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Reveiw Article

CAMYLOFIN DIHYDROCLORIDE – A REVIEW OF ANALYTICAL METHODS

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ABSTRACT

Camylofin dihydrochloride is a spasmolytic drug usually used in combination with other drugs like Paracetamol, Diclofenac. Few analytical methods have been proposed for the determination of Camylofin dihydrochloride. The aim of the present study is to evaluate the utility of different techniques for the quantification of Camylofin dihydrochloride content in Pharmaceutical formulations.

Keywords: Camylofin dihydrochloride, Review, Pharmaceutical formulations.

INTRODUCTION

Camylofin dihydrochloride (CAM) is 3 – methyl butyl 2 – (2 – diethyl amino ethyl amino) – 2 – phenyl acetate hydrochloride belongs to the group of spasmolytic, anticholinergic and gastro intestinal sedative [1]. CAM is used as an antispasmodic, usually in combination with diclofenac, paracetamol and nimesulide. CAM is used in the treatment of functional bowel disorders. CAM injection should be co – administered with caution in patients taking amantadine, quinidine and tricyclic antidepressants. CAM bulk drug and formulations are not official in any pharmacopoeia. The structure of the drug is shown in **Fig 1**.

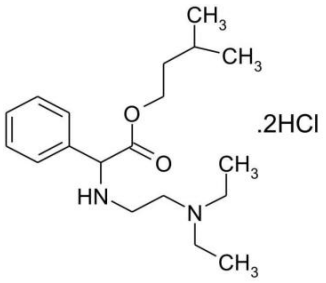

Fig. 1: Structure of Camylofin dihydrochloride ($C_{19}H_{32}N_2O_2$, 2HCl)

Several methods have been employed for the determination of CAM in formulation and in combination with other drugs.

The main objective of this review is classified, summarized and also it discusses the different proposed methods for the determination of CAM in formulations and in mixtures.

Chromatographic methods

The simultaneous determination of the active ingredients in multicomponent pharmaceutical products normally requires the use of a separation technique, such as high performance liquid chromatography or gas chromatography followed by their quantitation.

High Performance Liquid Chromatography

Among various separating analytical techniques, HPLC constitutes the most popular chromatographic method for separating the mixtures of drugs.

A stability indicating HPLC analysis of CAM was performed on zorbax eclipse XDP C_{18} column under reversed phase conditions [2]. The mobile phase comprised of 0.05% trifluoro acetic acid in water (mobile phase A): 0.05% trifluoro acetic acid in acetonitrile (mobile phase B) [60: 40v/v] at a flow rate of 1.0 mL min^{-1}using gradient program and UV detection at 220 nm.

An isocratic reversed phase HPLC method for the simultaneous determination of CAM and Paracetamol in pharmaceutical preparations has been developed by R. R. Singh et al [3]. The chromatographic separation was achieved with 0.05% trifluoro acetic acid in water (mobile phase A): 0.05% trifluoro acetic acid in acetonitrile (mobile phase B) [50: 40v/v] at a flow rate of 1.0 mL min^{-1}on waters C_{18} column and UV detection at 220 nm. Methyl paraben was used as an internal standard.

CAM and Diclofenac potassium were separated using an Inertsil C_{18} column by isocratic elution with a flow rate of 1.5 mL min^{-1}.The mobile phase composition was 35:65 v/v 0.05 M KH_2PO_4 in water: methanol with methyl paraben as internal standard and UV detection at 220 nm [4].

A stability indicating simultaneous RP HPLC method for the determination of CAM and Nimesulide in pharmaceutical preparations was reported by R. R. Singh et al [5]. Varian chromspher 5 C_{18} column with gradient pump was used. The mobile phase comprised of buffer solution pH 5: methanol (60: 40 v/v) and flow rate being 1.0 mL min^{-1}. The column temperature was maintained at 30^0 C and detection wavelength was at 220 nm. Caffeine was used as an internal standard.

CAM was determined in spasmomigraine tablet by liquid chromatography using ultra violet detection. The method used micro Bondapak C 18 column with acetonitrile: 25 mM KH_2PO_4 : acetic acid (45: 55: 0.2 v/v/v) as the mobile phase with a flow rate of 1.5mL/$min^{-1}$and the detection was at 234 nm at ambient temperature[6].

An isocratic reversed phase HPLC gradient elution method for simultaneous determination of CAM and Diclofenac potassium in pharmaceutical dosage form has been developed by Nishit kumar S. Patel et al [7]. The method required ODS C_{18} column with acetonitrile: 25 mM KH_2PO_4 (80:20 v/v) containing 0.1 % v/v acetic acid adjusted to pH 7 with triethyl amine as the mobile phase. The flow rate was 1.5 mL min^{-1} and the elution was monitored at 215 nm.

High Performance Thin Layer Chromatography

Since instrumental planar chromatography is regarded as a reliable, fast and accurate method for quantitative drug analysis, it is proved that HPTLC can be used as an alternative method of drug assay.

A simple and rapid HPTLC method for the determination of CAM and Diclofenac potassium in pharmaceutical dosage form has been developed by Nishit kumar S. Patel et al [7]. The determination were performed on pre coated HPTLC Silica gel aluminium plates 60 F 254 (10 cm x 10 cm) by means of a Linomat 5 semiautomatic sample applicator. The plates were prewashed with methanol and the development was achieved using chloroform: ethyl acetate: methanol: ammonia (5: 3: 2: 0.1 v/v/v/v). Spectrodensitometric scanning was performed in the reflectance – absorbance mode at 215 nm.

Another paper describes a HPTLC method for the simultaneous determination of CAM and Nimesulide in tablet samples [8]. The analytes were separated on Silica gel 60 F 254 HPTLC plates with benzene: methanol: ammonia (7.5: 2.5: 0.1 v/v/v) as the mobile phase and quantified at a wavelength of 220 nm.

Gas Chromatography

A GC method for the determination of CAM and Nimesulide in pharmaceutical preparations using benzoic acid as the internal standard has been developed by R. R. Singh et al [9]. RT X – 5 capillary column with flame ionization detector was used for the analysis. Helium was used as the carrier gas.

Another paper describes a stability indicating GC – FID method for the determination of CAM and Diclofenac potassium in pharmaceutical preparations [10]. The experiment was performed on RTX – 5 capillary column with FID. Helium was used as the carrier gas and benzoic acid being the internal standard.

A GC method for the determination of CAM, on a porous packing material has been reported by E. Crombez et al [11].

CONCLUSION

The first and principal conclusion is that there are only very few papers that report the determination of CAM in formulations by chromatographic methods. As from the literatures it is clear that no UV spectrophotometric methods and analysis of the drug in biological samples are reported for the determination of CAM so far.

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