ASSESSMENT OF THE POSSIBILITY OF DEVELOPING A NEW METHOD FOR QUANTITATIVE DETERMINATION OF PREDNISOLONE IN OINTMENT

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Quality control of soft dosage forms containing prednisolone is not only very important, but difficult task, because of many components in the ointments complicating pharmaceutical analysis. Current methods of analysis for prednisolone and other corticosteroids are less sensitive and need additional reagents (photocolorimetric methods) or need valuable equipment (HPLC using different detectors and solvents). The development of simpler methods is still relevant.

The aim of the study is assessment of the possibility of developing and validation a new simpler method for quantitative spectrophotometric determination of prednisolone by the standard method in the «Prednicarb-Darnitsa» ointment.

There was used such analytical equipment during the experiment: Mettler Toledo AB 204 analytical balance, Thermo Scientific Evolution 60S spectrophotometer, water heater, reagents and measuring glassware (class A) according to the State Pharmacopoeia of Ukraine (SPhU).

To an accurately weighted ointment, 0.025 g prednisolone equivalent, add 15-20 ml of 96% alcohol R and heated it on a water heater to the dissolution of the base, then cooled it in ice. The resulting mixture is filtered through paper filter previously soaked in ethanol. Repeat twice more, starting with “add 15-20 ml of 96% alcohol R”. Extraction of prednisolone is carried to the 50.0 ml volumetric flask and diluted with 96% alcohol to volume. 2.0 ml of this solution is carried to the 50.0 ml volumetric flask and diluted with 96% alcohol to volume. Determine the absorbance of the solution at the wavelength of maximum absorbance at about 243.5 nm against dehydrated alcohol. The standard solution is prepared in parallel according to the SphU.

Three dilutions for the standard substance of prednisolone and six dilutions for prednisolone of the ointment with a concentration of 0.002% were prepared for method's assessment. Measurement of the optical density of obtained model solutions was conducted three times with removing of the cell. The absorption spectrum of the extraction has the same properties as the standard spectrum. This indicates a lack of influence of the excipients.

According to results, quantitative content of prednisolone in the ointment was 97.40% of the nominal (0.5 g per 100 g of the ointment), that is practically identical with the data specified in the certificate of quality (98%) and fully complies with acceptable values.

Therefore, based on the fact that the character of the spectrum of the ointment extraction corresponds to the spectrum of the standard solution, the data of the quantitative determination statistically do not differ from the declared and the method is simpler than presently known, further validation of the method is sufficiently relevant and possible task.