FHAL-P1 RAZVOJ I VALIDACIJA IR SPEKTROSKOPSKE METODE ZA ODREĐIVANJE SADRŽAJA ETANOLA

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Etanol predstavlja značajnu komponentu brojnih farmaceutskih, kozmetičkih i dezinfekcionih preparata, zbog čega je neophodno razviti pouzdanu analitičku metodu za kontrolu njegovog sadržaja. Cilj ovog rada bio je razvoj i validacija IR spektroskopske metode za određivanje sadržaja etanola. Prednost IR spektroskopske metode je njena jednostavnost i brzina izvođenja, bez prethodne pripreme uzoraka. Identifikacija etanola zasniva se na praćenju karakterističnih apsorpcionih traka u oblasti 2800–3000 cm^{-1}. Kvantitativna analiza se zasniva na merenju visine apsorpcionog maksimuma koji odgovara specifičnim C-H valencionim vibracijama u navedenoj oblasti. Validacija optimizovane metode obuhvatila je ispitivanje linearnosti, tačnosti, preciznosti i limita kvantifikacije. Linearnost je ispitivana u koncentracionom opsegu etanola od 10% do 100% (R^2=0.999). Tačnost metode procenjena je izračunavanjem *Recovery* vrednosti, pri čemu su dobijeni rezultati bili u opsegu od 98,11% do 101,96%, što zadovoljava unapred definisane kriterijume prihvatljivosti. Preciznost metode je ispitivana kao ponovljivost (*intra-assay precision*) i potvrđena je vrednošću relativne standardne devijacije (RSD) od 0,63%, dok je limit kvantifikacije (LOQ) iznosio 7%. Validirana metoda je primenjena za određivanje sadržaja etanola u komercijalnom uzorku 70% etanola, kao i u uzorku parfema nepoznatog sadržaja etanola. Utvrđeno je da ne postoji značajno odstupanje od deklarisanog sadržaja etanola u komercijalnom 70% rastvoru, dok je u uzorku parfema određena koncentracija etanola od 83%. Dobijeni rezultati pokazuju da je razvijena IR spektroskopska metoda jednostavna, brza, tačna i precizna, te pogodna za rutinsko određivanje sadržaja etanola u preparatima koji ga sadrže.

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FHAL-P1 DEVELOPMENT AND VALIDATION OF AN IR SPECTROSCOPIC METHOD FOR ETHANOL DETERMINATION

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Ethanol is an important component of numerous pharmaceutical, cosmetic, and disinfectant products, making the development of a reliable analytical method for its content determination essential. The aim of this study was the development and validation of an IR spectroscopic method for the determination of ethanol. The main advantages of IR spectroscopy are its simplicity and rapid analysis, without prior sample preparation. Ethanol identification is based on monitoring characteristic absorption bands in the 2800–3000 cm^{-1} region. Quantitative analysis is based on measuring the height of the absorption maximum corresponding to specific C–H stretching vibrations in specified region. Validation of the optimized method included the assessment of linearity, accuracy, precision, and limit of quantification. Linearity was evaluated over a concentration range of 10–100% (R^2 = 0.999). Method accuracy was assessed by recovery studies, yielding values ranging from 98.11% to 101.96%, which met the predefined acceptance criteria. Precision was evaluated as repeatability and confirmed by a RSD value of 0.63%, while the limit of quantification was determined to be 7%. The validated method was applied for the determination of ethanol content in a commercial 70% ethanol sample and in a perfume with an unknown ethanol content. No significant deviation from the declared ethanol content was observed in the commercial ethanol solution, whereas the ethanol concentration in the perfume was determined to be 83%. The obtained results demonstrate that the developed IR spectroscopic method is simple, rapid, accurate, and precise, making it suitable for the routine determination of ethanol content.

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