

FORMULATION AND CHARACTERIZATION OF FLUORESCEIN SODIUM SOLUTION FOR INJECTION FOR DIAGNOSTIC ANGIOGRAPHY

Z Ćetković¹, M Ribar¹, M Jovović¹

¹University Clinical Center of Serbia, Belgrade, Serbia



Univerziteti klinički centar Srbije

BACKGROUND AND IMPORTANCE

Fluorescein sodium as diagnostic contrast agent belongs to World Health Organization's List of Essential Medicines. In our hospital fluorescein sodium injection is used in diagnostic fluorescein angiography to diagnose and monitor various eye diseases. After intravenous injection, dye quickly circulates through the blood vessels of the eye and illuminates them, thus enabling photographs to be taken with a special camera.

However, due to shortage of fluorescein sodium injection on our market during the past year, formulation had to be developed.

AIM AND OBJECTIVES

The aim of this work was to formulate and characterize fluorescein sodium solution for injection, and determine the stability at room temperature ($25 \pm 2^\circ\text{C}$) during its shelf-life period.

MATERIALS & METHODS

Fluorescein sodium solution for injection is prepared in laminar flow cabinet. Fluorescein sodium is completely dissolved in water for injection, then filtered through membrane filter with $0.22 \mu\text{m}$ pore size and packed into glass container. Obtained product was autoclaved at 120°C for 20 minutes, in its final container.

Characterization:

- ❖ *drug content (spectrophotometric method by USP)*
- ❖ *sterility testing (Ph. Eur., general chapter 2.6.1)*
- ❖ *test for pyrogens (Ph. Eur., general chapter 2.6.8)*

RESULTS

Brownish and homogenous solution of fluorescein sodium was obtained (Figure 1). No visual changes were observed during six-month period. Obtained fluorescein sodium concentration after sterilization was 98.58% of the defined concentration and it increased slightly after 3 and 6 months (Table 1).

Final product maintained to be sterile and pyrogen-free after six months. Therefore, shelf-life period was proven to be six months at room temperature ($25 \pm 2^\circ\text{C}$).

Table 1. Fluorescein sodium concentration

Concentration	
after sterilization	98.58%
after 3 months	99.20%
after 6 months	100.22%



Figure 1. Fluorescein sodium injection 200 mg/mL

CONCLUSION AND RELEVANCE

Fluorescein sodium injection is an indispensable diagnostic medicine in ophthalmology. The formulation of fluorescein sodium solution for injection (500 mg/2.5 mL) was successfully developed in our Hospital Pharmacy Service. The solution has been prepared since August 2023 and remained stable and active for at least six months.

