The total protein content was assessed using Lowry method, in order to avoid nucleic acids interferences. The method was validated according to the

EMEA/CHMP/EWP/192217/2009 "Guideline for bioanalytical method validation".

Conclusion: A controlled method for the generation and a validated method for the quantification of protein carbonyls using BSA as a model, with spectrophotometric assay were developed. The methods can be further used for human plasma protein assay. Also, it could be useful for the development of a new capillary electrophoresis method for protein carbonyls assay.

Keywords: Protein carbonyls, oxidative stress, spectrophotometry

10. SPECTROPHOTOMETRIC DOSING OF BETA CAROTENE IN TABLETS METHOD VALIDATION

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Introduction: Validation is a verification methodology, compliance and accreditation of validity as a method of scientific analysis. This methodology aims to demonstrate that the analysis method corresponds to the utilization for which it was forseen, and to the parameters of validation in accordance with regulatory organizations. It is now recognized that no drug substance or drug can enter the European and American market without being accompanied by corresponding validation folder. The results of this study will serve as support in concluding validation methods report for the determination of the active principles of EUROSEPT product.

Materials and methods: The study was conducted on lozenges EUROSEPT, series 041211 made in December 4th, 2012 and valid until 12.2014. 1 tablet contains: active substances: ascorbic acid, eucalyptus essential oil, Tolu balsam, β-carotene; auxeliary substances: aerosil, corn starch, talc, magnesium stearate, stearic acid, citric acid, aspartame, sorbitol, lactose. In the process of dosage methods validation the following parameters were analyzed: specificity, precision (repeatability, reproducibility), linearity, accuracy. Spectrophotometric dosage method was performed by using scanning spectrophotometer double perchin Elmer Lambda 25 UV-VIS.

Results: Comparative analysis performance of the validation parameters were done, according with the European and international regulatory organizations: ISO, FDA, ICH, USP. Empirical results expressed through absorbance value were used for reconstruction of five calibration graphs used for the completion of the final one. The correlation coefficient of linear regression model is 0.9997, which shows that the experimental points approximate and arrange around the regression line according to experimental conditions stipulated in the MFT. The calibration graph is an average of all data points, which is characterized by a relative error less than 2%. Standard deviation of residuals, standard deviation of intercept and slope values are less than 0.5%, which indicates that the calibration chart can be used to determine the specificity of the dosage method. At the maximum absorption of 454 nm, for the solution obtained in the placebo-controlled trial were not observed significant absorbance values, which indicates that the secondary constituents do not interfere the procedure of the active substances quantification (ascorbic acid, eucalyptus oil, balm Tolu) of the reconstitude pharmaceutical form. Statistical obliquity value does not exceed the 1.5%, which demonstrates the accuracy of the spectrophotometric dosage method of beta-carotene in the visible domain. The correlation coefficient r^2 is 0.9984, which indicates that with the change in the amount of beta-carotene concentration of 80-120%, the dependence of absorbance versus concentration signal is one almost linear.

Conclusion: Spectrophotometric UV-VIS validation method of β-carotene dosage within the preparation EUROSEPT was performed, according to validation parameters: linearity, repeatability, reproductibility, specificity, accuracy, according to regulatory organizations.

Keywords: Validation, Spetrophotometry UV-VIS, Eurosept, β-Carotene