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Formulation and evaluation of sustained release microspheres of trihexyphenidyl hydrochloride

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The aim of present work was to formulate sustained release microsphere of trihexyphenidyl hydrochloride. The therapeutic agent was homogeneously distributed throughout the matrix as a molecular dispersion of particles. Trihexyphenidyl hydrochloride is a rapidly and completely absorbed drug but plasma level achieved is highly variable after oral administration. Trihexyphenidyl hydrochloride with a short half-life (3.3-4.1 hr) requires frequent dosing and this makes it an ideal candidate for a sustained-release formulation which would maintain reasonably stable plasma concentration. Drug and excipients were evaluated for identification and drug excipients interaction by various methods. Trihexyphenidyl HCL microspheres were prepared by ionic gelation method. Various formulations were prepared using different amount of polymer (Carbopol 934P, Sodium alginate and sodium CMC) with affixed amount of drug (i.e., 100 mg). Different polymers (Carbopol 934P, Sodium alginate and sodium CMC) were tried in different ratio with different concentration. High molecular weight polymer was used to modify the density of the formulations. Formulations were evaluated for different parameters like drug content, drug entrapment efficiency, flow property, particle size analysis by optical microscopic method, shape of microspheres from optical microscope, scanning electron microscopy (SEM), *in vitro* dissolution, *in vitro* mucoadhesive strength (Falling liquid film technique) and stability study. Drug purity and excipients interaction study was carried out by DSC, IR spectroscopy and found that drug was pure and no interactions with selected polymers. The best batch was selected on the basis of percentage drug entrapment, mean particle size, mucoadhesive strength and kinetic drug release. The drug entrapment efficiency of batch F9 was very high 98.57% and assay was 98.55%. Mean particle size of the batch F9 was 71.1 μm and the 94.13% drug release from the formulation within 12 hours means it was a prominent batch for sustained release formulation. The mucoadhesive strength of the batch F9 was 96%, and the kinetic drug release was maximum. This optimized batch F9 was stored for one month stability study and that data was found to be satisfactory. Trihexyphenidyl hydrochloride sustained released microspheres were prepared and successfully evaluated for various parameters hence formulation objectives were achieved.

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