as a photostabilizing agent for FD & C Red No. 3 solutions when exposed to various light sources.

EXPERIMENTAL

Materials: FD & C Red No. 3, thiourea, citric acid, sodium hydroxide, sodium acetate, glacial acetic acid, monobasic potassium phosphate, dibasic potassium phosphate and potassium hydroxide were obtained from commercial sources in reagent or pharmaceutical grade and were used without further purification.

Equipment: The following were used: A light-stability cabinet equipped with an 18-inch, 15-watt Westinghouse long-wavelength "black light" tube emitting most of its radiations at approximately 3660 Å, and 18-inch, 30-watt Westinghouse fluorescent tube and a 30-inch, 30-watt General Electric short-wavelength germicidal tube; Orion digital pH meter; a Spectronic 20 spectrophotometer.

Exposure to light: The spectrophotometer tubes containing the solutions to be exposed to light were kept 8 cm from the light source.

Procedure: The typical experimental procedure was as follows: Volumes of solutions prepared with and without thiourea were placed in 10x100 mm spectrophotometer tubes, covered with parafilm and exposed to the various light sources. Absorbance readings were made on at least duplicate samples every two hours for a period of 12 hours on the Spectronic 20 spectrophotometer at 525 nm using appropriate blanks. The concentration of FD & C Red No. 3 used in this investigation was 1 mg%.

To study the effect of variation of thiourea concentration on the photostability of FD & C Red No. 3, the dye solutions were made to contain 50, 75 and 100 mg% of thiourea.

The effect of pH on the photostabilizing action of thiourea for FD & C Red No. 3 was investigated using phosphate buffers of pH values of 4.5, 7 and 7.9. The influence of buffer species was studied in acetate, phosphate and citrate buffers of pH 4.5.

DISCUSSION OF RESULTS

Influence of Thiourea on the Photostability of FD & C Red No. 3 Solutions:

It can be seen from Figures 1-4 that the incorporation of 50mg% of thiourea into solutions of FD & C Red No. 3 in distilled water and in the various buffers of pH 4.5 enhanced the rate of photodegradation of the dye on exposure to long-wave or short-wave ultraviolet light sources. However, thiourea demonstrated a photostabilizing effect for FD & C Red No. 3 solutions in phosphate buffers of pH values of 7 and 7.9 as shown in Tables 1 and 2. The photostabilizing effect of thiourea for FD & C Red No. 3 on exposure to fluorescent light was studied in phosphate buffer of pH 7. The results indicated that thiourea in a concentration of 50 mg% enhanced the photostability of the dye solution as shown in Figure 5.

Kuramoto, et al. (1), evaluated the influence of several pharmaceutical materials on the rate of fading of FD & C Blue No. 2 in aqueous solution at pH 6.64. They found that sugars such as dextrose, lactose and sucrose increased the rate of fading of the dye. However, Brownley and Lachman (2) reported that in aqueous buffered solutions (pH 6.6-6.8), FD & C Red No. 4, FD & C Yellow No. 5, FD & C Green No.3 and FD & C Blue no 1 were relatively stable when exposed to exaggerated lighting and temperature in presence of sugars such as lactose, glucose and galactose. Inskeep and Kretlow (9) observed that a common property of dyestuffs is their ability to take up hydrogen with the formation of colorless compounds. It appears therefore, that maintaining an acid pH in solutions containing FD & C Red No. 3 would catalyze its fading in presence or absence of thiourea.

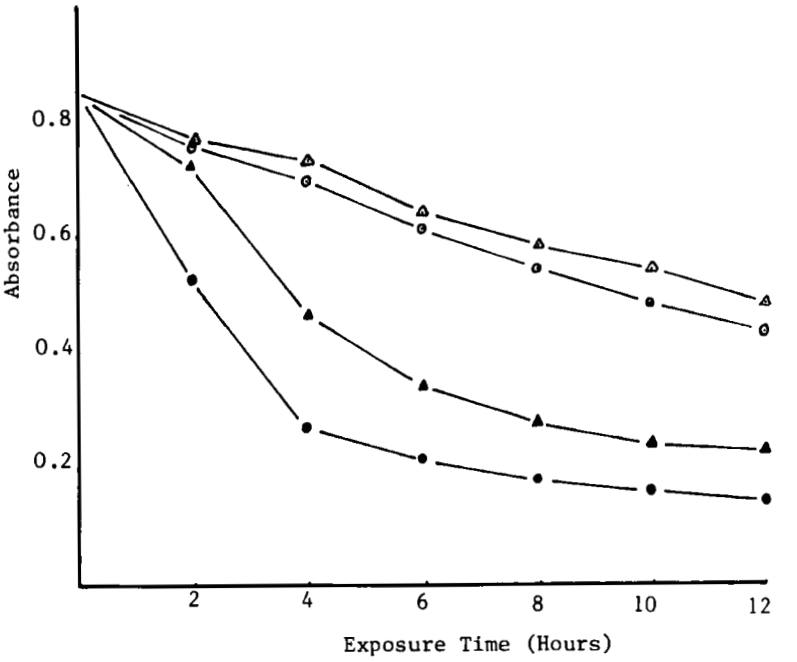

FIGURE 1. Photodegradation of FD & C Red No. 3 Solutions in Distilled Water

- ⊙ Solutions without Thiourea Exposed to Longwave UV
- ● Solutions with Thiourea Exposed to Longwave UV
- △ Solutions without Thiourea Exposed to Shortwave UV
- ▲ Solutions with Thiourea Exposed to Shortwave UV

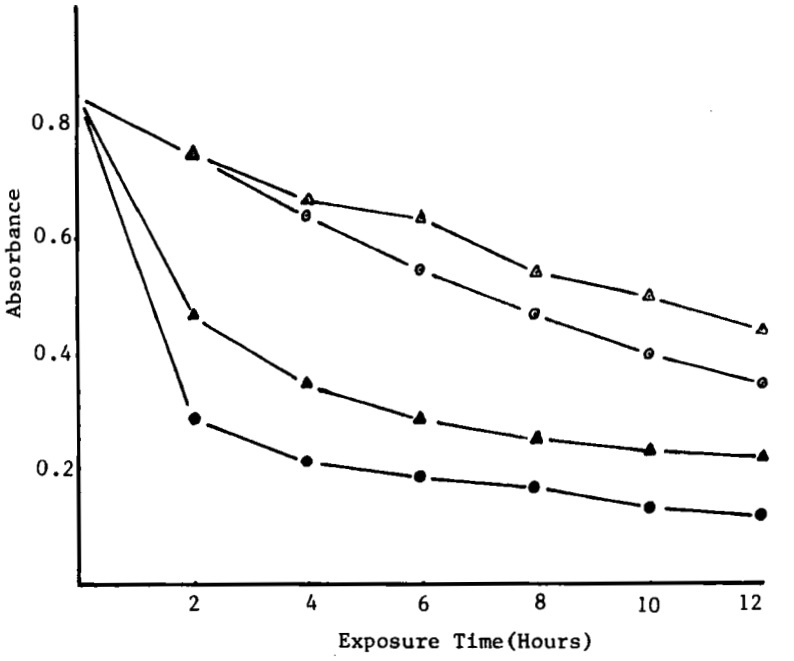

FIGURE 2. Photodegradation of FD & C Red No. 3 Solutions in Acetate Buffer of pH 4.5

Key: As in Figure 1.

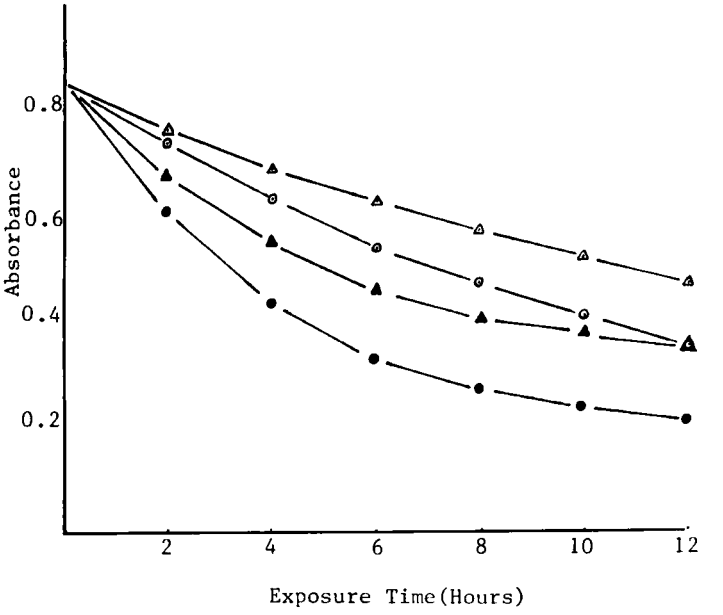

FIGURE 3. Photodegradation of FD & C Red N. 3 Solutions in Citrate Buffer of pH 4.5

Key: As in Figure 1

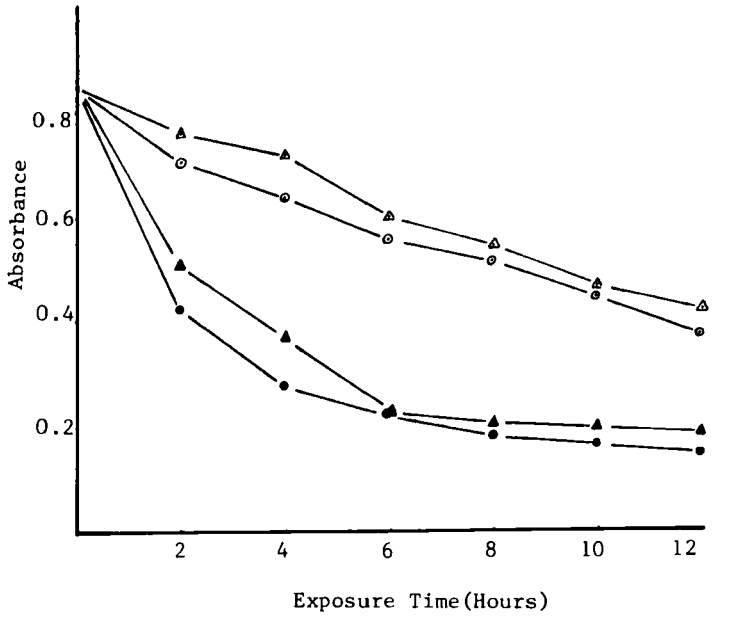

FIGURE 4. Photodegradation of FD &-C Red No. 3 Solutions in Phosphate Buffer of pH 4.5

Key: As in Figure 1.

TABLE 1

Effect of pH on the Photostability of
FD & C Red No. 3 Solutions Exposed to Shortwave UV

Exposure Time (Hours)	Absorbance of Solutions in Phosphate Buffer of pH Values of:					
	4.5		7.0		7.9	
	(a)	(b)	(a)	(b)	(a)	(b)
2	0.76	0.51	0.79	0.80	0.78	0.82
6	0.60	0.22	0.60	0.73	0.63	0.64
8	0.55	0.21	0.55	0.67	0.58	0.63
10	0.47	0.20	0.50	0.64	0.50	0.61
12	0.43	0.19	0.45	0.63	0.47	0.59

(a) Solutions without thiourea.
(b) Solutions with thiourea.

TABLE 2

Effect of pH on the Photostability of
FD & C Red No. 3 Solutions Exposed to Longwave UV

Exposed Time Hours)	Absorbance of Solutions in Phosphate Buffers of pH Values of:					
	4.5		7.0		7.9	
	(a)	(b)	(a)	(b)	(a)	(b)
2	0.71	0.43	0.76	0.79	0.75	0.80
6	0.56	0.22	0.60	0.71	0.57	0.57
8	0.52	0.19	0.54	0.68	0.49	0.53
10	0.45	0.17	0.47	0.60	0.44	0.52
12	0.38	0.15	0.43	0.57	0.37	0.51

(a) Solutions without thiourea
(b) Solutions with thiourea

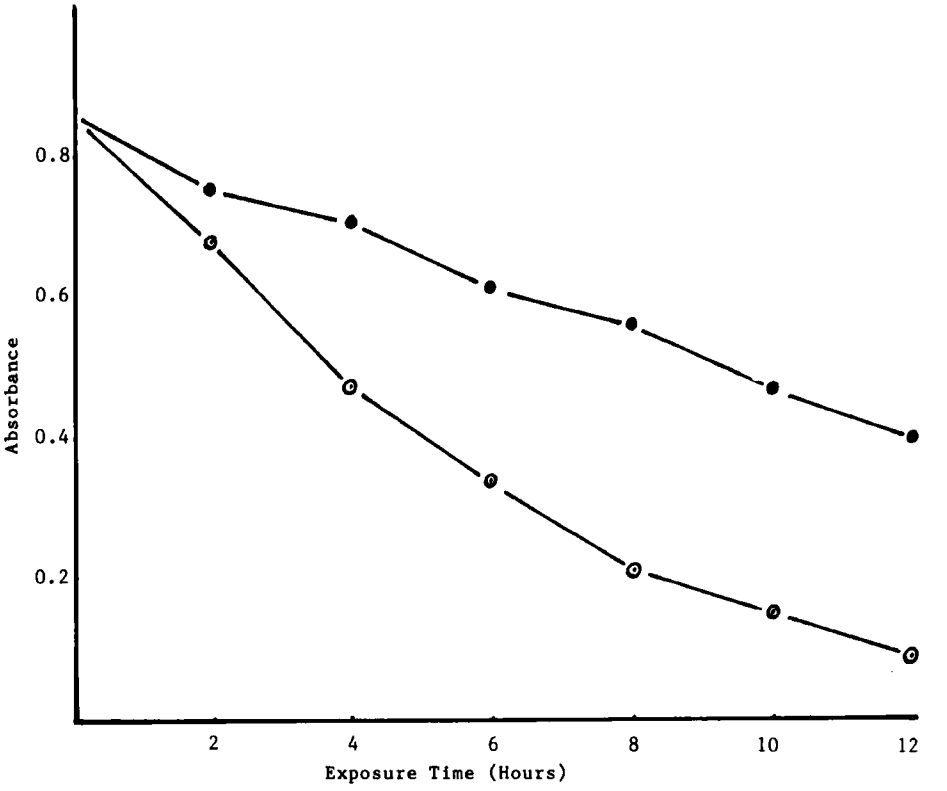

FIGURE 5. Effect of Fluorescent Light on Stability of FD & C Red No. 3 in Phosphate Buffer of pH7.

● Solution with Thiourea
● Solution without Thiourea

Effect of pH:

In order to eliminate the possibility that the rate of color fading was associated with variation in pH, the effect of thiourea as a photo-protective agent was studied in phosphate buffers of pH values of 4.5, 7 and 7.9. It appears from Tables 1 and 2 that FD & C Red No. 3 in presence of thiourea was least stable at pH 4.5 and most stable at pH 7.

Effect of Buffer Species:

It can be seen from Table 3 that the influence of buffer species on the instability of FD & C solutions in absence of thiourea appeared to be

TABLE 3

Effect of Buffer Species on the Photostability of FD & C Red No. 3 in Presence of Thiourea

Exposure Time (Hours)	Absorbance of Solutions in Various Buffers of pH 4.5					
	Acetate		Citrate		Phosphate	
	LUV	SUV	LUV	SUV	LUV	SUV
2	0.29	0.47	0.61	0.68	0.43	0.51
4	0.21	0.35	0.43	0.55	0.28	0.38
6	0.19	0.29	0.33	0.46	0.22	0.22
8	0.17	0.25	0.27	0.40	0.19	0.21
10	0.13	0.23	0.24	0.38	0.17	0.20
12	0.12	0.22	0.21	0.35	0.15	0.19

LUV = Long wavelength ultraviolet
SUV = Short wavelength ultraviolet

TABLE 4

Effect of Thiourea Concentration on the Photostability of FD & C Red No. 3 Solutions in Phosphate Buffer of pH 7

Exposure Time (hours)	Absorbance Values of Solutions Containing Various Concentrations of Thiourea and Exposed to Fluorescent Light. Thiourea Concentration (mg%)		
	50	75	100
2	0.70	0.64	0.64
6	0.61	0.53	0.50
8	0.56	0.44	0.40
10	0.47	0.37	0.34
12	0.40	0.32	0.28

practically negligible. However, in the presence of thiourea, the citrate ions produced the least detrimental effect to the photostability of the dye as compared to either the acetate or the phosphate ions.

Effect of Thiourea Concentration:

It appears from Table 4 that thiourea in a concentration of 50 mg% produced a better photostabilizing effect for the dye solution than either of the two concentrations of 75 mg% and 100 mg%. The results are in agreement with the findings of Lachman (10) who reported that there is an optimum point beyond which further addition of antioxident begins to yield diminishing returns. Asker and Collier (5) also reported an optimum concentration of uric acid to be used as a photoprotective agent for FD & C Blue No. 2 solutions.

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