ABSTRACT

VALIDATION OF VISIBLE SPECTROPHOTOMETRIC METHOD FOR ASSAY OF BENZALKONIUM CHLORIDE IN CIPROFLOXACIN EYE DROPS FORMULATION

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Benzalkonium Chloride (BKC) is a preservative commonly used in eye drops, yet if ≥0.03% of its concentration enters the eye, one must seek immediate medical treatment. Therefore, a validated assay method is required to determine preservative concentration in eye drops. The analysis was performed by using spectrophotometry in visible light region using color reagent. The reagents used were Eosin Y in Silver nitrate, Eosin Y and bromthymol blue. The selected color reagent was Eosin Y due to its selectivity to BKC. The wavelength of 552 nm was shown to be λmax because there was no absorbance of eosin Y reagent. In selectivity validation, Y eosin reagent only reacted with BKC alone, shown by the absorbance of benzalkonium chloride yet the absence absorbance of eosin Y reagent on placebo (Absorbance value obtained was 0.08920) at λmax of 552 nm. In linearity validation, the linear regression equation obtained was y = 0.0039x +0.2042, with correlation coefficient (r) of 0.9996 and Vxo of 1.94%. In accuracy validation, 3 times replication was done on each level of addition placebo into each level. At 50%, 100% and 120% the mean % recovery obtained were 96.24%, 103.44% and 98.31%, respectively, thus the mean % recovery of three was 98.31%. In precision validation, each of six replications were performed a test, with the mean % recovery of 101.17 and the RSD of 0.48%. Interday variation study showed a mean % recovery of 97.90% and RSD of 0.72%. In this study the assayed level of Benzalkonium Chloride in the eye drop preparation of Ciprofloxacin was 0.0061%.

Keywords: Validation method, visible spectrophotometry, Benzalkonium chloride, Eosin Y