Development and validation of the GC method for the chemical stability estimation of the compounding ointment with Eucalyptus tincture

V. Georgiyants[1], L. Savchenko[1], K. Uminska[1], L. Ivanauskas[2]

1. National University of Pharmacy, Kharkiv, Ukraine
2. Lithuanian University of Health Sciences, Kaunas, Lithuania

The composition of many semisolid dosage forms includes the Eucalyptus alcoholic tincture. It can be used for the treatment of burns, blisters, herpes, cuts, wounds, skin infections and insect bites. This is due to the basic pharmacological effect of tincture - antimicrobial. It caused by the presence in the Eucalyptus essential oil its main component - 1,8-cineole. The object of our study was the compounding ointment: Eucalyptus tincture 2,5ml; wool fat 1,25; white soft paraffin 21,25. Since the main pharmacological effect of the ointment is due to the Eucalyptus tincture, it is advisable to analyze its chemical stability by determination of 1,8-cineole quantitative content. A promising in this field is the using of GC method, which is used for the quantitative analysis of plant essential oil components.

Chloroform was used as a solvent for the ointment sample preparation. In this solvent the base of the ointment is dissolved easily upon brief heating.The studies were carried out on a gas chromatograph GC-2010 Plus Shimadzu with a FID detector, auto sampler AOC-20i+s and Rxi-5MS column (30.0 m×0.25 µm). Injection volume was 1 µL, injection temperature 240^{0}C, injection mode – split (split ratio 1:10), carrier gas helium, column flow 1,25ml/min., FID detector temperature 320^{0}C. Temperature program: initial temperature 50^{0}C, heating up to 200^{0}C with rate 5^{0}C/min., heating up to 310 ^{0}C with rate 40^{0}C/min. Total program time – 51,75min. Analysis of all system suitability parameters showed the possibility of using the method for the ointment stability analysis. Validation of the method according to the State Pharmacopoeia of Ukraine (SPhU) requirements was done. The linearity of the method was assessed by constructing a calibration curve at eight concentration levels ranging from 1,73×10^{-6} to 2,22×10^{-4}g/ml of 1,8-cineole. LOD value was 3,03×10^{-8}g/ml and LOQ value was 9,17×10^{-8}g/ml. Method precision evaluation was performed by six independent determinations of the 1,8-cineole standard sample solution *($Area_{mean}$=9255, RSD=1,09%; $Concentration_{mean}$=4,18×10^{-6} g/ml, RSD=1,25%)*. RSD value corresponds to the SPhU requirements (for six parallel injections not more than 2,75%). The validation results allow to recommend the method for the 1,8-cineole quantitative determination in studied compounding ointment during its chemical stability evaluation.