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RESEARCH ARTICLE

Application of Central Composite Design for screening and Optimization of HPTLC method for simultaneous quantitation of Aprepitant, Dexamethasone and Ondansetron in their synthetic mixtures

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ABSTRACT:
New HPTLC method was developed and optimized for estimation of Ondansetron (OND), Dexamethasone (DEX) and Aprepitant (APT) in laboratory prepared ternary mixtures by using Central composite design (CCD). The independent variables used for the optimization were the acetone content in mobile phase (%mL), distance of developing solvent (cm) and saturation time (min). HPTLC Separation was performed on Precoated silica gel F_{254} aluminum plate (10X10 cm, 100µm thickness) with a mobile phase consisting of chloroform: methanol: acetone: ethyl acetate: ammonia (9:4:2:5:0.2 % v/v/v/v). Quantification of OND, APT and DEX were achieved based on a Densitometric analysis over the concentration range of 200-1200 ng/band, 500-1000 ng/band and 1000-2000 ng/band, respectively, at 254nm. The method was yielded dense and well-resolved bands at Rf values of 0.54± 0.02, 0.79±0.02 and 0.23±0.01 for OND, APT and DEX, respectively. The linear regression analysis for the calibration plots produced r^2= 0.9997, r^2= 0.9998 and r^2=0.9997 for OND, APT and DEX, respectively. The method was validated according to the ICH guidelines. The robustness test was determined that the selected factors have an insignificant effect on the responses. The results indicated that the method is suitable for the routine quality control testing of OND, APT and DEX in their bulk form.

KEYWORDS: Aprepitant, Dexamethasone, Ondansetron, HPTLC, Central Composite design and Response Surface Methodology.

INTRODUCTION:
Chemotherapy is usually systemic treatment of cancer. Regardless of the fact that chemotherapy improves survival, but it has its own toxicity and side effects, which comprise a negative impact on the patients' quality of life. Though, Nausea and vomiting continue to be significant side-effects of cancer therapy and can affect patient compliance.[1] Therefore, it is important to provide prophylactic treatment for chemotherapy-induced nausea and vomiting (CINV). Thus, by addition of a neurokinin-1 receptor antagonist (NK1RA) (Aprepitant) to a standard 5-hydroxytryptamine (5-HT3) receptor antagonist (Ondansetron) and dexamethasone antiemetic regimen can be significantly improved the prevention of CINV throughout the overall period of risk (0-120 hours) of chemotherapy[2].

Dexamethasone (DEX) (Fig. 1a), is chemically 9-Fluoro-11b, 17, 21- trihydroxy-16a-methyl pregna-1, 4-diene-3, 20-dione a potent synthetic corticosteroid[3]. It is frequently used as an anti-inflammatory agent and also having immune suppressive properties. It is official in Indian Pharmacopoeia[4].Similarly, Ondansetron (Fig.1b)

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