

An Instant Pudding-like Gel Formulation for the Delivery of Oral Medicines to Patients with Swallowing Difficulties

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INTRODUCTION: Although oral route is widely accepted for administration of medicines owing its simplicity, convenience and non-invasiveness, statistics show that almost 60-79% of the elderly population will experience some form of swallowing difficulty and likewise 25-45% of typically developing children [1]. To overcome the problems associated with other oral formulations, a patient-friendly, cost-effective and a simple semi-solid pudding-like gel structure to deliver a drug product is proposed. The aim was to develop a medicated pudding-like gel formulation that can be prepared from dry materials and water in less than five minutes.

MATERIALS AND METHODS: The required excipients (all GRAS listed) were weighed according to their respective ratios and mixed together and 4 mL of glycerol was added to the mixture. Once the ingredients dispersed in glycerol, 5 mL of distilled water (at room temperature) was added to the same mixture. After five minutes, the characteristics of the product were visually examined in terms of texture and brittleness. Similar experiments were also performed by incorporating clinical dose of Ibuprofen as model drug into prototype gel formulations. Rheology testing was conducted using TA Instruments' AR G2 rheometer and 40 mm HA Aluminium parallel plate to determine viscosity profiles. To determine the gel strength and elasticity of the pudding gel formulations a Texture Analyser (TA.XTplus) was used.

RESULTS AND DISCUSSION: Preliminary screening experiments performed on different polymers alone and in combination revealed starch, xanthan gum and sugar in combination with either sodium alginate or sodium carboxymethylcellulose as a suitable excipient combination to product pudding-like structure and therefore used further screening and drug-loading experiment.

The total dry weight of each formulation is 4.47 g and the weight of the pudding gel once prepared is 13.47 g (without drug). Ibuprofen's clinical dose of 200 mg was also incorporated into the formulations for testing. Each dry formulation was successfully prepared into a pudding-like gel in under five minutes. Glycerol was needed as a dispersion agent to form homogenous structures and prevent lump formation, a common problem observed with majority of hydrophilic polymers.

All of the formulations displayed shear-thinning behaviour i.e. decreasing viscosity (Pa.s) with increasing shear rate (1/S). Texture analysis of the formulation showed there was a dramatic decrease in cohesiveness and increase in brittleness of the mixed gels when ibuprofen was added (Red line compared to green in figure 1). This could mean that texture of the pudding-like gels can vary depending on the drug material used.

All of the formulations when compared to marketed products showed more adhesiveness and stickiness texture profiles but pudding-like gels prepared using starch, sodium alginate, xanthan gum and sugar in ratio (g) of 0.8:0.5:0.17:3 showed similar texture profiles in terms of brittleness and rupture strength when compared to the marketed pre-formulated jelly product (Figure 1, right).



Figure 1. A representative image of reconstituted pudding-like gel (left) and the texture profiles of reconstituted pudding-like gel and selected pre-formulated marketed products (right).

CONCLUSION: The studies show that developing a medicated pudding-like gel formulation that can be reconstituted from dry materials on addition of normal water in under five minutes is possible but requires the use of a dispersion agent to avoid lump formation. Future research will be focused on drug release experiment and identifying effect of increasing drug loading as well as drug's physicochemical properties on gel characteristics. This medicated pudding-like gel formulation is seen as more suitable for paediatric, geriatric and dysphasic patients as it represents a suitable consistency for safe swallowing and it is universally accepted as a dessert for all ages.

REFERENCES

[1] Liu, F. Ranmal, S., Batchelor, H., Orlu-Gul, M., Ernest, T., Thomas, I. (2014). *Drugs*, 74(16), 1871-1889.