

PHOTOPROTECTIVE EFFECT OF DIMETHYL SULFOXIDE  
FOR FD & C RED NO. 3 SOLUTIONS

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ABSTRACT

The effect of dimethyl sulfoxide as a photoprotective agent for various solutions of FD & C Red No. 3 was investigated. Dimethyl sulfoxide (DMSO) was found to enhance the photostability of the dye solutions when exposed to fluorescent long-wave ultraviolet or short-wave ultraviolet light sources. Fluorescent light was more detrimental to the stability of the dye solutions than any of the other two light sources. The higher the concentration of DMSO, the greater was its photoprotective action within the concentration range studied. The pH of the solution did not appear to influence the photostability of the dye in the presence of DMSO. However, among the buffer species studied, the citrate ions slightly reduced the photoprotective action of DMSO.

INTRODUCTION

The stability of certified dyes in various dosage forms has been of continued interest to the pharmaceutical formulator. The fading of dyes as a result of exposure to light has been studied by several workers (1-4). Ultraviolet absorbers have

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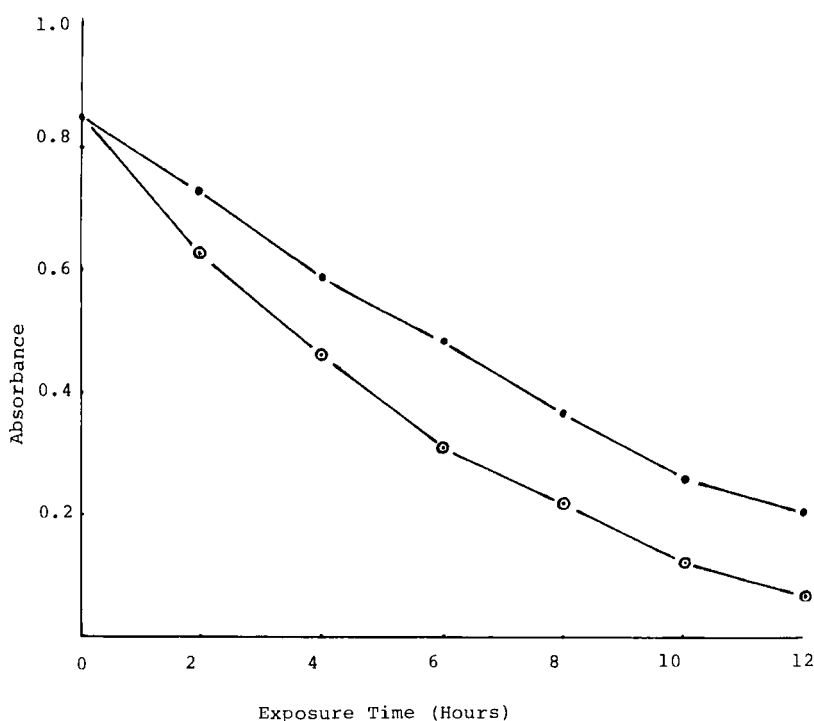


FIGURE 1. Effect of Fluorescent Light on Stability of FD & C Red No. 3 in distilled water

● Solution with DMSO  
 ○ Solution without DMSO

been reported to enhance the color stability of tablets coated with certified dyes (5,6). Uric acid was reported by Asker and his associates (7,8) to enhance the photostability of FD & C Blue 2 solutions. In another report (9), dimethyl sulfoxide was found to act as a photoprotective agent for sodium nitroprusside solutions. Therefore, it appeared worthwhile to investigate the effect of dimethyl sulfoxide as a photostabilizing agent for FD & C Red No. 3 solutions when exposed to various light sources.

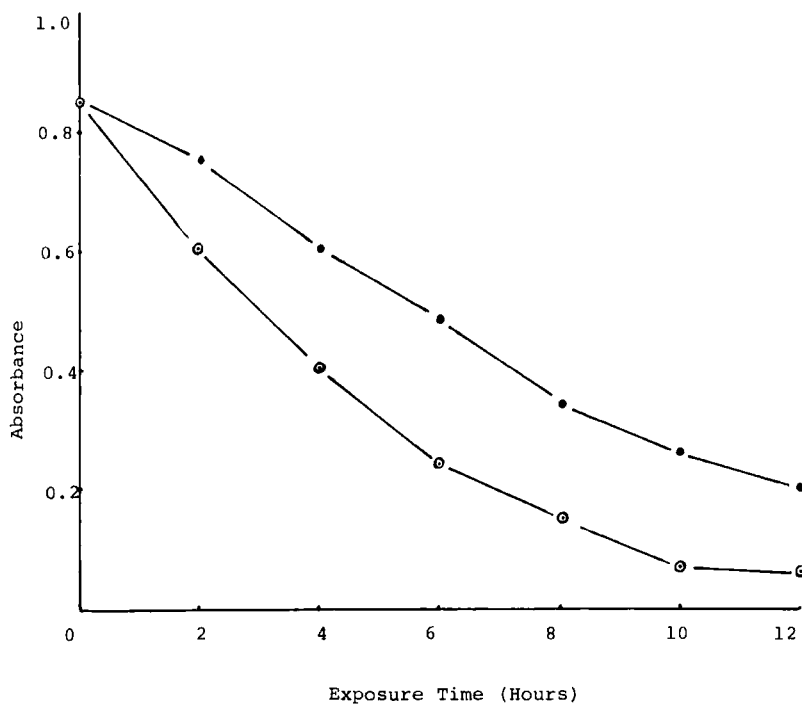


FIGURE 2. Effect of Fluorescent Light on Stability of FD & C Red No. 3 in Acetate Buffer of pH 4.5

● Solution with DMSO  
○ Solution without DMSO

#### EXPERIMENTAL

Materials: FD & C Red No. 3, dimethyl sulfoxide, 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-

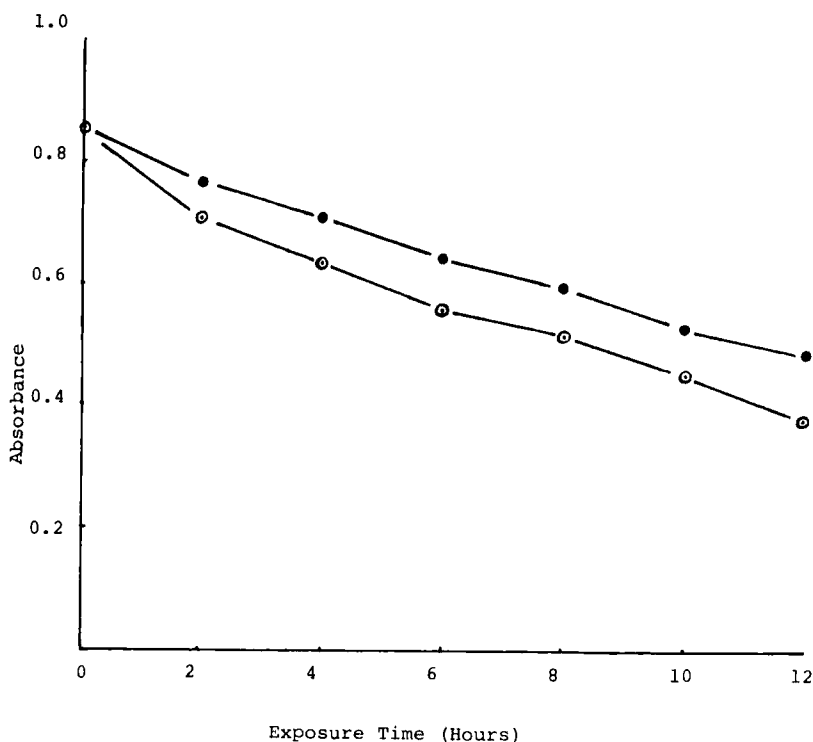


FIGURE 3. Effect of Long-wave ultraviolet Light of stability of FD & C Red No. 3 in Phosphate Buffer of pH 4.5

● Solution with DMSO  
 ○ Solution without DMSO

wavelength "black light" tube emitting most of its radiations at approximately 3660 Å, an 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

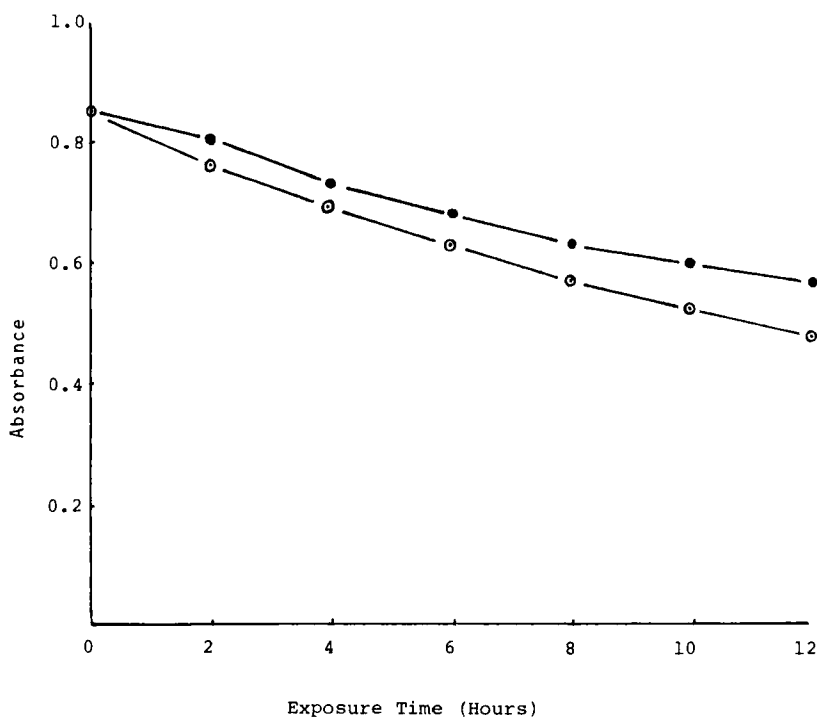


FIGURE 4. Effect of Short-wave ultraviolet Light of stability of FD & C Red No. 3 in citrate Buffer of pH 4.5

● Solution with DMSO  
○ Solution without DMSO

DMSO were placed in 10x100 spectrophotometer tubes, covered with parafilm and exposed to the various light sources. Absorbance reading 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 DMSO concentration on the photostability of FD & C Red No. 3, the dye solutions were made to contain 5%, 10% and 15% v/v of DMSO.

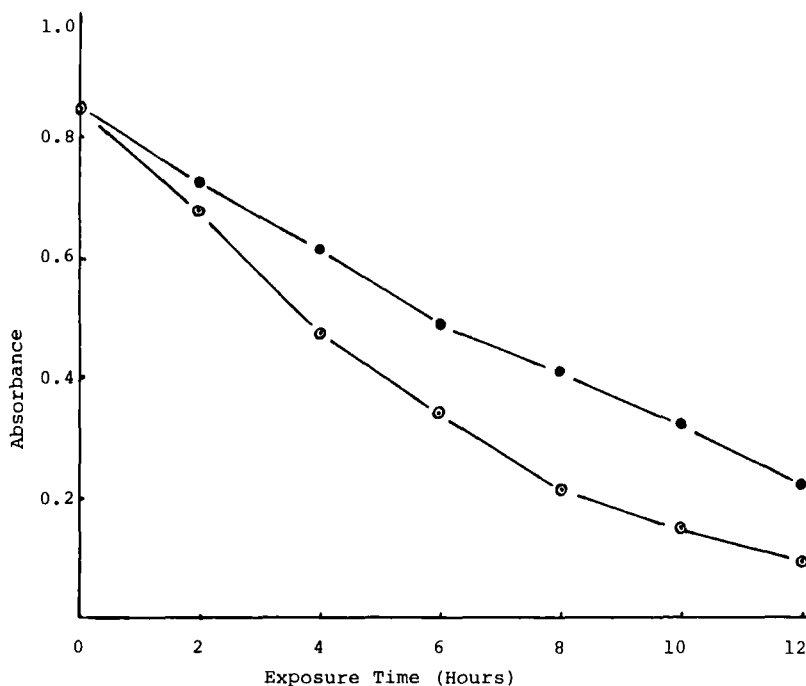


FIGURE 5. Effect of fluorescent Light on stability of FD & C Red No. 3 in Phosphate Buffer of pH7.  
 ● Solution with DMSO  
 ○ Solution without DMSO

The effect of pH on the photostabilizing action of DMSO for FD & C Red No. 3 was investigated using phosphate buffers of pH values of 4.5, 7.0 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 DMSO on the photostability of FD & C Red No. 3 Solutions:

Selected typical plots of the effect of light source on the stability of FD & C Red No. 3 in distilled water and in

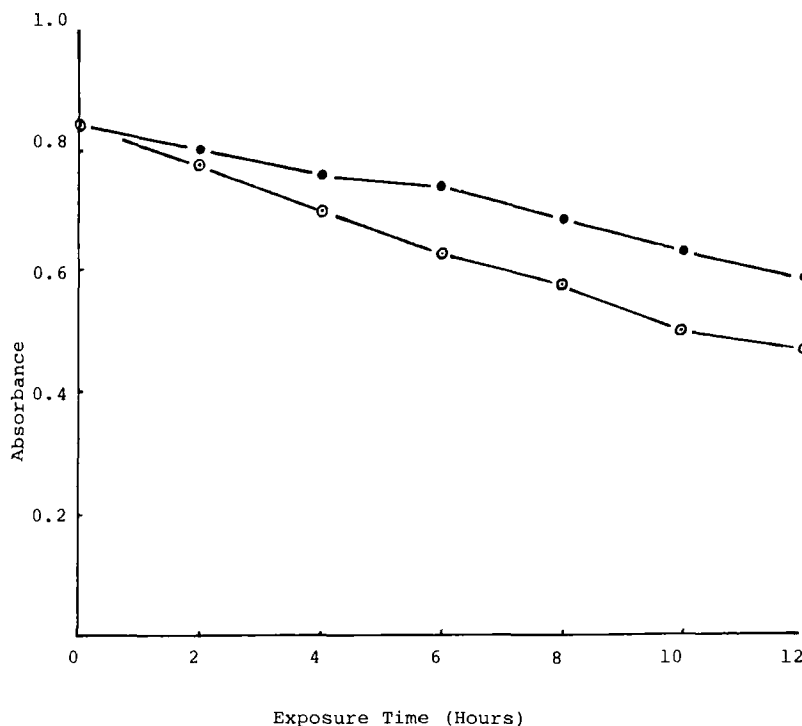


FIGURE 6. Effect of short-wave ultraviolet light on stability of FD & C Red No. 3 in Phosphate Buffer of pH 7.9

● Solution with DMSO  
 ○ Solution without DMSO

various buffers with or without DMSO are shown in Figures 1-6.

These figures show that the incorporation of 5% v/v of DMSO into 1% mg% solutions of FD & C Red No. 3 produced a measurable protective action against degradation of the dye by the various light sources. Fluorescent light appeared to produce a more detrimental effect on the stability of the dye followed by long-wave ultraviolet and then short-wave ultraviolet light as can be seen from Table 1.

TABLE I  
Effect of Light Source on the Stability of  
FD&C Red No. 3 Solutions

Vehicle	Absorbance Values after Exposure for 12 Hours					
	Fluorescent		Long-Wave UV		Short-Wave UV	
	Without DMSO	With DMSO	Without DMSO	With DMSO	Without DMSO	With DMSO
Distilled Water	0.07	0.21	0.43	0.52	0.48	0.60
Acetate Buffer, pH 4.5	0.06	0.20	0.35	0.48	0.44	0.55
Citrate Buffer, pH 4.5	0.05	0.11	0.35	0.45	0.43	0.56
Phosphate Buffer, pH 4.5	0.07	0.20	0.38	0.49	0.43	0.54
Phosphate Buffer, pH 7.0	0.09	0.22	0.43	0.53	0.45	0.60
Phosphate Buffer, pH 7.9	0.07	0.25	0.37	0.53	0.47	0.59



TABLE 2  
Effect of pH on the Photostability  
of FD & C Red No. 3 in Presence of DMSO

Exposure Time (Hours)	Absorbance of Solutions in Phosphate Buffers of pH Values of:								
	4.5			7.0			7.9		
	FLU	LUV	SUV	FLU	LUV	SUV	FLU	LUV	SUV
4	0.59	0.71	0.74	0.61	0.74	0.62	0.62	0.75	0.76
8	0.36	0.60	0.60	0.41	0.64	0.67	0.44	0.64	0.69
12	0.20	0.49	0.54	0.22	0.53	0.60	0.25	0.53	0.59

FLU = Fluorescent

LUV = Long Wavelength Ultraviolet

SUV = Short Wavelength Ultraviolet

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

Exposure Time (Hours)	Acetate			Phosphate			Citrate		
	FLU	LUV	SUV	FLU	LUV	SUV	FLU	LUV	SUV
4	0.60	0.70	0.73	0.59	0.71	0.74	0.53	0.71	0.73
8	0.34	0.58	0.62	0.36	0.60	0.60	0.29	0.59	0.63
12	0.20	0.48	0.55	0.20	0.49	0.54	0.11	0.45	0.56

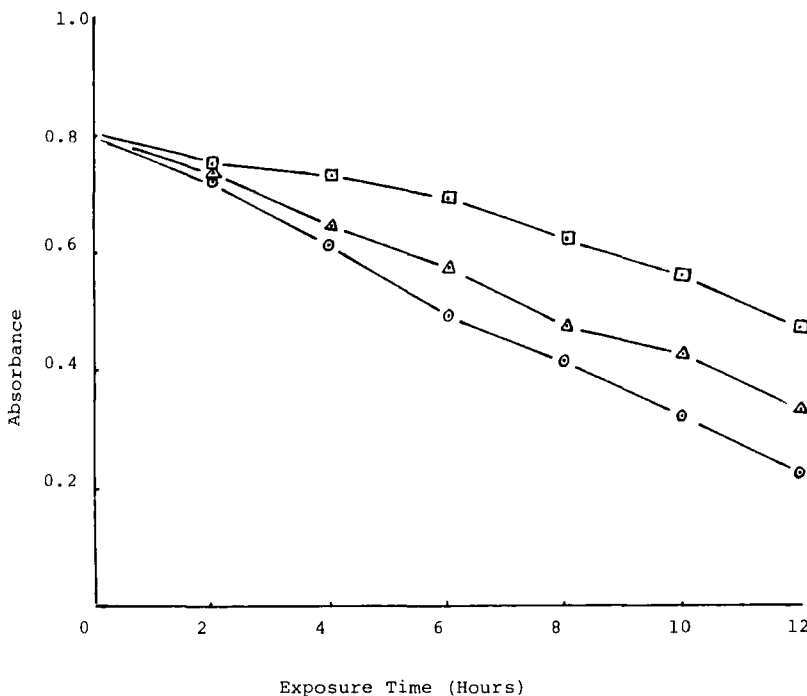


FIGURE 7. Effect of DMSO Concentration on Stability of FD & C Red No. 3 in Phosphate Buffer of pH 7 Exposed to Fluorescent Light

- 5% v/v DMSO
- △ 10% v/v DMSO
- 15% v/v DMSO

#### Effect of pH:

In order to eliminate the possibility that the rate of color fading was associated with variation in pH, the effect of DMSO as a photoprotective agent was studied in phosphate buffers of pH values of 4.5, 7 and 7.9. It is evident from Table 2 that the pH of the solutions had little or practically no effect on the photoprotective action of DMSO for FD & C Red No. 3 solutions exposed to the various light sources.

#### Effect of DMSO Concentration:

It is evident from Figure 7 that the photostability of the dye increased as the concentration of DMSO increased within the concentration range of 5 - 15% v/v.

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