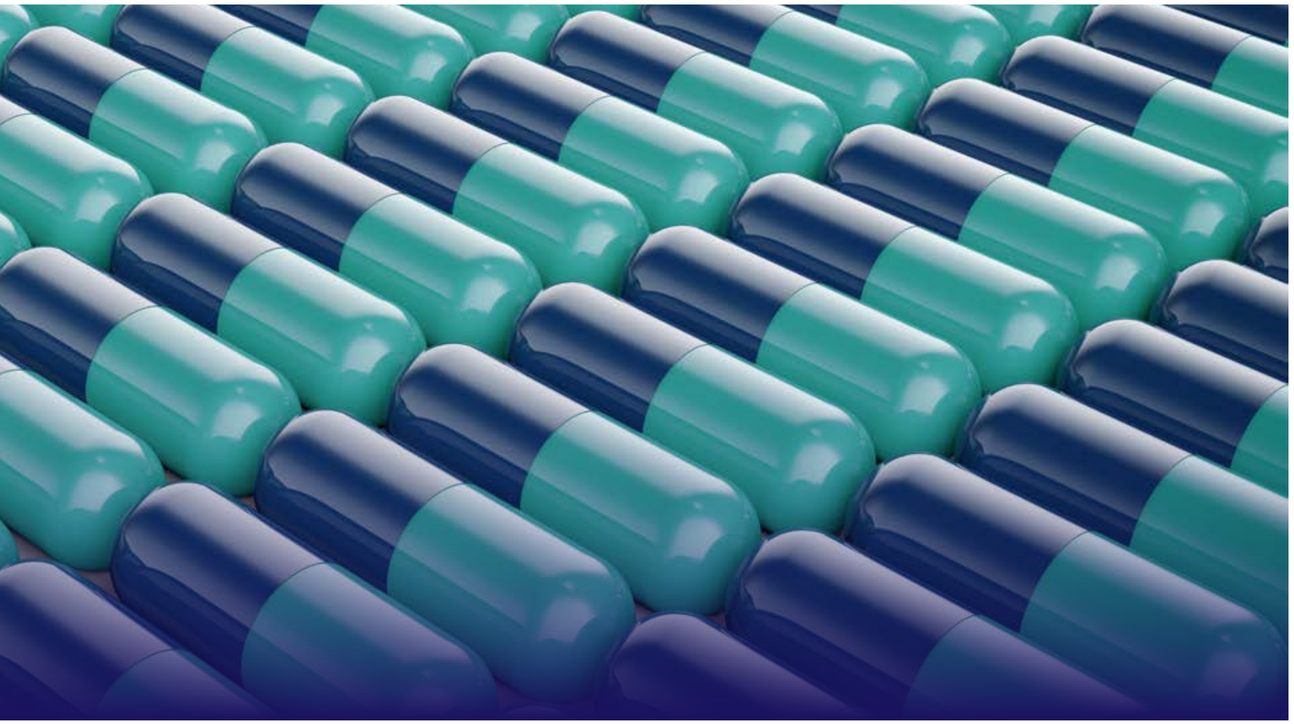
ADARE PHARMACEUTICALS



ABOUT ADARE PHARMA | PATIENT-CENTRIC SOLUTIONS | DEVELOPMENT & MANUFACTURING

OUR FACILITIES | REGULATORY & CLINICAL SUPPORT | OUTLICENSING

Parvulet
PATIENT-CENTRIC DOSING SOLUTION

AdvaTab
ORALLY DISINTEGRATING TABLETS

Diffucaps
CUSTOMIZED RELEASE TECHNOLOGY

Microcaps
TASTE MASKING TECHNOLOGY

Minitabs
CONTROLLED RELEASE TECHNOLOGY

BioRise
BIOAVAILABILITY SOLUTIONS

A LEADING GLOBAL SUPPLIER OF INNOVATIVE ORAL DOSE TECHNOLOGY PLATFORMS

A legacy of success

- Decades of expertise
- Proprietary capabilities
- Global presence
- Continuous improvement to adapt and identify new obstacles to meet evolving market demands
- Complete in-house end-to-end capability with R&D and regulatory affairs team with global expertise
- Turnkey Regulatory and Clinical Support
- Proud to be leading partners across Branded, Specialty, Generic, Veterinarian, and OTC segments

Transforming today's medicine

- Focused on creating dosage form solutions for patients left behind
- Overcoming oral delivery challenges with proprietary product solutions
  - » *Taste Masking and ODTs*
  - » *Customized Drug Release*
  - » *Bioavailability Enhancement*
- +30 years of expertise
- +40 products developed & manufactured
- Sold in >100 countries

TASTE MASKING AND ODTs

FOR IMPROVING TASTE AND PROVIDING ALTERNATIVE DOSAGE FORMS

CUSTOMIZED DRUG RELEASE

FOR OPTIMIZING THERAPEUTIC PERFORMANCE

BIOAVAILABILITY ENHANCEMENT

FOR IMPROVING SOLUBILITY

ADARE PHARMACEUTICALS

PATIENT-CENTRIC SOLUTIONS

Proprietary product solutions for patients with unique needs

- Differentiated delivery systems
  - » *Taste Masking and ODTs*
  - » *Customized Drug Release*
  - » *Bioavailability Enhancement*
- High dose, IR, and/or customized release
- Drug formulations exhibiting unique release profiles can be combined in a single dosage form
- Patient-friendly, ideal for those who experience difficulty swallowing regular capsules and tablets

Customized drug release profiles

- Proprietary delivery systems overcome formulation challenges
- Optimize efficacy, safety, and dosing frequency
- Unique release profiles can be combined in a single dosage form
- Improve onset of action, variability of absorption between patients, and food effects variation
- Optimize therapeutic performance and increase patient acceptability

ADARE PHARMACEUTICALS

DEVELOPMENT & MANUFACTURING

Research and Development

- Integrated R&D validated through to commercial manufacturing
- Full-service capabilities for even the most complex product creation
- In-house regulatory affairs team with proven global track record
- Flexible Business Model customized to fit your program ranging from *Fee-for-service* to *Co-development*

Manufacturing

- Experts in scale up from product development through commercial scale
- Global expertise with manufacturing facilities in the United States and Europe
- Approved for controlled substances (US) and solvents (EU and US)
- Outstanding environmental credentials

ADARE PHARMACEUTICALS

OUR FACILITIES

A GLOBAL FOOTPRINT THAT ENSURES THE SECURITY OF YOUR SUPPLY

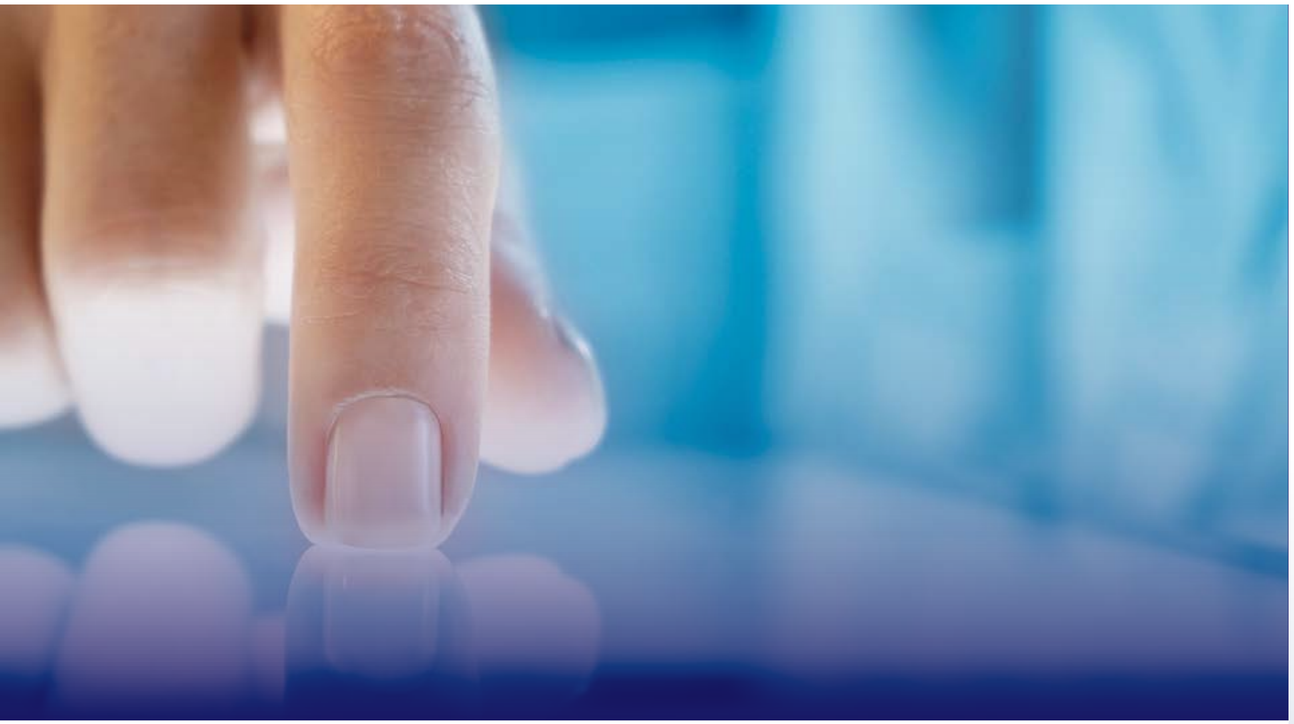
Four manufacturing facilities in the United States and Europe

- Pharmaceutical Development and Manufacturing
  - » *VANDALIA, OHIO*
- Manufacturing, Pancreatic Enzyme Center of Excellence
- Solid Oral Dosage
  - » *PESSANO (MILAN), ITALY*
- Manufacturing Solid Oral Dosage
  - » *S. GIULIANO (MILAN), ITALY*
- Manufacturing Lactobacillus
  - » *HOUDAN (PARIS), FRANCE*

Our proprietary technology and processes lead the way

- Increase productivity, manufacture complex products, and extend product lifecycles through our global R&D facilities
- >300 Patents adding valuable IP to commercialized and developing products
- Our proprietary delivery systems improve drug formulations and increase product impact

ADARE PHARMACEUTICALS



Parvulet · AdvaTab · Diffucaps · Microcaps · Minitabs · BioRise

REGULATORY & CLINICAL SUPPORT

Proven expertise in regulatory and quality

- Substantial global experience in all aspects of regulatory strategies required for NDA filing (including 505(b)(2)) and ANDA filings
- Expertise to file both European and US submissions
- Support for a complete filing or for CMC section filing, depending on need
- Support in maintaining approved submissions globally
- Harmonized quality system certified and periodically verified by the major regulatory bodies such as FDA, EMEA, ANVISA and audited by more than 15 customers per year across the sites.

Strict adherence to cGMP regulations

- Experts in international protocol and standards
- Outstanding environmental credentials
- Compliant handling of controlled substances and solvents

Full-service clinical support for complex product creation

- Full-service capabilities for even the most complex product creation
- The resources to engage in full-scale clinical product development
- Understanding of current regulatory, scientific and market access challenges
- Regulatory support at early and late stage product development
  - » *Pre-IND FDA meeting support*
  - » *IND filing to Pre-NDA support*
  - » *Management of NDA submissions*
- Strategic and tactical consulting
- Clinical support through the entire product development process

ADARE PHARMACEUTICALS

ABOUT ADARE PHARMA | PATIENT-CENTRIC SOLUTIONS | DEVELOPMENT & MANUFACTURING

OUR FACILITIES | REGULATORY & CLINICAL SUPPORT | OUTLICENSING

Parvulet · AdvaTab · Diffucaps · Microcaps · Minitabs · BioRise

OUTLICENSING OPPORTUNITIES

Diverse portfolio with global availability

- License our products in territories around the world through our global R&D facilities
- Our technologies include taste-masking, customized release, and bioavailability enhancement in diverse platforms
  - » *Extended Release Capsules*
  - » *Extended Release Tablets*
  - » *Taste Masked*
  - » *Orally Disintegrating Tablets*
  - » *Sachet*
  - » *Liquid-to-Solid Suspension*
  - » *Targeted Release*

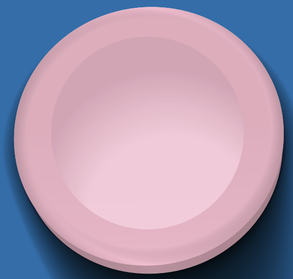
Rx and OTC products available across specialized and diverse therapeutic categories

- Cardiovascular
- Allergy/Sleep Aid
- Pain
- Gastrointestinal
- Respiratory
- Nutrition
- Veterinary
- Central Nervous System

A PROVEN TRACK RECORD WITH OVER 40 PRODUCTS FOR BLUE-CHIP PARTNERS IN MORE THAN 100 COUNTRIES

Abbott · Bayer · Allergan · Takeda · Sanofi · Johnson & Johnson · teva · adcock ingram · GSK GlaxoSmithKline · Bristol-Myers Squibb · Pfizer

ADARE
PHARMACEUTICALS



Parvulet™

PATIENT-CENTRIC DOSING SOLUTION

ABOUT ADARE PHARMA | PATIENT-CENTRIC SOLUTIONS | DEVELOPMENT & MANUFACTURING
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PROPRIETARY TECHNOLOGIES

Parvulet addresses multiple challenges

- Ideal for patients with swallowing difficulties
  - » *Dysphagic patients*
  - » *Mucositis patients*
  - » *Pediatric & geriatric populations*
- Allows for high drug loading
- Accurate dosing with every treatment
- Improves patient adherence
- Texture is easy to swallow
  - » *Masked for taste and smell*

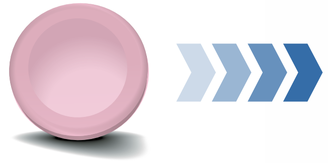
Parvulet is a patient-friendly format

Studies show 60-79% of the geriatric population and 25-45% of the pediatric will experience difficulty in swallowing.

Oral solid dosage form with final texture similar to that of apple sauce:

- Easily administered in 30 seconds
- Swallowing aid built into formulation
- Mimics natural swallowing mechanism with no choking hazards

Click here to watch a video and learn how Parvulet can provide the perfect solution for patients who have difficulty swallowing.



COMBINE PARVULET WITH OTHER ADARE TECHNOLOGIES

TASTE MASKING
Microcaps®

CUSTOMIZED RELEASE
Diffucaps® | MMTS® Minitabs

ADARE
PHARMACEUTICALS

AdvaTab®

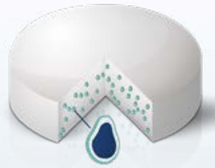
ORALLY DISINTEGRATING TABLETS

Parvulet · AdvaTab · Diffucaps · Microcaps · Minitabs · BioRise

PROPRIETARY TECHNOLOGIES

AdvaTab Advanced ODT technology

- Composed of finely micronized particles rapidly dispersing into a smooth, viscous suspension
- An easy-to-take dosage solution:
  - » *Masks bitter drug taste*
  - » *Rapidly dissolves in the mouth without water*
- Easy ingestion for pediatric, geriatric and dysphagic patients
- AdvaTab tablets have been proven bioequivalent to immediate or sustained release formulations



AdvaTab with embedded Microcaps Technology

Patented formulations and manufacturing process

- Advatabs® incorporate uniformly dispersed, coated drug particles in a low-moisture, rapidly disintegrating matrix
- Formulated for acceptable taste, a disintegration time <30 seconds
- Suitable for push-through blister packs and multiple-packing configurations
- Up to 500 mg drug-loading capability

Micrographs of Formulation Stages

API Granule
(Irregular Shape)

Microcaps API
(Complete & Uniform Taste-masking)

AdvaTab ODT
(Final Dosage Form)

COMBINE ADVATAB WITH THESE ADARE TECHNOLOGIES FOR IMMEDIATE RELEASE OR CONTROLLED RELEASE OPTIONS

CUSTOMIZED RELEASE
Diffucaps® | Microcaps®

ADARE
PHARMACEUTICALS

Diffucaps®

CUSTOMIZED RELEASE TECHNOLOGY

ABOUT ADARE PHARMA | PATIENT-CENTRIC SOLUTIONS | DEVELOPMENT & MANUFACTURING
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PROPRIETARY TECHNOLOGIES

Diffucaps controls drug delivery and optimizes release profiles

- Adjustable dosage strength and dissolution profile to achieve the desired in vivo pharmacokinetic profile
- Available as a capsule, orally disintegrating tablet, rapidly disintegrating tablet, or as a sprinkle
- Enhances drug solubility in sections of the gastrointestinal tract through combined use with other Adare technologies
- Reduces gastric mucosal irritation and food effect

Multiparticulate system with release-controlling polymers

- One or more functional polymer membranes are applied to a drug core resulting in a small, multi-layered bead
- Solubility-modulation technology can be used to create an optimal pH
- Organic acid layer is placed underneath the drug layer, while the alkaline buffer is placed over the drug layer
- Coatings ensure that the individual layers are not depleted until release of the drug is complete

Examples of Release Profiles

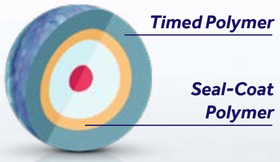
Immediate Pulse

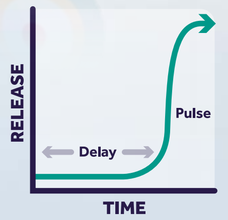
Polymer

Inert Core Material

Drug Substance

Timed Pulsatile





Timed Sustained

ADARE
PHARMACEUTICALS

Microcaps®

TASTE MASKING TECHNOLOGY

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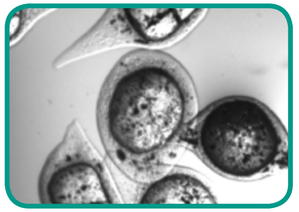
PROPRIETARY TECHNOLOGIES

Microcaps taste masking and pore-former technology

The drug particles are coated using a combination of coacervation (phase separation) and spray coating to build polymeric membranes of varying porosity and thickness. The final dosage forms can be produced in:

- Powders
- Dry syrups
- Orally disintegrating tablets

The pore-former rapidly dissolves in the stomach for fast drug release, enhancing the probability of achieving bioequivalence to an immediate release (IR) reference listed drug (RLD).

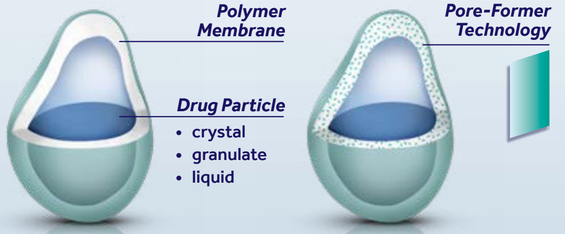


KCl During Micro-Encapsulation

KCl Microcapsule After Drying

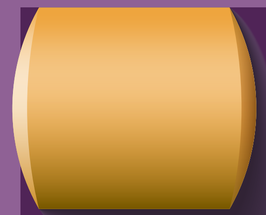
Precisely and uniformly coated

- Individual drug particles deliver a smooth, pleasant mouthfeel, with no aftertaste
- (ODTs) in dosage strengths up to 500 mg
- Rapidly disintegrating tablets (RDTs) in higher-dosage strengths up to 1500 mg
- Sprinkles, dry sachets, and stick packs, chewable tablets
- Powder for extemporaneous suspensions



ADARE IS THE LEADER IN ORGANIC PHASE COACERVATION FOR PHARMACEUTICAL PRODUCTS

ADARE
PHARMACEUTICALS



EURAND

Minitabs®

CONTROLLED RELEASE TECHNOLOGY

PROPRIETARY TECHNOLOGIES

MMTS™ Minitabs provide the flexibility of multiparticulate dosage forms

- Flexible dose delivery
  - » *capsules*
  - » *sachets*
  - » *sprinkles*
- Allows for a wide range of customized release profiles within a single capsule
- Precise delivery at lower dosage strengths through a range of tablet sizes
- Wide range of customized release profiles within a single capsule allows for titration of a broader range of dosages

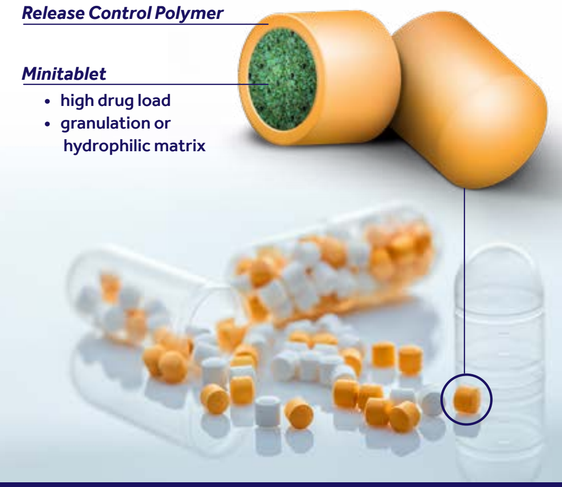
Multiparticulate system with release-controlling polymers

- Functional membranes are applied to 1.0-2.0 mm cylindrical tablets to control release rates
- The small size facilitates the development of products that can offer multiple drugs or varying release profiles within a single capsule
- High drug-loading capability with the possibility to combine with a high-density formulation for high-strength formulations

2 mm
Eurand Minitabs®

1.5 mm
Microtablets

1.2 mm
Ultra Microtablets



MINITABS CAN BE COMBINED WITH

CUSTOMIZED RELEASE
Diffucaps®

ADARE PHARMACEUTICALS

BioRise™

BIOAVAILABILITY SOLUTIONS

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PROPRIETARY TECHNOLOGIES

Thermodynamically activated to increase solubility profiles

- High-energy mechano-chemical activation (HEMA) or a solvent-induced activation (SIA) system is converts drugs to their thermodynamically activated state increasing solubility
- Can be applied to class II compounds with <10 to 500 µg/mL solubility
- Stabilized in a carrier system to maintain the drug in its activated form throughout its shelf life

With BioRise new physical entities are created

- New physical entities are created by breaking down the crystalline drug into nanocrystals and/or amorphous particles
- Higher rate and extent of absorption in the gastrointestinal tract
- May allow oral dosing and reduced food effect for poorly soluble drugs
- May provide faster onset of action, equivalent therapy at lower doses