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**WORLD SCIENCE:  
PROBLEMS, PROSPECTS  
AND INNOVATIONS**



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# **WORLD SCIENCE: PROBLEMS, PROSPECTS AND INNOVATIONS**

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**QUALITATIVE DETECTION OF QUINOLINE YELLOW DYE IN  
MEDICINES FOR ORAL ADMINISTRATION  
BY THIN-LAYER CHROMATOGRAPHY**

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**Abstract:** in recent years, the perception of excipients has changed significantly, as their significant effect on the action of drugs has become clear. Excipients have their own physicochemical properties and, therefore, can affect the active pharmaceutical ingredient and, ultimately, the properties of pharmaceutical products [1]. There is a large number of excipients in the pharmaceutical market of Ukraine, a separate group of which are dyes.

According to the literature, dyes are added to medicines for masking unattractive color, protection of active pharmaceutical ingredients from light, exclusion of the possibility of confusing similar drugs in the same dosage forms [2, p. 70]. The legislation of Ukraine allows the use of dyes in medicines, in particular, order of the Ministry of Health of Ukraine № 339 from 19 of June 2007 approved The list of names of dyes which are a part of medicines [3].

This group includes synthetic dye quinoline yellow. In order to control quality of medicines which contain this substance, an urgent issue is the creation of a method

for the identification of the above-indicated dye in medicines for oral administration.

Quinoline yellow is a synthetic dye, organic compound of heterocyclic series. It is applied in Food Industry, production of cosmetics and in medicine [4]. Analyzing the published data it was found that there is a screening method for detection of artificial dyes in saffron after precipitation of crocetin (using the method of ultraviolet spectrometry) [5], method of thin-layer chromatography using computer densitometry in food [6, p. 544] and photolorimetric method of detection of synthetic dyes in food [7, p. 43]. Information of experimental detection of quinoline yellow with the help of electrochemical method using multi-walled carbon nanotubes also was found [8, p. 3530].

**Keywords:** medicines, dyes, synthetic dyes, quinoline yellow, thin-layer chromatography.

**Aim.** Develop a methodology of the detection of synthetic dye quinoline yellow in three dosage forms: solution for oral cavity "Фортеза" (test solution №1), film-coated tablets "Алохол" (test solution №2) and powder for oral solution "Терафлю від грипу та застуди зі смаком лимона" (test solution №3).

**Materials and methods.** The instrumental method of analysis was used in our research - thin-layer chromatography. This method is simple, fast, universal in use, does not require special expensive equipment. During the research we used a standard solution of dye quinoline yellow and solutions of medicines: solution for oral cavity "Фортеза" (test solution № 1), film-coated tablets "Алохол" (test solution № 2) and powder for oral solution "Терафлю від грипу та застуди зі смаком лимона" (test solution № 3). The standard solution was prepared according to the following technology: 5,0 mg of standard sample of quinoline yellow was put in a volumetric flask with a capacity of 50 ml. Then we added 40 ml of purified water, mixed until dissolving and added water to 50 ml. 5,0 ml of the resulting solution was put in measuring flask with a capacity of 25 ml and added water to the mark. We used the solution of medicine as test solution № 1. For preparing test solution № 2 we removed the shell of two tablets, added 5,0 ml of purified water, mixed until

dissolving of the shell and centrifuged 6000 rp/10 min. We used the supernatant as test solution. Test solution № 3 was prepared by the following technology: we put 25,0 g of powder in measuring flask with a capacity of 50 ml, dissolved in purified water and added water to 50 ml, mixed and centrifuged 6000 rp/10 min (solution has opalescence). We filtered the supernatant through a glass pore filter 16 and used it as test solution.

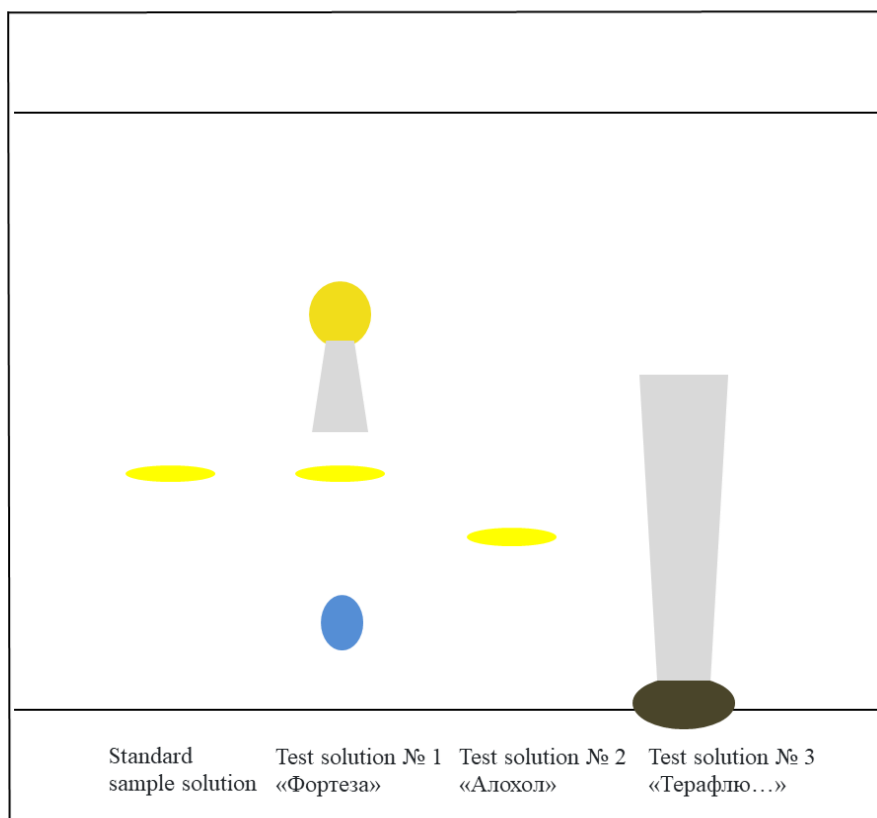
We relied on literature data regarding the most rational reagents for moving phase and solvent in developing the methodology. An important component for this method of analysis was right selection of plate sorbent. No less important factor was the method of applying test solutions and analysis of results of the research. We relied on basic physical and chemical parameters of dye for right selection of the moving phase.

Optimal conditions for chromatography were: moving phase – ammonia, water, butanol and ethyl alcohol (10:5:35:50) and plate TLC Silica gel 60 F254 (manufacturer - Germany) on an aluminum basis.

Sample preparation was carried out taking into account the presence of excipients as a part of medicines. We dissolved samples of each medicine in the water. After dissolution we filtered samples using membrane filters with a pore size 0,45 mkm and by centrifugation of 6000 rpm, during 10 min. The volume of the sample applied to the chromatographic plate was 20 mkl of each test solution. The application of solutions was made by using microsyringes. After evaporation of the solvents from applied samples we put plate into prepared chromatographic chamber. We performed vertical elution in a closed chamber. Detection was performed by viewing in ultraviolet light at wavelength 365 nm. The spots of the tested solutions were visually compared with the spot of the comparison solution (standard) by color, size and retention factor (Rf).

**Results and discussions.** During our experiment we obtained a chromatogram with standard and test solutions. The scheme of the thin-layer chromatogram is shown in the picture 1. For test solution № 1 we observed a yellow spot at the level of the comparison solution of the same size and other spots: yellow spot higher than the

comparison solution, and blue spot which is lower than the comparison solution (other sizes). This is due to the presence of other excipients as a part of this medicine, in particular the dye patented blue V (E 131). Test solution № 2 showed a yellow spot and size as standard solution but it was lower than the standard sample solution. The possible reason for this is the presence of other excipients in the shell of medicine such as: hypromellose, titanium dioxide (E 171), polyethylene glycol, polyvinyl alcohol, talc, lecithin, indigo carmine (E 132). For test solution № 3 we observed the spot at the initial level and continuous strand of substances from it. This can be explained by the presence of a large amount of excipients in the powder (saccharose, anhydrous citric acid, natural lemon flavor, sodium citrate dihydrate, calcium phosphate, malic acid, titanium dioxide (E 171), dye yellow sunset (E 110).



**Picture 1. The scheme of the thin-layer chromatogram of standard and test solutions (viewing in ultraviolet light at wavelength 365 nm)**

**Conclusions.** Thus, the method of thin-layer chromatography is usable for detection of synthetic dye quinoline yellow in solution for oral cavity "Фортеза". The presence of excipients such as saccharose, hypromellose, polyethylene glycol,

polyvinyl alcohol and others significantly affects qualitative detection of dye in film-coated tablets "Алохол" and powder for oral solution "Терафлю від грипу та застуди зі смаком лимона" using this method. They interfere with detection of dye in the above dosage forms. To remove these excipients additional methods of cleaning solutions are required. For this researchers need to further develop conditions (methods) of extraction of dye on sorbents such as polyamide, silica gel or other but it is economically impractical and requires a lot of time from researchers. Given the above factors we made a conclusion that using the method of thin-layer chromatography for these dosage forms is inappropriate so for the detection of quinolone yellow in the above medicines it is appropriate to use other methods of analysis, for instance, high performance liquid chromatography.

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