

## Formulation development of sustained release Theophylline pellets by drug layering method

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The controlled release and sustained release drug delivery has increased considerably during the past decade in selected areas. The preparation of sustained release dosage forms which utilize water miscible drugs as substrates have long been plagued by problems. One major problem has been the tendency of such drugs to "dump" or "surge" into the body during the first hour or two after an oral dosage form containing them is swallowed. The problem is caused by their affinity for aqueous environments. In the present invention certain readily water soluble drugs are administered in unique slow-or sustained-release oral, vaginal or rectal dosage forms. These dosage forms comprise a novel two-part system, a core or inner portion in which the drug is dispersed in a matrix of water soluble polymers like hydroxypropyl-methylcellulose and hydroxyethyl-cellulose. This core is then coated with an aqueous coating solution consisting of a water soluble polymeric system containing a hydroxypropyl-cellulose polymer (Klucel) and Aquateric TM. The polymer matrix is one that provides a prolonged release of the medicament by forming a gel-like layer under the action of water. This layer retards the diffusion of the active ingredient from the dosage form. The amount of the initial release of a medicament is controlled by varying the proportions of hydroxypropyl-cellulose and cellulose-acetate-phthalate or polyvinyl-acetate-phthalate in the formulation. In present work a total 10 trails batches were prepared among these, batch no -9 was found to be the best to achieve spherical shape, uniform size with maximum yield. Theophylline 60% pellets were prepared by using processing conditions employed in batch no-9. The drug layered pellets were than coated with hydroxypropyl methylcellulose phthalate (HPMCP) on fluidized bed coater to achieve sustained release of Theophylline. The formulated Theophylline sustained release product gave a release profile similar to that of marketed sustained release product.

## Validated liquid chromatographic method for the determination of zolpidem tartrate

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Zolpidem Tartrate is an imidazopyridine derivative, is a non benzodiazepine hypnotic agent binds preferentially to one benzodiazepine receptor subtype  $\omega$ -1 bezodiazepine-1 thought to mediate hypnotic effects. Zolpidem behaves as a sleep inducer without the muscle relaxant and anticonvulsant effects of the benzodiazepines. An isocratic RP-HPLC method was proposed for the determination of Zolpidem Tartrate in pharmaceutical formulations. Isocratic elution was performed using water and methanol as mobile phase. The overall run time was 10 min. and the flow rate of the mobile phase was 1.2 mL/min. with UV detection at 254 nm. 20  $\mu$ L of sample was injected into the HPLC system. In the present work chromatographic separation was achieved by using a C-18 (250mm  $\times$  4.6mm i.d., 5  $\mu$ m particle size) column of Shimadzu Model CBM-20A/20 Alite, equipped with SPD M20A prominence photodiode array detector, maintained at 25  $^{\circ}$ C. Linearity was observed with a correlation coefficient 0.999 and the method was validated as per ICH guidelines. The RSD for intra-day and inter-day precision were found to be less than 2 %. The percentage recovery was in good agreement with the labeled amount in the pharmaceutical formulations and the method is simple, precise, accurate and robust for the determination of Zolpidem Tartrate.