



AN EASY-TO-SWALLOW DEPRESSION DRUG FOR ELDERLY PATIENTS



Treating depression in the elderly is an important mission for health care providers. The maker of a drug used to treat depression asked Adare Pharma Solutions to create a version of their drug that would better serve the geriatric population.

THE CHALLENGE

An Easy-To-Swallow Depression Drug

A CDC study in 2017 found that depression affects about 1%-5% of the general elderly population, and that number rises significantly in elderly hospital patients (11.5%) and in those who require home healthcare (13.5%).

There are many reasons for the high rate of depression among older people. Of course, major causes are the loss of mobility, freedoms, and acuity that come with getting older, as well as the death of spouses and other loved ones. Many medical problems, especially chronic conditions, can also trigger or worsen the symptoms of depression. Finally, certain medications often prescribed for ailments suffered by the elderly are also associated with higher incidents of depression.

The treatment of depression in the elderly is an important mission for health care providers. A pharmaceutical company, the maker of a drug that is used to treat depression, approached Adare Pharma Solutions to create a version of their drug that would better serve significant portions of the geriatric population.

Dysphagia And The Elderly

However, many elderly patients have difficulty swallowing tablets or can't swallow them at all. Dysphagia, the medical term for difficulty swallowing, can be caused by a variety of factors, including: stroke, head injury, multiple sclerosis, dementia, cancer, or GORD. Dysphagia disproportionately affects the elderly.

Dysphagia often leads to a sharp decline in treatment compliance, since patients will often delay or skip doses of medication to avoid pain or discomfort. In one study, 69% of older patients reported missing or deliberately skipping doses because of their difficulty swallowing.

Ruling Out A Compounded Formulation

Most dysphagic patients, when prescribed the tablet form of a medication, are given a compounded formulation, where the tablets are ground into a powder and placed into an inert liquid.

There were two major issues with pursuing this strategy with our client's depression drug, however. First, it is extremely bitter, so any compounded version would be very difficult to administer.



Second, compounded formulations can exhibit significant dosing inconsistencies. A 2006 survey found that 12 of the 36 compounded products surveyed by the FDA failed quality testing, exhibiting potency ranges from 68% up to 268% of the labeled dosage. Both the FDA and the NIOSH list discourage compounded formulations if there are alternatives available.

THE SOLUTION

Our mission, then, was to formulate a dosage form for our client's depression drug that was easy for the elderly and other dysphagic patients to swallow while also taste masked for easier application and compliance. After reviewing the goals of the project, the scientists at Adare Pharma Solutions determined that two separate Adare technologies could be combined for possible formulation success: Microcaps® and Parvulet®.

Microcaps uses microencapsulation to enclose one or more active ingredients within a protective polymeric material. This creates a physical barrier around the API and is useful for combining incompatible APIs, developing a customized release profile, turning non-aqueous liquids into powders, and for achieving effective taste masking.

The final dosage forms of microencapsulated API can be used in powders, dry syrups, orally disintegrating tablets, and Adare's Parvulet dosage form.

Parvulet technology is a patented oral dosage form that is dispensed to patients in tablet or powder formats, but which is then converted into a semi-solid at the time of dosage through the administration with water. The final dosage is a soft food-like texture that resembles applesauce, and the conversion is complete in under 30 seconds. It's ideal for geriatric populations and patients with dysphagia.

By combining microencapsulation and the novel Parvulet technology into a tablet form, Adare's team felt they would be able to meet the challenges of an easily swallowable and taste masked dosage form of the depression drug.

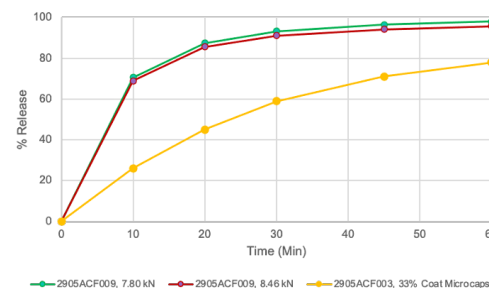
Compression Testing Yields Results

The Parvulet blend containing a 100mg dose of API microcaps was compression tested. The compression batches yielded tablets with both adequate swelling behavior and taste-masking. The tablets swelled in under 30 seconds during testing. The final tablet weight was 625 mg.

Two compression forces ranging from 7.80 – 8.45 kN were evaluated, and there was no difference in dissolution results observed between the two.

To see a short video demonstration of the solid Parvulet dosage form becoming a semi-solid during this testing, click here:

<https://vimeo.com/720653310/fe45310fc9>



THE OUTCOME

Adare successfully developed a taste masked, easy-to-swallow dosage form of the client's depression drug. This dosage form will help increase adherence in patients who avoid their medications due to difficulty swallowing. Additionally, unlike liquid or compounded formulations, dysphagic patients can easily carry the solid dosage form of their medication with them, then transform it into a semi-solid for ease of consumption in under a minute. With the concept's viability proven, Adare is currently manufacturing batches for feasibility stability monitoring.

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TRANSFORMING DRUG DELIVERY. TRANSFORMING LIVES.

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.

Connect with our experts today: BusDev@adareps.com

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