



ABSTRACT

Objectives

1. Demonstrate how single-step encapsulation of a water core can be achieved using Strat μ m[™] technology
2. Understand the process parameters needed to manipulate particle size and release type in microcapsules
3. Describe how Strat μ m technology delivers finer precision in microsphere fabrication compared to traditional methods.

Methods

Microcapsules were fabricated from a proprietary process described previously.¹ Briefly, a high molecular weight PLA (R207S, Evonik) was dissolved in dichloromethane and processed through a proprietary nozzle as an annular stream enclosing an aqueous 1% w/v gelatin stream with red dye. The microcapsule droplets were collected in an aqueous phase which extracted the solvent allowing the shell to harden. Following, particles were isolated and filtered.

Results

Highly monodisperse red dye-encapsulated microcapsules were obtained with the described process. Shell thicknesses for microcapsules were approximately 5 μ m, with an overall mean diameter of 50 μ m.

¹Berkland C., Kim K., and Pack D., "Fabrication of PLG microspheres with precisely controlled and monodisperse size distributions," *Journal of Controlled Release*, May 2001, 73(1):59-74.

Formulation of Aqueous Core Poly(lactic acid) Microcapsules

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INTRODUCTION

Poly(lactic acid), or PLA, is a biodegradable, biocompatible polyester commonly used in many medical, pharmaceutical, and biotechnology products. The molecular weight of PLA can be tailored to impart various degradation kinetics and subsequent release profiles. The ability to make microcapsules with a thin PLA shell,

however, is non-existent in the controlled release space. Here, using a proprietary Strat μ m[™] technology, we have created 50 μ m capsules with an aqueous core and thin PLA shell. The microcapsules have implications for encapsulating water-soluble molecules such as peptides and proteins, which can be released with a discrete pulse, or slow ramp in release rate.

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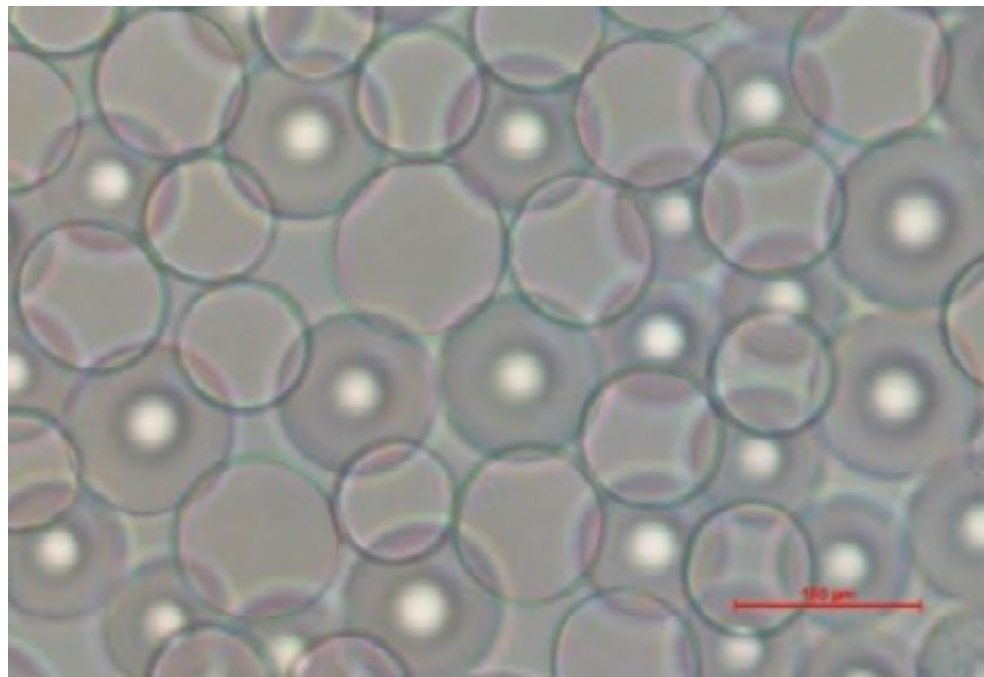


Figure 1. Representative optical microscopy picture of dye-loaded microcapsules with a diameter of ~50 μ m.

Presenter
NATHAN DORMER, PH.D.



Dr. Dormer is the Director of Drug Product Development at Adare Pharma Solutions in Lenexa, KS. Dr. Dormer is a pharmaceutical scientist and bioengineer with over a decade of experience developing microsphere-based solid oral and parenteral/implantable dosage forms, with an emphasis on controlled release and other innovative formulation concepts. He is responsible for pharmaceutical development activities such as creation of prototypes, analytical method development, CMC and IP documentation, pharmacokinetic correlations, tech transfer, manufacture of clinical supplies, and commercial scale process optimization and validation. Dr. Dormer received his B.S. in Chemical Engineering and his Ph.D. with Honors in Bioengineering, both from The University of Kansas.



Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, controlled release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare has developed and manufactures more than 65 products sold by customers worldwide.

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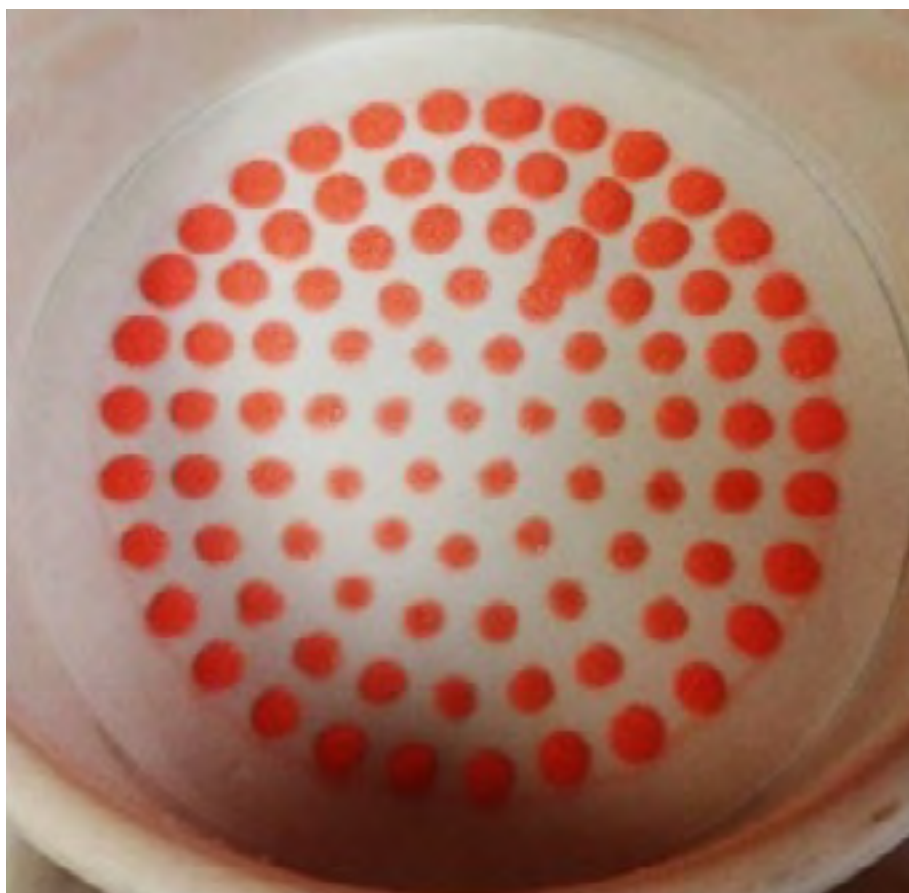


Figure 2. Macro images of filtered PLA microcapsules.

CONCLUSION

This process demonstrated that the Stratum technology could be used to encapsulate aqueous-based high-viscosity solutions containing biological molecules. Parameters of drug release could be tailored by adjusting polymer shell co-block

ratio (such as PLGA), molecular weight, or type (such as surface eroding polyanhydrides or bulk-eroding PLGAs). Depending on the microcapsule characteristics, shell thickness or microcapsule diameter could vary release profile.