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Milk oral lyophilisates with loratadine: screening for new excipients for paediatric use

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Milk-based formulations are promising approaches for drug delivery. Its nutritional function, considerable effect on the drug solubility and taste masking capacity, recommended milk as potential excipient. This work aimed to investigate the properties of milk for paediatric oral lyophilisates (OLs) preparation and its influence on the quality profile.

A D-Optimal screening experimental design, with three independent variables: suspended active pharmaceutical ingredient (API) dose - loratadine, alveolae volume and the type of milk (1.5% and 3.5%) was generated and led to 16 formulations. The OLs were characterized for the disintegration time, texture and dissolution profile and particle size analysis upon reconstitution.

The independent variables included into the experimental design had significant influences on the output and gave robust models for all responses. A good OL excipient should allow fast disintegration and good mechanical profile. Disintegration was facilitated by high API content, small alveolae and low fat milk, correlated to weaker mechanical structures. However, appropriate mechanical profiles with hardness over 600g were obtained for most formulations, especially for the ones containing low doses of API. Dissolution was favoured by high API content and low fat milk. Low particle sizes upon reconstitution could improve both palatability and API dissolution and were granted by high alveolae volumes and low lipid content.

These results showed the feasibility of milk structures that meet OLs' quality criteria, indicated a rational way to choose the type of milk and highlighted the effects of the API dose and product volume.

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