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DEVELOPMENT OF METHOD OF QUANTITATIVE DETERMINATION OF BENZOKAINE AND METRONIDAZOLE IN COMPOSITION STOMATOLOGICAL GEL

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ABSTRACT

In the article there are presented results of quantitative and high-quality determination actively of pharmaceutical ingredients (AFI) of soft medication in form gel. Researches conducted using the method of high-efficiency liquid khromatografi (HPLC). Time of delay of peaks of the probed solution and solution of comparison is set.

Key words: high-efficiency liquid chromatography, soft medications, time of delay of peaks, active-pharmaceutical ingredient, quantitative maintenance.

INTRODUCTION

HPLC – most often in-use presently method of analysis of organic matters. As a method of HPLC combines in itself and the stage of division, and stage actually registrations of signal of matters, he is major for multicomponent determination of connections, often different nature, at the joint being in difficult matrices. Advantages of HPLC before other methods of analysis it is been:

- possibility of research of practically any objects without limitations on their physical and chemical properties;
- large range of molecular the masses of matters with which it is possible to work;
- mildness of terms, when a division can be conducted at temperatures near to the room, in default of HPLC contact with air;
- high efficiency of division;
- high sensitiveness;
- possibility of automation of division and analysis of difficult mixtures of organic and inorganic matters.

HPLC presents the well designed instrumental method which is widely applied in different areas by scitechs: biochemistry, molecular biology, phytochemistry, in chemical, petrochemical, food and pharmaceutical industry [1, 3].

The purpose of work was a study of quantitative and high-quality composition of stomatological gel with metronidazole and benzokaine.

MATERIALS AND METHODS

Materials and methods of research were stomatological gel which maintenance metronidazole and benzokaine. Quantitative determination and authentication conducted the method of HPLC in obedience to the requirements of the European Pharmacopoeia [2, 4].

Identification of metronidazole and benzokaine carried out by HPLC. Determination carried out according

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to the procedure for the quantitative determination of induced API. In the chromatogram of the test solution latency peak of metronidazole and benzokaine should coincide with a retention time of the peak of metronidazole and benzokaine on the chromatogram obtained with reference solution with an accuracy of ± 2%.

API methods of quantitative determination carried out by HPLC. Identifying and defining the API performed on a liquid chromatograph «Agilent 1100." Mobile phase: A elyuent - methanol elyuent B - water; elyuent In - acetic acid (56:40:4). The rate of the mobile phase - 1.0 mL /min. Column temperature-35°C, 50ml volume sample. Chromatographic column YMC-PackODS-AQ size 250×4,6mm, filled with sorbent silica gel for chromatography R with a particle size of 5 microns (Phenomenex Luna 5μ C18). Detection carried out using a spectrophotometric detector at 294 nm wavelength.

Preparation of test solution: Approximately 1 g (accurately weighed) of the drug placed in a volumetric flask of 100.0 ml, 5 ml of ultrapure water and stirred until smooth. 5 ml of ultrapure the driver, shaken and the contents of the flask adjusted to the mark with methanol and mix. 1.0 ml of the resulting solution transferred into a volumetric flask of 20 ml, brought up to the mark with mobile phase and mixed. The resulting solution filtered through a membrane filter PTFE 0, 45 microns, discarding the first 2 ml of filtrate.

The concentrations of metronidazole and benzocaine in the test solution were approximately 2.5 and 5.0mg/ml, respectively. Preparation of the reference solution . 25.0 mg (accurately weighed) of the standard sample metronidazole and 50.0 mg (accurately weighed) of the standard sample of benzocaine placed into a volumetric flask 50.0 mL function adds 30 ml of mobile phase and stirred until complete dissolution. Solution adjusted to the mark with mobile phase and stirred. 2.0 ml of the resulting solution transferred into a volumetric flask of 20 mL and adjusted to the mark with mobile phase 1.0 ml of this solution 1.0 ml of the resulting solution transferred into a volumetric flask of 20 mL and adjusted to the mark with mobile phase. The concentration of metronidazole and benzokaine in the test solution were about 2.5 and 5.0 mg / ml, respectively.

The contents of metronidazole and benzokaine, in grams calculated from the formula

$$X = \frac{S_1 \times m_0 \times 5 \times 200 \times 25 \times P \times b}{S_0 \times 100 \times 20 \times m_1 \times 10 \times 100}$$

where:

S1 - an average value of the peak areas of metronidazole and benzokaine calculated from the chromatogram of the test solution, respectively;

S0 - average value of the peak areas of metronidazole and benzokaine, calculated from the chromatogram of the reference solution, respectively;

m0 - sample weight standard sample metronidazole and benzokaine respectively, in mg;

b - the average weight of a gel, in grams;

m1 - mass of sample equivalent, in grams;

F - content of metronidazole and benzokaine standard sample respectively, in %.

RESULTS AND DISCUSSION

Figure 1 - 2 shows the chromatogram of the test solution and the comparison solution. Chromatographic studies allowed todetermine the time delay peaks all API. Approximate peaks retention times were metronidazole - 3, 5 min and benzokaine 5, 2 min.

Retention time and peak metronidazole and benzocaine in the chromatograms of test solution must match the peak retention time metronidazole and anestezina chromatogram of the reference solution at ± 2%. Chromatographic column efficiency calculated for peak metronidazole and benzocaine were at least 2000 theoretical plates. Table 1 shows the results of studies quantifying of the API.

Table 1. Quantitative content API in preparation

Ingredients	Content, mg	Defined		
		mg / g	%	Metrological characteristics
Benzokaine	1000 mg	985,0 976,2 988,1 992,4 mean value. 985,4	98,5 97,6 98,8 99,2	X = 98,52 $S_{(X)}$ = 0,68 $S\bar{x}$ = 0,30 ε = ± 0,85 $X \pm S\bar{x}$ =98,52 ±0,85
Metronidazole	500 mg	471,3 495,6 474,4 483,7 mean value. 481,2	94,26 99,12 94,88 96,74	X = 96,25 $S_{(X)}$ = 2,18 $S\bar{x}$ = 0,97 ε = ± 2,82 $X \pm S\bar{x}$ =96,25±0,97

From the above results show that the content of metronidazole in a 1 gr of gel was 1000 mg (normal 900 - 1100 mg) and content of benzocaine was 500 mg (normal 450 - 550 mg).

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Figure 1. chromatogram of the test solution

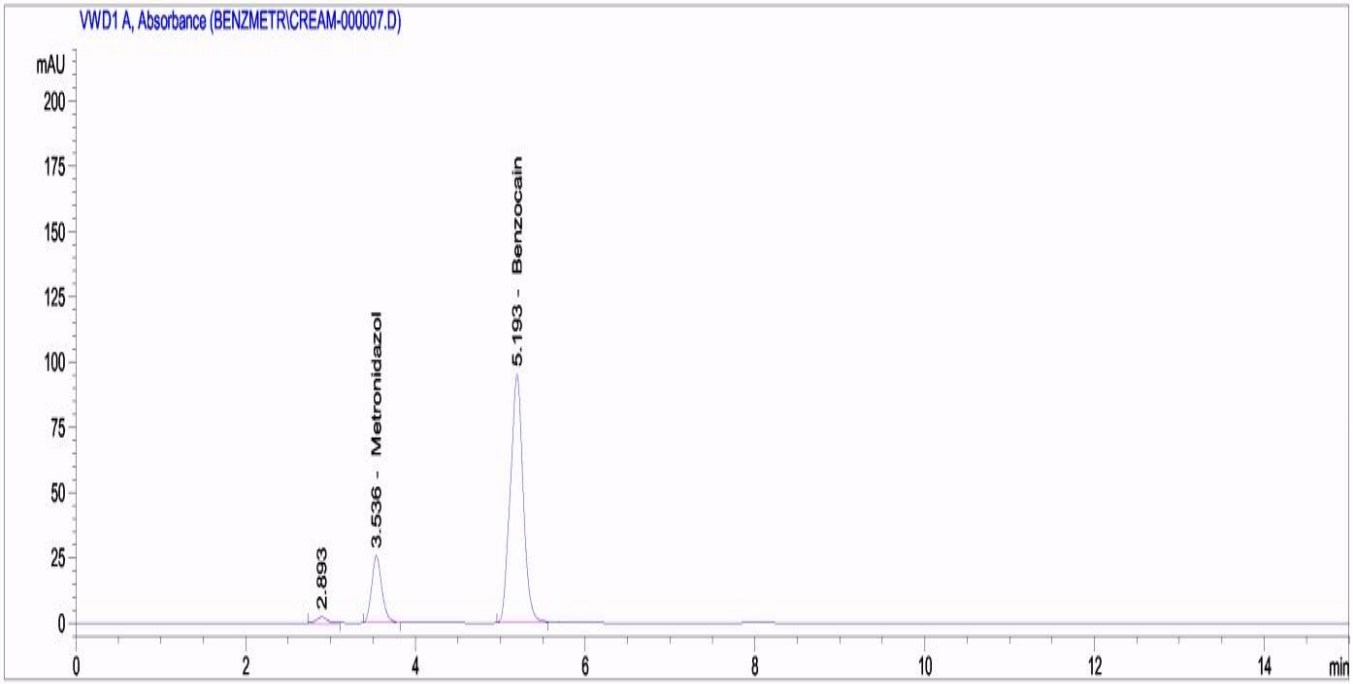
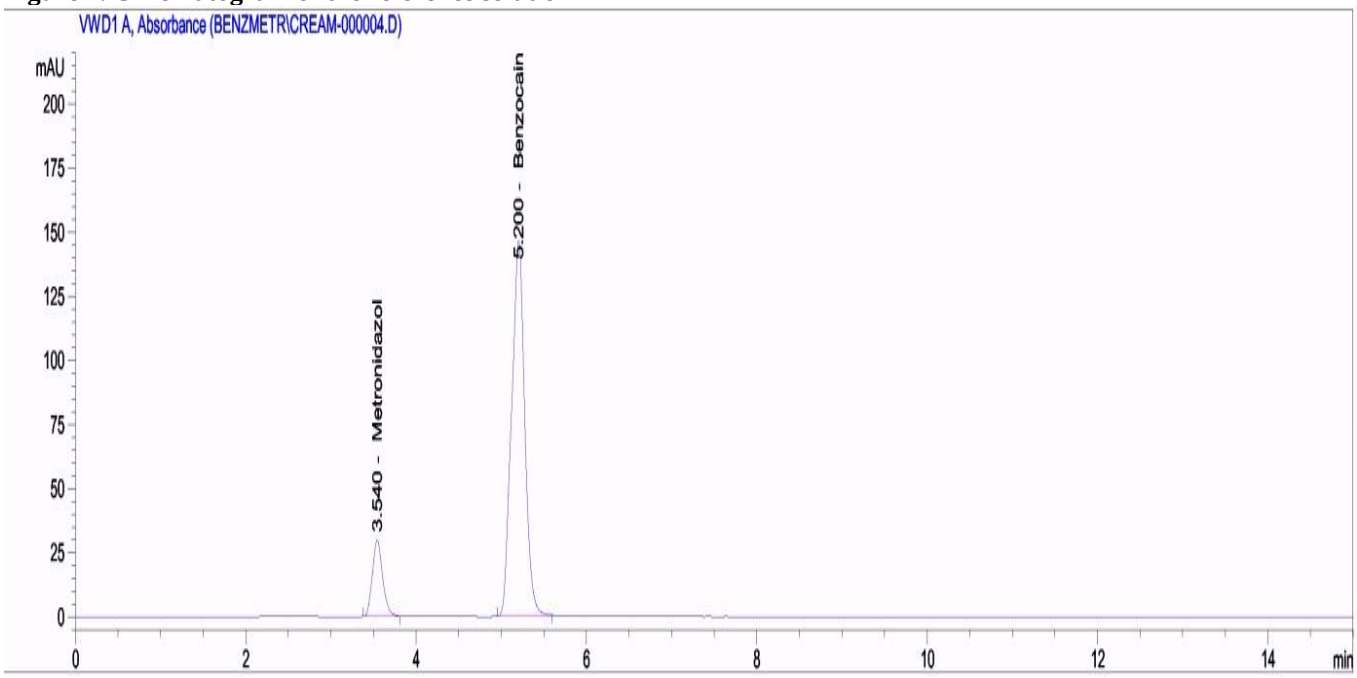


Figure 2. Chromatogram of the reference solution



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