Validated stability-indicating chromatographic methods for the determination of chlordiazepoxide and clidinium bromide in the presence of its alkali-induced degradation product.

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Abstract

Accurate, simple and selective stability-indicating reversed phase HPLC and TLC-densitometric methods with UV detection have been developed and validated for simultaneous determination of chlordiazepoxide (CDZ) and clidinium bromide (CDB) in the presence of its alkali-induced degradation product (DEG). Successful separation of the drugs from the degradation product was achieved. For the RP-JRNE" ogvjqf."vjg"uvcvkqpct{"rjcug"ycu"CEG/348/4768"CS"E/3:"*472" "608"o o" k0f0."7 o "rctvkeng"uk|g+"eqnwo p"cv"47"ÅE."kp"cp"kuqetcvke" oqfg."wukpi"oqdkng"rjcug" containing a mixture of 25 mM ammonium acetate (pH 5.4): acetonitrile in the ratio of (20:80, v/v), at the flow rate of 1.0 mL min 3"and UV detection was performed at 444"p o 0"Vjg" tgvgpvkqp"vk o gu" y gtg"*6035"Õ"2023+"cpf"*:07"Õ"2023+" okp"hqt"EF\ "cpf" CDB, respectively. For the TLC-densitometric method, the separation was performed using a stationary phase of precoated Silica Gel G/UV254 and mobile phase composed of a mixture of ethyl acetate: methanol: ammonia (8:3:1, v/v/v) and uecppgf"cv"444"p o 0"Vjg"T h"xcnwgu" y gtg"*209;Õ"2024+"cpf"*2033"Õ"2023+"hqt"EF\ " and CDB, respectively. The linearity graphs for CDZ and CDB, respectively, were found to be linear over *207662+" g mL 3"and *4667+" g mL 3"with mean rgtegpvcig"tgeqxgtkgu"*;;08;Õ"20:58+"cpf"*;02:"Õ"30:7+"hqt"TR/JRNE" ogvjqf" and *3636+" g band 3"and *207632+" g band 3"with mean percentage recoveries *322022"Õ"209:4+"cpf"*32203;Õ"30232+"hqt"VNE/fgpukvo ogvtke o gvjqf0"C" comparative study of different analytical validation parameters such as accuracy, precision, specificity and robustness were conducted. The obtained results were statistically compared with those of the official and reported methods; using Studentøs t test, F test and one-way ANOVA, showing no significant difference with high accuracy and good precision. The proposed RP-HPLC method was also used to study the kinetics of the alkaline hydrolysis of clidinium bromide that was found to follow pseudo-first order kinetics. The t 1/2 was 8.5729 min while k (the degradation rate constant) was 0.0808353 min 3"