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Taste masking approach to optimize an immunosuppressant loaded rapid disintegrating tablets

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This investigation aimed at mining the critical formulation parameters affecting the *in vitro* performance and palatability of immunosuppressant loaded nanoemulsifying system in oral rapid disintegrating tablets (RDT). The efficiency of the formulation to mask the bitter taste of the drug was assessed using an electronic tongue. RDTs were prepared by lyophilizing the dispersion of nanoemulsion vesicles and synthetic silica followed by direct compression. The influences of the tablet hardness and superdisintegrant concentration were evaluated to optimize critical tablet characteristics. The optimized nanoemulsified formulations showed vesicular size of 48.5 nm, polydispersity index of 0.95, turbidity of 40.7 NTU and rapid drug dissolution and emulsification rate. Assessing the processability of the powders and the produced RDT demonstrated an acceptable flow, hardness and friability. The interaction and Pareto charts showed a higher influence of low hardness value to increase the RDT porosity and hence facilitating their disintegration rather than their deformation by the superdisintegrant action. On the other hand, the employed superdisintegrant concentration was more important to control the drug dissolution rather than the hardness valueand their combined effect. Moreover, the Euclidean distance values and discrimination indices obtained from electronic tongue data analysis showed that the bitter taste and taste aversion effect of the drug were masked in its optimized nanoemulsions incorporated RDTs.

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Insights into non-viral vectors for gene therapeutics

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Gene delivery has shown a great promise in pre-clinical and clinical trials, with new treatment options for a number of diseases. Non-viral gene therapy with cyclodextrins as vectors for gene delivery has gained more interest due to overcoming problems of viral vectors such as immunogenicity, mutagenicity and oncogenicity. Cyclodextrins interaction with enclosed DNA results in condensation of DNA which should remain stable and protected from nuclease digestion and hence be efficiently delivered into cells. The purposes of this research were: To stabilise the deoxyribonucleic acid (DNA) via using β- and γ-cyclodextrins (CD) to condense and include the DNA; to evaluate the influence of co-polymers (poly 1-vinylpyrrolidone-co-vinylacetate and Pluronic F127) and their concentrations on stability of DNA-CD complexes, encapsulation efficiency of DNA and charge of the DNA formulations and to study the effect of drying of formulations on DNA stability. The DNA (from calf thymus), CDs and copolymers were dissolved in phosphate buffer saline (pH 7.4) in different concentrations. Freshly prepared and dried DNA formulations were evaluated after storage at ambient temperature (25˚C). UV-Vis spectroscopy and fluorescence were used to study DNA stability and inclusion efficiency, respectively. DNase I activity measurement was used to assess availability of the DNA outside the CD complexes; Fourier Transform Infra-Red (FT-IR) investigates interactions of excipients in inclusion complexes with the DNA and the charge was measured employing zeta potential. Scanning Electron Microscopy (SEM) was applied to study the morphology of dried DNA samples. The γ-CD significantly ($p<0.05$) enhanced DNA protection against DNase I degradation and β-CD led to higher ($p<0.05$) DNA inclusion. The interactions between excipients and the DNA stabilise the DNA; this has been confirmed by FT-IR results and by the DNase Itest (for example: there was only 0.92 µg DNA/mL loss from fresh solution of 200 µg β-CD/mL with 20 µg DNA/mL and 100 µg poly 1-vinylpyrrolidone-co-vinylacetate/mL formulation kept at ambient temperature for two weeks; the DNA inclusion in the same formulation, as determined by the fluorescence spectroscopy, was 28.8%). For dried samples in the presence of β-CD, particles show uniform size and shape as indicated by the SEM. Excipients concentration had no effect on percentage inclusion of DNA within CDs. The presence of poly 1-vinylpyrrolidone-co-vinylacetate with either β-CD or γ-CD resulted in formation of positively charged DNA-CD complexes and this is desirable for cell transfection. In conclusion,: cyclodextrin complexes in the presence of copolymers protect DNA. The copolymers/CDs led to formation of positively charged DNA complexes which is favourable for cell transfection..