

DETERMINATION OF BENZALKONIUM CHLORIDE IN AEROSOL PREPARATIONS CONTAINING SODIUM CHLORIDE BY HPLC TECHNIQUE

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Benzalkonium chloride is a biocidal agent used in the pharmaceutical industry as a preservative. Benzalkonium chloride is a mixture of alkylbenzyltrimethylammonium chloride, of which the three are the most important with alkyl substituents C12, C14, C16 in the quaternary ammonium salt. The purpose of this study was to develop a method for determining the content of benzalkonium chloride in aerosol preparations containing sodium chloride of different concentrations. For this purpose, the method of high performance liquid chromatography (HPLC) was used (1). Chromatographic analysis was performed using a Hypersil Gold CN column (4.6 mm × 250 mm, particle size 5 microns) with isocratic mobile phase consisting of 0.1 M sodium acetate solution pH 5.0 and acetonitrile in a ratio of 40:60 v/v at a flow rate of 1 mL/min (2). The column temperature is 25°C and the detection wavelength is 260 nm. The method was successfully validated in accordance with the AOAC guideline. The method is linear for the selected concentration range from 10 mg/L to 200 mg/L ($r^2 = 0.9999$) for C-12, C-14 and C-16 BKC homologues. The accuracy and precision of the method was determined at the lowest and middle calibration level. The results showed good linearity in relation to the selected range, as well as accuracy and precision. The developed method is suitable for routine analysis of benzalkonium chloride in the presence of sodium chloride in various aerosol preparations, simple and does not require special preparation of samples for analysis.

References

1. Pornchai Rojsitthisak, Wisut Wichitnithad, Ongart Pipitharome, Kingkan Sanphanya and Peeracha Thanawattanawanich, Sample HPLC Determination of Benzalkonium Chloride in Ophthalmic Formulations Containing Antazoline and Tetrahydrozoline, PDA Journal of Pharmaceutical Science and Technology September 2005, 59 (5) 332-337
2. Liena Alagib H Edress, Dhia Eldin Elhag, Development and validation of Stability Indicating HPLC Method for Benzalkonium Chloride in Betaxolol (0,5%) Ophthalmic solution, University of Medical Sciences and Technology, UMST, Khartoum, Sudan, Received: 03 March 2019; Accepted: 18 April 2019; Published: 24 April 2019

ODREĐIVANJE BENZALKONIJUM HLORIDA U AEROSOLNIM PREPARATIMA KOJI SADRŽI NATRIJUM HLORID HPLC TEHNIKOM

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Benzalkonijum hlorid (BAC) je biocidni agens koji se koristi u farmaceutskoj industriji kao konzervans. Benzalkonijum hlorid je mešavina alkilbenzildimetilamonijum hlorida, od kojih su tri najvažnija sa alkil supstituentima C12, C14, C16 u kvaternarnoj amonijum soli. Svrha ovog istraživanja je bila da se razvije metoda za određivanje sadržaja benzalkonijum hlorida u aerosolnim preparatima u koje sadrže natrijum hlorid različitih koncentracija. U tu svrhu je korišćena metoda tečne hromatografije visokih performansi (HPLC) (1). Hromatografska analiza je izvršena korišćenjem Hypersil Gold CN kolone (4,6 mm × 250 mm, i.d, veličina čestica od 5 mikrona) sa izokratskom mobilnom fazom koja se sastoji od 0,1 M rastvora natrijum acetata pH 5,0 i acetonitrila u odnosu 40:60 v/v pri brzini protoka od 1 mL/min (2). Temperatura kolone je 25°C, a talasna dužina detekcije 260 nm. Metoda je uspešno validirana u skladu sa AOAC smernicom. Metoda je linearna za opseg odabrane koncentracije od 10 mg/L do 200 mg/L ($r^2 = 0,9999$) za C-12, C-14 i C-16 BKC homologe. Preciznost i tačnost metode je određena na najnižem i srednjem kalibracionom nivou. Rezultati su pokazali dobru linearnost u odnosu na izabran opseg, kao i tačnost i preciznost. Razvijena metoda je pogodna za rutinsku analizu benzalkonijum hlorida u prisustvu natrijum hlorida u različitim aerosolnim preparatima, jednostavna je i ne zahteva posebnu pripremu uzoraka za analizu.

Literatura

1. Pornchai Rojsitthisak, Wisut Wichitnithad, Ongart Pipitharome, Kingkan Sanphanya and Peeracha Thanawattanawanich, Sample HPLC Determination of Benzalkonium Chloride in Ophthalmic Formulations Containing Antazoline and Tetrahydrozoline, PDA Journal of Pharmaceutical Science and Technology September 2005, 59 (5) 332-337
2. Liena Alagib H Edress, Dhia Eldin Elhag, Development and validation of Stability Indicating HPLC Method for Benzalkonium Chloride in Betaxolol (0,5%) Ophthalmic solution, University of Medical Sciences and Technology, UMST, Khartoum, Sudan, Received: 03 March 2019; Accepted: 18 April 2019; Published: 24 April 2019