

An Alternative To Tablets And Capsules

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Abstract

Introduction: Until now, the great advances in pharmaceutical sciences and technologies are yet to offer an economic, large-scale and practical solution to personalized dosing of highly potent solid drugs, especially those with narrow-therapeutic-indexes. We hope, one day, physicians will be able to freely and accurately prescribe any increment of a drug dose to their patients. We have proposed the concept of designing large-sized beads (2.5 to 5.5 mm) as individual solid unit oral dosage form that could replace tablets and capsules, with similar accuracy and scale of production.

Methods: Initially, Mega-beads, 2.5 to 5.5 mm in diameter were made of micro-crystalline cellulose using a modified cold extrusion/spheronization technique. Mega-beads were classified according to their size which correlates to their weights. Subsequently size and process of extruded particles were controlled mechanically to enhance weight accuracy of unit doses. Finally, drug layering and coating were performed to achieve a finished product. Manufactured Mega-beads were evaluated for their mechanical and physical properties; i.e. size, weight, hardness, friability, and disintegration time, using USP methods. Student t-Test was applied to independently evaluate the statistical significance of single comparisons.

Results: Mega-Beads Manufactured had hardness values between 20-40 Kg force and friability values of 0.1% to 1.14%. Disintegration time was 2-6 min. When mechanical controls were applied to processing parameters such as speed of extruder's chopper and frequency of extrusion, variability in unit weights was reduced from baseline of 16.5% to 12.4% to 5.7% Relative Standard Deviation (RSD), respectively. Weight accuracy within 2.0% RSD were statistically significant.

Conclusion/Implications: A solid unit dosage form in the weight range of 20 mg to 100 mg were successfully developed with similar or exceeding mechanical and physical properties of Standard Tablets or Capsules. Mega-Beads can be made so that an almost continuous function of dosing can be accurately administered to patients.



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References: Formulation of Mega-beads; a novel oral dosage form AAPS Symposium 360 2019

Keywords: Route/target of delivery - Oral/Buccal/Gastrointestinal, Type of delivery agent -

Small molecule, Patient population/context - Personalized medicine, Delivery vehicle - Rational design, Research approaches/methods/tools - Novel methods, Non-drug delivery topics - Manufacturing

Learning Objectives:

- Demonstrate novel delivery technique
- Evaluate suitability
- Design and develop pharmaceuticals