

# A TECHNOLOGY-DRIVEN CDMO DELIVERING INTEGRATED END-TO-END SERVICES



## The Capacity, Experience, And Global Track Record To Support You

- 30+ years experience in oral drug development
- 70+ contract development projects
- 65+ commercial products globally across multiple therapeutic areas
- Capacity up to 4 billion units per year
- 92% Right First Time rate
- 7 sites in the US and Europe
- 800 global employees
- Leading partner to 100+ pharmaceutical companies with NCEs, NDAs, 505(b)(2), specialty pharma, generics and OTCs
- A leadership team with decades of CDMO experience & expertise

## Your Partner For Small Molecule Oral Solid Dose Success

- Early Stage Development
- Preformulation
- Formulation Development
- Optimization Scale-Up
- Manufacturing & Registration
- Packaging & Logistics
- Validation
- Post-Manufacturing Support

ABOUT ADARE PHARMA SOLUTIONS	EARLY STAGE DEVELOPMENT	DEVELOPMENT SERVICES
NITROSAMINE MITIGATION	MANUFACTURING CAPABILITIES	HIGH POTENCY SOLUTIONS
PACKAGING & LOGISTICS	OUR FACILITIES	SITE CAPABILITIES
SOLUBILITY ENHANCEMENT	PATIENT-CENTRIC SOLUTIONS	SOLUTIONS CENTER



TASTE MASKING

**IMPROVED PALATABILITY**

CUSTOMIZED DRUG RELEASE

**OPTIMIZED PERFORMANCE**

SOLUBILITY ENHANCEMENT

**EFFECTIVE ORAL DOSING**

PATIENT-CENTRIC DOSING SOLUTIONS

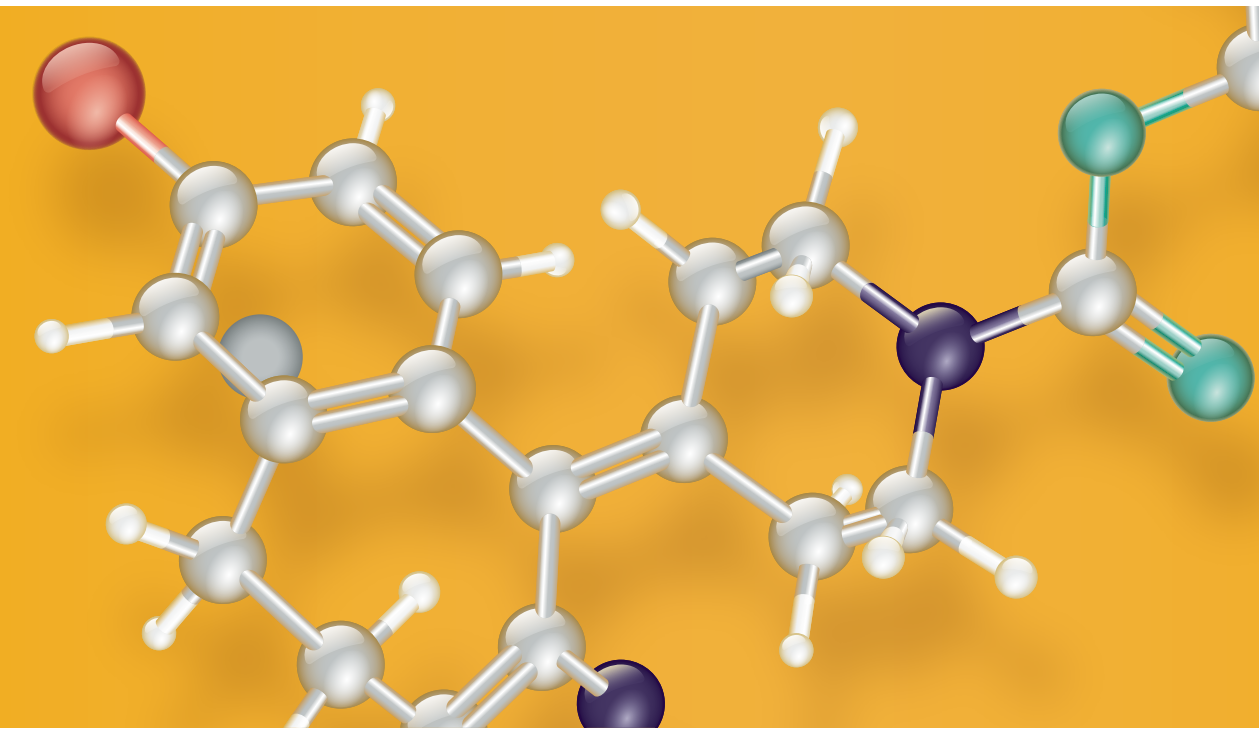
**IMPROVED ADHERENCE**



# EARLY STAGE DEVELOPMENT

## GET TO THE CLINIC FASTER WITH ADARE PHARMA SOLUTIONS

Adare is your go-to CDMO for early stage development services. Our scientists provide hands-on insight, helping you build a solid foundation for successful proof-of-concept studies. We're not just quick... we're flexible, adaptable, and innovative.



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### Comprehensive Preformulation Capabilities

- Physicochemical characterization
  - » pH-dependent solubility profile
  - » Solubility profile in solvents (aqueous, non-aqueous and buffered fluids)
  - » pKa and Log P
  - » Particle size and shape
  - » Microscopy (SEM, polarized microscope, etc)
  - » Flowability, bulk/tap density
- Solid state characterization
  - » Crystal forms
  - » Hygroscopicity
  - » DSC, DVS and PXRD (outsourced)
  - » Solid state stability (heat/humidity & light)
- Solution stability (pH, oxidation, heat & light)

### Development & Validation of Analytical Methodology

- Formulation support
- Physical characterization
- Controlled substance handling
  - » Schedules I, II, 2N, III, 3N, IV, V, and L1
- Clinical supplies testing
- Method transfer
- Analytical Method Development & Validation
- Onsite Stability & Storage
- Stability-indicating impurity methods







# DEVELOPMENT SERVICES

## Comprehensive R&D Services

- Sourcing of APIs & excipients
- Analytical services
  - » Method development and validation
  - » Stability studies - ICH compliance
- Preformulation & Formulation design and development
  - » Conventional IR and MR capsules, tablets, powders, powder for reconstitution
  - » Taste masked formulations
  - » Easy to swallow formats (ODT, chewables, Parvulet, sprinkles on food)
- 3D Printing Capabilities
- Clinical Material Manufacturing
  - » Phase I/2/3/Bioequivalence
  - » Release for US/EU with in-house QP release
- Process Scale up & Optimization (DOE/QbD)
- Registration/Process Validation
- Packaging Development: bottles, blisters, and stickpack



## An experienced team dedicated to your development projects:

- Integrated R&D validated through to commercial manufacturing
- Full-service capabilities for even the most complex product creation
- Phase-appropriate analytical and formulation development
- In-house regulatory affairs team with proven global track record
- Flexible business model customized to fit your program

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# NITROSAMINE IMPURITIES

## ARE YOU COMPLIANT?

**GUIDANCE ON NITROSAMINE HAS BEEN ISSUED... AND DEADLINES ARE APPROACHING FAST**

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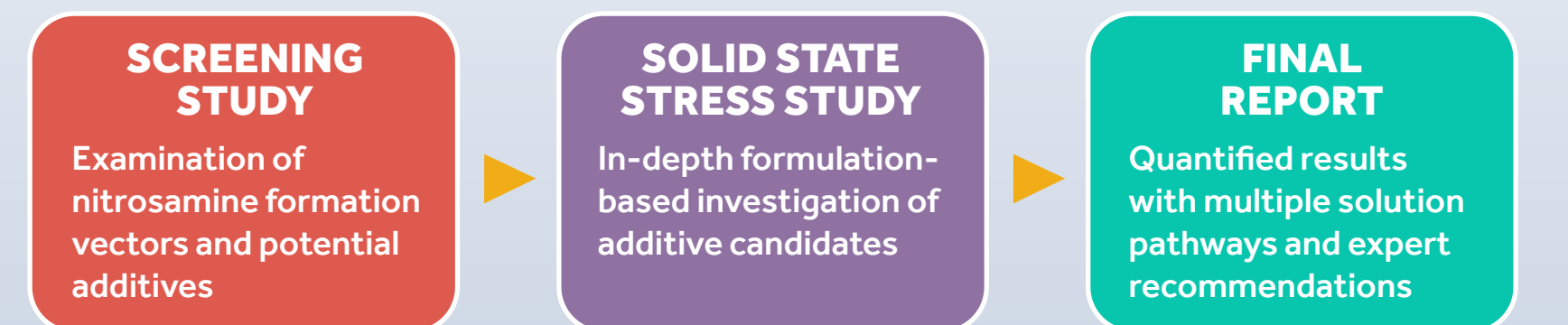


Very few CDMOs can claim Adare's level of experience in mitigating the presence of nitrosamine. We can employ our own in-house mitigation processes to develop the best long-term control strategies for your product.

### Regain control of your product with NitroCLEARx

- Receive real-world mitigation support at every step of the process
- Find the right balance between all effective approaches
- Evaluate a range of potential strategies that put you back in charge
- Make informed decisions on the solution that meets your needs
- Evolve your strategy as your final formulation develops

**LET OUR EXPERTS CREATE A QUANTIFIED MITIGATION STRATEGY DEVELOPED SPECIFICALLY FOR YOUR MOLECULE, YOUR FORMULATION, AND YOUR MICROENVIRONMENT.**





# MANUFACTURING CAPABILITIES



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## Standard Services

- Granulation and mixing
- Fluid bed processing
  - » Wurster
  - » Top Spray
- Pan coating
- Blending (Bin and Static)
- Tableting
- Multi-layer tablets
- Capsule filling
- Oven drying
- Spray drying
- Small-scale GMP manufacturing
- Tech Transfer
- Warehousing & Distribution



## Specialized Services

- High Potency: 1 mcg/m<sup>3</sup> and above
- Microencapsulation of solids and liquids
- Melt-Spray-Congel
- Orally disintegrating tablets (ODT)
- Dry syrup/suspensions
- MMTS™ Minitabs
- DEA controlled substances
  - » Manufacturing License for Schedules II, 2N, III, 3N, IV, V, and L1
  - » Analytical Labs authorized for Schedules I-V
- Fixed-dose combination manufacturing
- Liquid filling in hard-shell capsules with banding
- Solvent granulation and coating processes
- Food sprinkle dosage forms





# HIGH POTENCY SOLUTIONS

**EXPANDED HIGH POTENCY CAPABILITIES IN THE US & EUROPE**



## Pilot & Commercial Scale

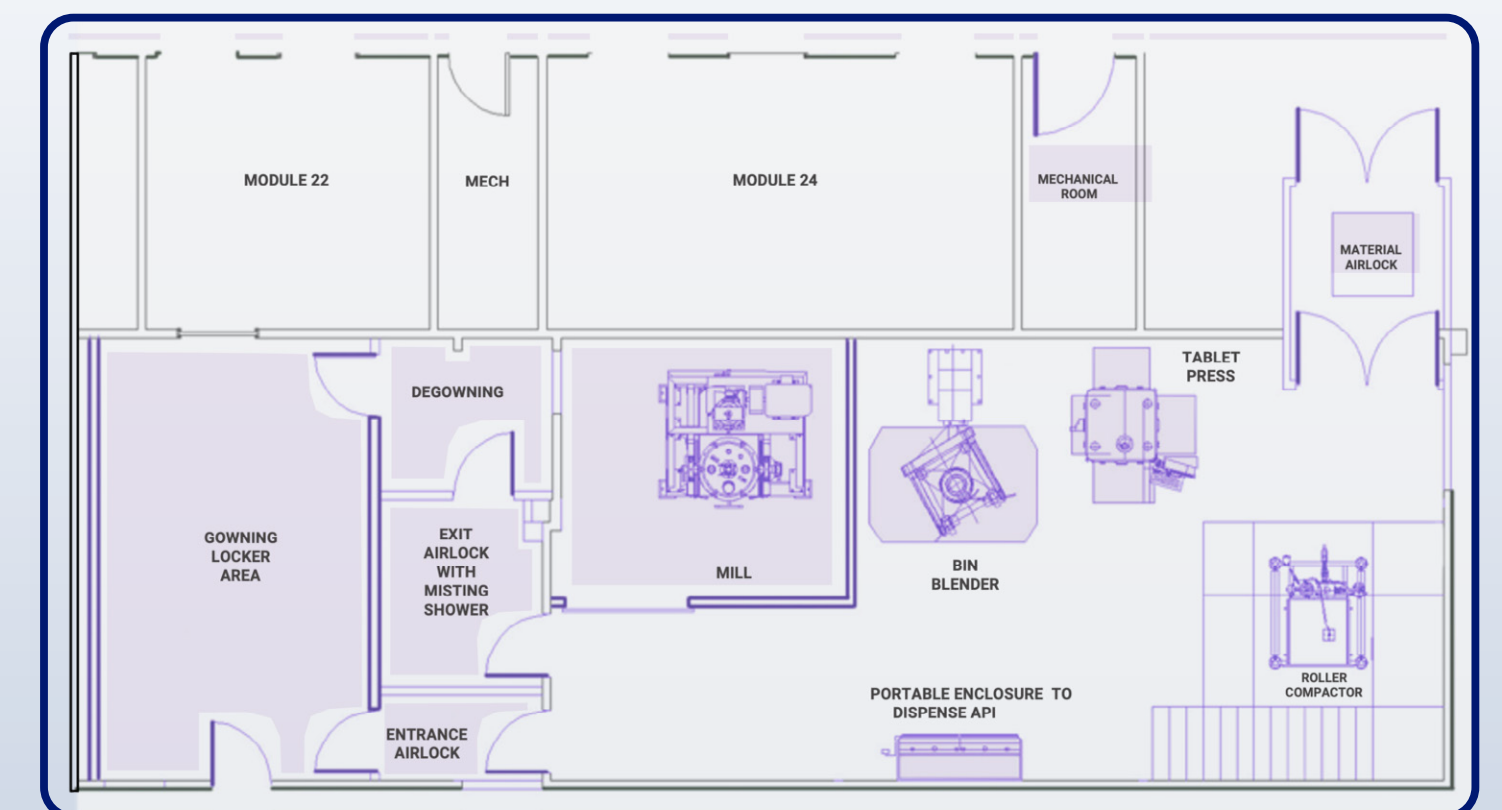
- Dedicated GMP manufacturing and development areas for dry blend high potency products
- Substances with occupational safety levels down to 1 mcg/m<sup>3</sup>, subject to safety/facility assessment
- Authorized to develop and produce pain management and CNS therapies

## Potent Suites

- Milling Room
- Roller Compactor » Fitzpatrick
- Tablet Press » IMA Synthesis 500
- High Potent Airlocks, Locker Room, and Material Airlock
- Bin Blender
- High potency packaging of tablets
- High shear granulation
- Capacity to offer: » Portable blending » Wet granulation

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Our Orthodox St site in Philadelphia PA features dedicated state-of-the-art suites specifically for the development, manufacturing, and packaging of high potency drug products







# PACKAGING & LOGISTICS



MULTILANE  
STICKPACK  
MACHINE

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## Clinical & Commercial Packaging Services

- High-speed bottle filling
- Blister packaging
- Stick pack filling
- Flow wrap packaging
- Clinical supply services
- Repackaging license
- Packaging of DEA Schedules II, 2N, III, 3N, IV, L1
- Serialization & aggregation

## Logistics Support

- Market forecasting
- Stability testing
- Expanded labeling support
- Warehousing
- Distribution



## Proven Regulatory Expertise

- ANDA and NDA filings, including 505(b)(2)
- European and US submissions
- Complete filings or CMC section filings
- FDA, AIFA, EMA, ANVISA, EAEU, and PMDA

## Recent Expansions

- » Expanded packaging in Europe
- » Small-scale blister packaging and high potency packaging lines in Philadelphia



BLISTER PACKAGING LINE







# OUR FACILITIES

## A GLOBAL FOOTPRINT THAT ENSURES THE SECURITY OF YOUR SUPPLY

Seven development & manufacturing sites in the US and Europe

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<p><b>Lenexa, KS</b></p> <ul style="list-style-type: none"> <li>5k sq ft (465 m<sup>2</sup>)</li> <li>R&amp;D center</li> <li>Non-GMP development scale</li> <li>Long-acting injectables</li> </ul>	<p><b>Vandalia, OH</b></p> <ul style="list-style-type: none"> <li>179k sq ft (16.6k m<sup>2</sup>)</li> <li>R&amp;D center</li> <li>Commercial scale manufacturing</li> <li>Organic solvent capabilities</li> <li>Manufacturing License for DEA Schedules II, 2N, III, IV, V</li> </ul>	<p><b>Philadelphia, PA (Orthodox St)</b></p> <ul style="list-style-type: none"> <li>128k sq ft (12k m<sup>2</sup>)</li> <li>R&amp;D center</li> <li>Commercial scale manufacturing</li> <li>High potency development, manufacturing &amp; packaging</li> <li>Manufacturing &amp; Packaging Licenses for DEA Schedules II, 2N, III, 3N, IV, L1</li> </ul>	<p><b>Philadelphia, PA (Dungan Rd)</b></p> <ul style="list-style-type: none"> <li>175k sq ft (16.2k m<sup>2</sup>)</li> <li>Packaging &amp; Warehousing</li> <li>4 packaging lines &amp; 1 powder filling line</li> <li>Packaging of DEA Schedules 2N, III, 3N, IV</li> </ul>
<p><b>Aurora, IL</b></p> <ul style="list-style-type: none"> <li>33k sq ft (3k m<sup>2</sup>)</li> <li>R&amp;D center</li> <li>Commercial scale manufacturing</li> <li>Fluid bed technology center</li> <li>Manufacturing License for DEA Schedules II, 2N, III, 3N, IV, V, L1</li> </ul>	<p><b>San Giuliano, IT</b></p> <ul style="list-style-type: none"> <li>93k sq ft (8.6k m<sup>2</sup>)</li> <li>Commercial scale manufacturing</li> <li>Organic solvent capabilities</li> <li>Focused on customized release technologies</li> <li>Tablet &amp; capsule filling</li> </ul>	<p><b>Pessano, IT</b></p> <ul style="list-style-type: none"> <li>220k sq ft (20.4k m<sup>2</sup>)</li> <li>Expanded R&amp;D and High Potency Capabilities</li> <li>Clinical &amp; commercial scale manufacturing</li> <li>Packaging &amp; Warehousing</li> <li>Organic solvent capabilities</li> <li>Controlled substances</li> </ul>	







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# SITE CAPABILITIES

Adare offers a wide range of capabilities across a global network of sites

DOSAGE FORMS	VANDALIA	AURORA	LENEXA	PESSANO	SAN GIULIANO	ORTHODOX	DUNGAN
API IN CAPSULE						D C	
EMULSIONS & MICROEMULSIONS			D			D	
INJECTABLES			D				
LIPID FORMULATIONS			D			D	
LIQUID-FILLED HARD CAPSULES						D C	
BILAYER TABLETS	D					D C	
ORALLY DISINTEGRATING TABLETS & CHEWABLES	D C	D C		D C	C	D C	
SOLUTIONS & SYRUPS			D			D C	
STANDARD ORAL SOLIDS (TABLETS & CAPSULES)	D C	D C	D	D C	C	D C	
SUSPENSIONS (STANDARD & MICRO)	D		D			D C	
MULTIPARTICULATES	D C	D C	D	D C	C	D C	
SERVICES							
3D PRINTING	D			D			
BIOAVAILABILITY/SOLUBILITY ENHANCEMENTS	D					D	
CAPSULE BANDING						D C	
FLUID BED	D C	D C		D C			
HIGH POTENCY (from 1 mcg/m <sup>3</sup> )	D			D C		D C	
MODIFIED RELEASE SYSTEMS	D C	D C	D	D C	C	D C	
PACKAGING	D			D C			D C
TABLET PRINTING						D C	
TECHNOLOGIES							
ADAPTDOS <sup>™</sup>	D C					D C	
ADVATAB <sup>®</sup>	D C			D C			
DIFFUCAPS <sup>®</sup>	D C	D C		D C	C		
DURAGRAN <sup>™</sup>		D C					
MICROCAPS <sup>®</sup>	D C			D C			
MINITABS <sup>™</sup>	D C	D C		D C	C	D C	
OPTIMUM <sup>®</sup>	D		D				
PARVULET <sup>®</sup>	D C			D C		D C	
STRATUM <sup>®</sup>			D				
UNISUN <sup>®</sup>			D				

D DEVELOPMENT SCALE C COMMERCIAL MANUFACTURING





# SOLUBILITY ENHANCEMENT

Adare's innovative technology platform can enable and improve the solubility of drugs with low solubility or an extreme pH-dependent solubility profile, providing:

- Substantial global experience in all aspects
- Effective oral dosing of poorly soluble drug candidates
- Equivalent therapy at lower doses
- Faster onset of action
- Minimization of food effect
- Adjustable dosage strength and dissolution profile to achieve the desired in vivo pharmacokinetic profile
- Enhanced drug solubility in sections of the gastrointestinal tract through combined use with other Adare technologies
- A wide range of dosage forms, including:
  - » Capsules
  - » Orally disintegrating tablets
  - » Rapidly disintegrating tablets
  - » Sprinkles



## Solubility Enhancement Technologies

- Diffucaps<sup>®</sup>
- Bench-to-pilot scale Spray-drying
- Hot Melt (Leistritz ZSE 18)
- Dyno-mill
- Conventional approaches using:
  - » Solubilizers
  - » Cyclodextrins
  - » Surfactants
  - » Super-disintegrants



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**Microcaps**  
TASTE MASKING TECHNOLOGY

**Optimum**  
ORAL DOSE MICROENCAPSULATION

**Diffucaps**  
CUSTOMIZED RELEASE TECHNOLOGY

**Minitabs**  
MMTS™ MULTI MINI TABLET SYSTEM

**Duragran**  
FLEXIBLE PARTICLE SIZING

**Adaptdose**  
MULTI-DELIVERY PLATFORM

**AdvaTab**  
ORALLY DISINTEGRATING TABLETS

**Parvulet**  
PATIENT-CENTRIC DOSING SOLUTIONS

**Stratum**  
INJECTABLE MICROENCAPSULATION

**Unisun**  
OTIC INJECTABLE TECHNOLOGY

# PATIENT-CENTRIC SOLUTIONS

## Specialized product solutions for patients with unique needs

- Differentiated delivery systems
  - » Taste Masking
  - » Customized Drug Release
  - » Solubility Enhancement
  - » ODTs and Novel Dosage Forms
- High dose, IR, and/or customized release
- Easily swallowed dosage forms for patients with difficulty swallowing

## Customized drug release profiles

- Specialized 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







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# SOLUTIONS CENTER

Adare provides a full spectrum of dosage formulation technologies that are designed to address a wide variety of drug delivery requirements

	ADAPTDOSE™	ADVATAB®	DIFFUCAPS®	DURAGRAN™	MICROCAPS®	MINITABS™	OPTIMUM®	PARVULET®	STRATUM® (INJECTABLE)	UNISUN® (INJECTABLE)
TASTE MASKING			✓	✓	✓		✓			
SOLUBILITY ENHANCEMENT			✓							
MODIFIED RELEASE			✓	✓	✓	✓	✓		✓	✓
PEDIATRIC FORMULATIONS		✓	✓	✓	✓	✓	✓	✓		
COMBINATION PRODUCT	✓		✓	✓		✓	✓			
POOR ACCEPTABILITY		✓		✓	✓	✓	✓	✓	✓	✓
SWALLOWING ISSUES		✓						✓		
DOSING FLEXIBILITY			✓	✓	✓	✓	✓		✓	✓
CHEMICAL INCOMPATIBILITIES			✓	✓	✓	✓	✓			
ORALLY DISINTEGRATING		✓								
DOSING CONVENIENCE	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CONTROLLED SUBSTANCES	✓	✓	✓		✓	✓	✓	✓		



# Microcaps<sup>®</sup>

TASTE MASKING TECHNOLOGY

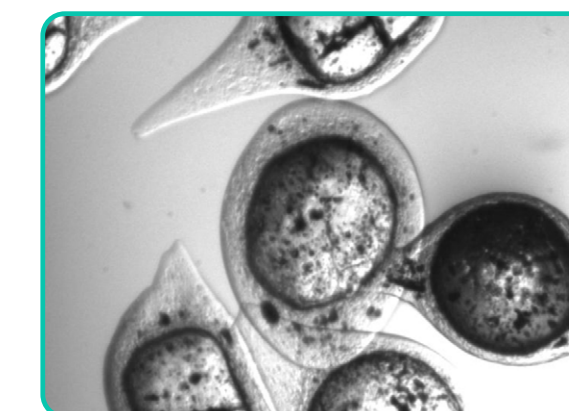
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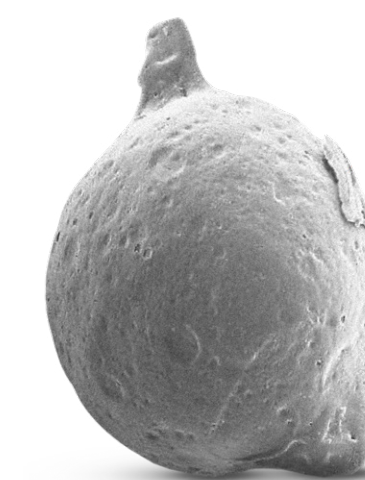
# SPECIALIZED TECHNOLOGIES

Individual drug particles deliver a smooth, pleasant mouthfeel, with no aftertaste

- A free-flowing powder containing microencapsulated API (or API substrate) in a wide range of particle sizes
- Can be applied to multiple dosage forms for both immediate and modified-release profiles, including:
  - » Powders
  - » Dry syrups
  - » Orally disintegrating tablets
  - » Parvulet<sup>®</sup> doses (a soft, food-like texture)
- Provides dose flexibility and convenience
- Achieved by the uniform and efficient coating of drug particles by coacervation (phase separation) to build polymeric membranes of varying porosity and thickness



*KCl During Microencapsulation*



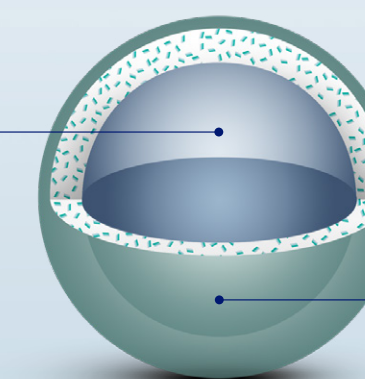
*Microcapsule After Drying*

## Microencapsulation by coacervation:

- Uniform coating of a solid particle or liquid droplet with a rigid semi-permeable polymer
- Creates a physical barrier
  - » Effective taste masking
  - » Customized release profile
  - » Turn non-aqueous liquids into powders
  - » Combine incompatible APIs

*Drug Particle*

- crystal
- granulate
- liquid

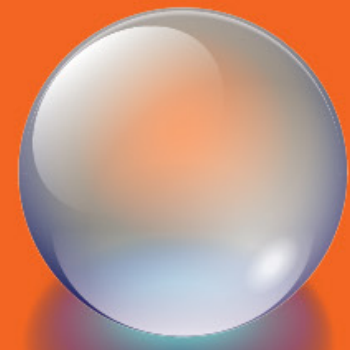


*Polymer Membrane*



**ADARE IS THE LEADER IN ORGANIC PHASE COACERVATION FOR PHARMACEUTICAL PRODUCTS**





# Optimum<sup>®</sup>

ORAL DOSE MICROENCAPSULATION

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TASTE MASKING TECHNOLOGY

**Optimum**<sup>®</sup>  
ORAL DOSE MICROENCAPSULATION

**Diffucaps**<sup>®</sup>  
CUSTOMIZED RELEASE TECHNOLOGY

**Minitabs**<sup>™</sup>  
MMTS<sup>™</sup> MULTI MINI TABLET SYSTEM

**Duragran**<sup>™</sup>  
FLEXIBLE PARTICLE SIZING

**Adaptdose**<sup>™</sup>  
MULTI-DELIVERY PLATFORM

**AdvaTab**<sup>®</sup>  
ORALLY DISINTEGRATING TABLETS

**Parvulet**<sup>®</sup>  
PATIENT-CENTRIC DOSING SOLUTIONS

**Stratum**<sup>®</sup>  
INJECTABLE MICROENCAPSULATION

**Unisun**<sup>®</sup>  
OTIC INJECTABLE TECHNOLOGY

# SPECIALIZED TECHNOLOGIES

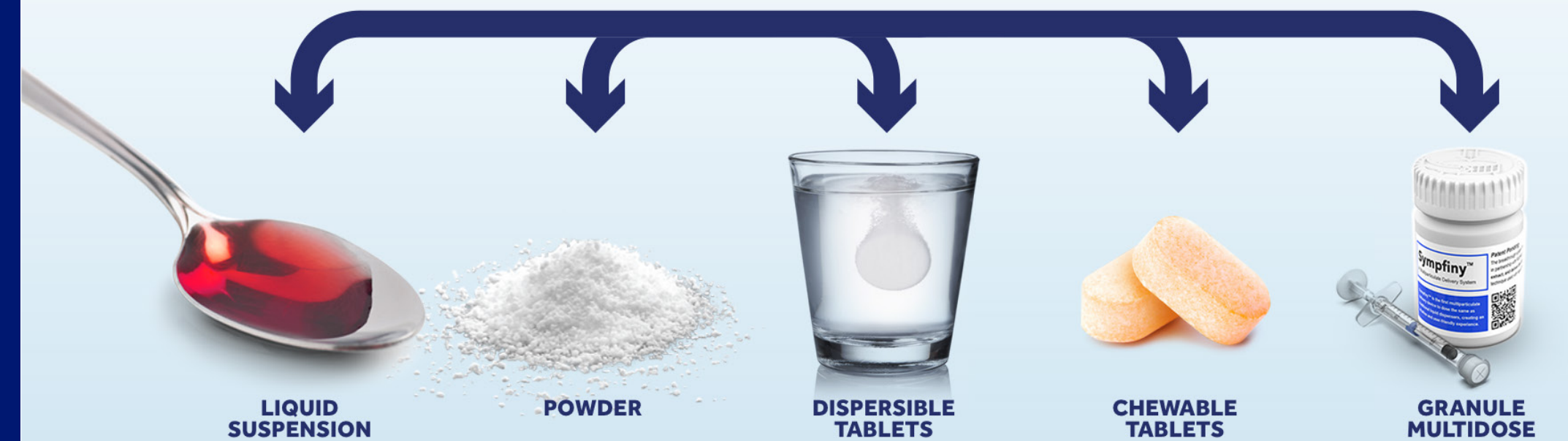
**You don't have to sacrifice taste to achieve a dispersed solid oral dosage form**

- Microspheres with high drug loading suitable for taste masking, enteric coatings, and extended release oral applications
- Offers numerous modified release options that can be used in a wide variety of final dosage forms
- Overcomes many of the inefficiencies and deficits of traditional formulation techniques
- Can match an extended release tablet's performance in a suspension format

**Optimum delivers on the promise of precision microparticles at a previously unachievable scale**

- Particle sizes down to 75 µm with Span values as low as 0.40
- Uses a nitrogen "carrier" stream
- Analogous to spray congealing
- No drying step or coating required
- Compatible with waxes, lipids, stearates, and gelatins
- Good for oral small molecules, nutraceuticals, agricultural applications, flavorings, and heat stable molecules

## FORMULATION FLEXIBILITY



## DOSING FLEXIBILITY





# Diffucaps<sup>®</sup>

CUSTOMIZED RELEASE TECHNOLOGY

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 <b>Microcaps</b> <sup>®</sup> TASTE MASKING TECHNOLOGY	 <b>Optimum</b> <sup>®</sup> ORAL DOSE MICROENCAPSULATION	 <b>Diffucaps</b> <sup>®</sup> CUSTOMIZED RELEASE TECHNOLOGY	 <b>Minitabs</b> <sup>™</sup> MMTS <sup>™</sup> MULTI MINI TABLET SYSTEM	 <b>Duragran</b> <sup>™</sup> FLEXIBLE PARTICLE SIZING
 <b>Adaptdose</b> <sup>™</sup> MULTI-DELIVERY PLATFORM	 <b>AdvaTab</b> <sup>®</sup> ORALLY DISINTEGRATING TABLETS	 <b>Parvulet</b> <sup>®</sup> PATIENT-CENTRIC DOSING SOLUTIONS	 <b>Stratum</b> <sup>®</sup> INJECTABLE MICROENCAPSULATION	 <b>Unisun</b> <sup>®</sup> OTIC INJECTABLE TECHNOLOGY

# SPECIALIZED TECHNOLOGIES

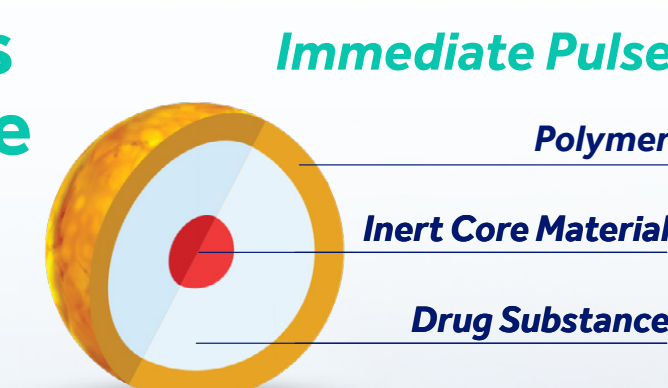
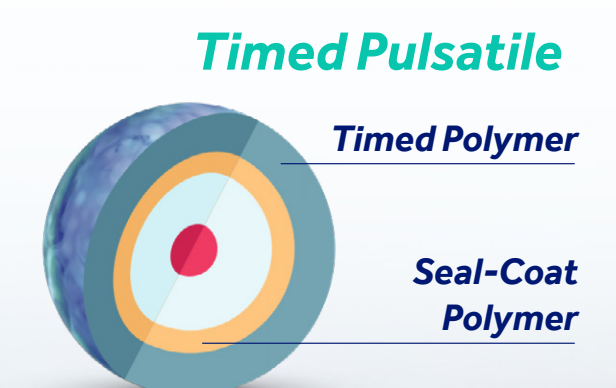
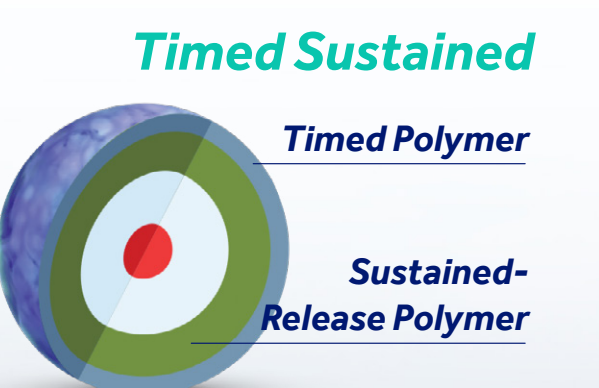
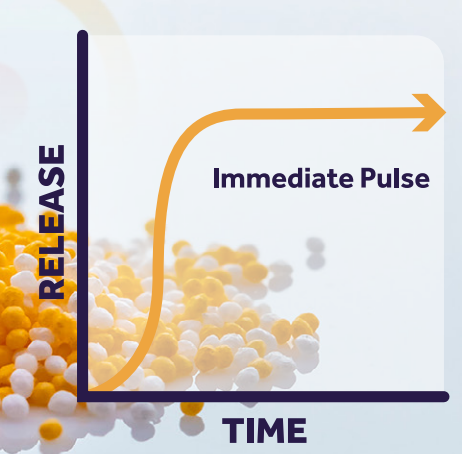
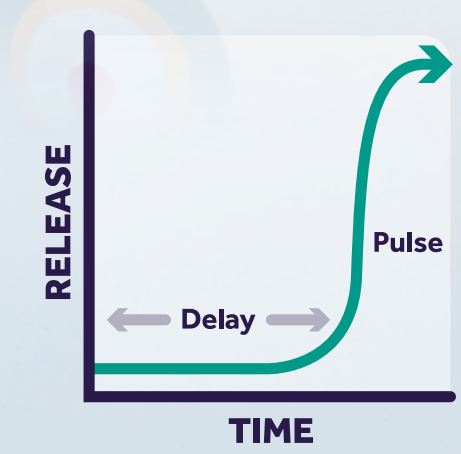
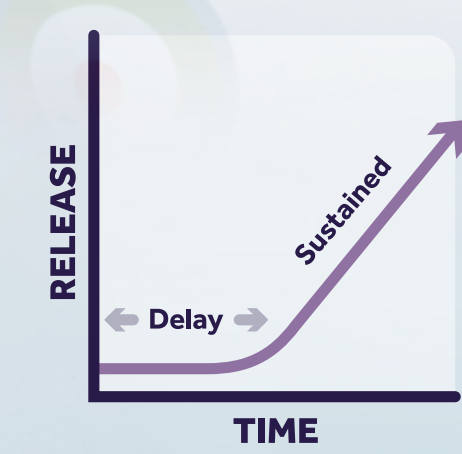
## Diffucaps<sup>®</sup> controls drug delivery and optimizes release profiles

- 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

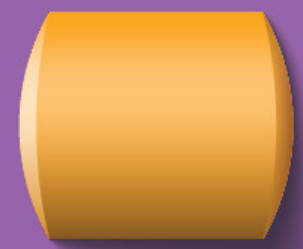
## Multiparticulate system with release-controlling polymers

- 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





# Minitabs<sup>™</sup>

MMT<sup>™</sup> MULTI MINI TABLET SYSTEM

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NITROSAMINE MITIGATION	MANUFACTURING CAPABILITIES	HIGH POTENCY SOLUTIONS
PACKAGING & LOGISTICS	OUR FACILITIES	SITE CAPABILITIES
SOLUBILITY ENHANCEMENT	PATIENT-CENTRIC SOLUTIONS	SOLUTIONS CENTER

**Microcaps**<sup>®</sup>  
TASTE MASKING TECHNOLOGY

**Optimum**<sup>®</sup>  
ORAL DOSE MICROENCAPSULATION

**Diffucaps**<sup>®</sup>  
CUSTOMIZED RELEASE TECHNOLOGY

**Minitabs**<sup>™</sup>  
MMT<sup>™</sup> MULTI MINI TABLET SYSTEM

**Duragran**<sup>™</sup>  
FLEXIBLE PARTICLE SIZING

**Adaptdose**<sup>™</sup>  
MULTI-DELIVERY PLATFORM

**AdvaTab**<sup>®</sup>  
ORALLY DISINTEGRATING TABLETS

**Parvulet**<sup>®</sup>  
PATIENT-CENTRIC DOSING SOLUTIONS

**Stratum**<sup>®</sup>  
INJECTABLE MICROENCAPSULATION

**Unisun**<sup>®</sup>  
OTIC INJECTABLE TECHNOLOGY

# SPECIALIZED TECHNOLOGIES

## Adare is a pioneer in flexible 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**  
*Minitablets*



**1.5 mm**  
*Microtablets*

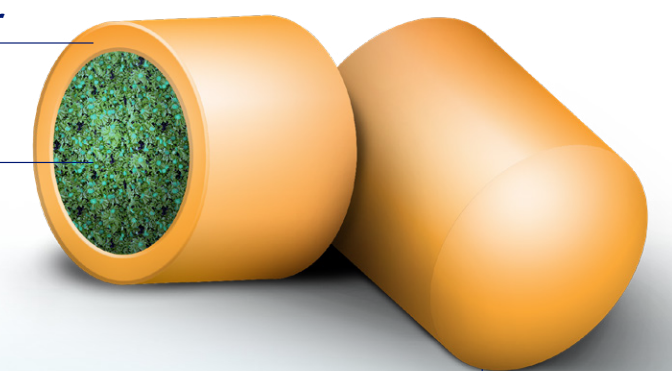


**1.2 mm**  
*Ultra Microtablets*

### Release Control Polymer

### Minitablet

- high drug load
- granulation or hydrophilic matrix



### MINITABS CAN BE COMBINED WITH

CUSTOMIZED RELEASE

**Diffucaps**<sup>®</sup>







# Duragran<sup>™</sup>

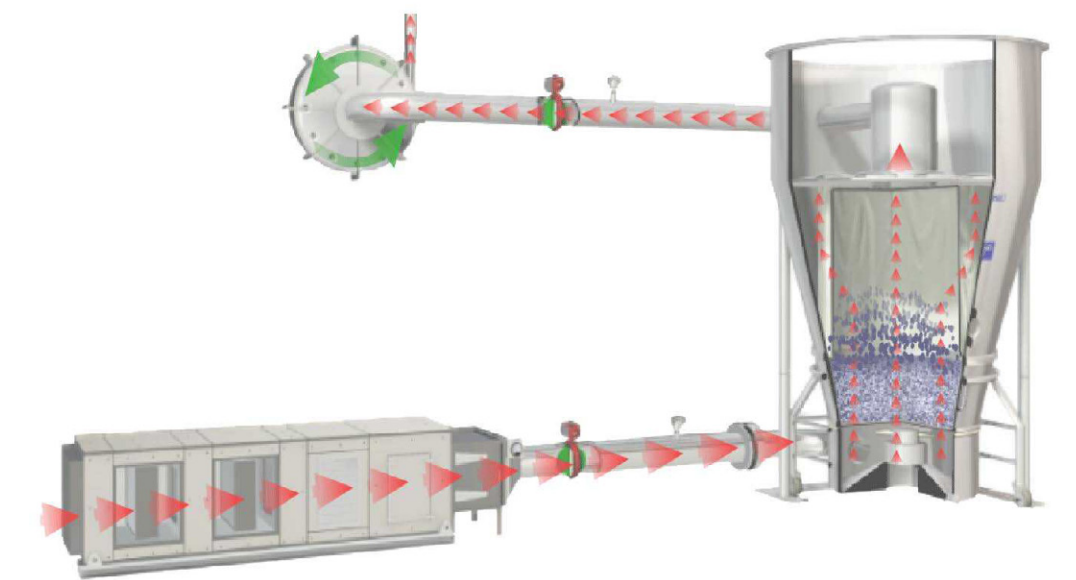
FLEXIBLE PARTICLE SIZING

# SPECIALIZED TECHNOLOGIES

**MORE UNIFORMITY AND PRECISE CONTROL OF TARGETED PARTICLE SIZES WHILE PROVIDING PRODUCTION TIME AND COST SAVINGS**

Reduce the amount of excipients and/or process steps used to build beads or controlled release granules

- Fast Dissolve Tablets (ODTs) where a small, durable taste-masked granule is desired
  - » The Duragran<sup>™</sup> process enables us to make a fine granule (less than 0.5mm) that contains very few superfines
  - » The material is coated in a subsequent process with the appropriate taste masking material, combined with the appropriate flavored cushioning granulation, and then compressed into tablets



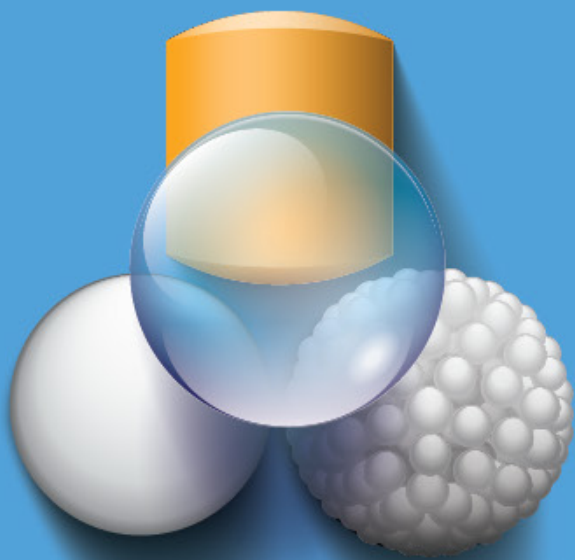
- Formulations with API loading as high as 90% or more
  - » As an alternative to the extrusion/spheronization process
- Larger granules can be formed and then coated in a subsequent process to provide the desired targeted release profile
- Granules can provide a unique product look
  - » Large, colored granules in a white tablet with minimal color bleed into the white portions of the tablet
  - » These colored granules can be for appearance only or formulated to provide a delayed-release portion of the dose



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SOLUBILITY ENHANCEMENT	PATIENT-CENTRIC SOLUTIONS	SOLUTIONS CENTER







# Adaptdose<sup>™</sup>

MULTI-DELIVERY PLATFORM

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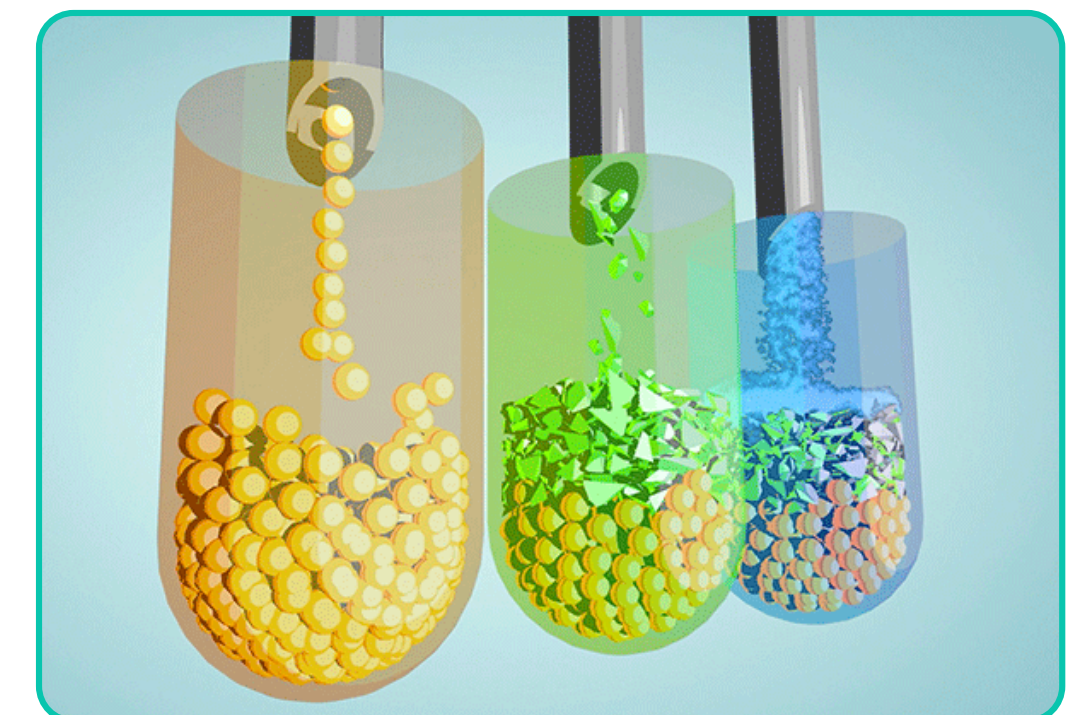


# SPECIALIZED TECHNOLOGIES

**A HIGHLY FLEXIBLE, MULTI-DELIVERY ENCAPSULATION TECHNOLOGY THAT ELIMINATES THE NEED FOR POST PHASE I TRIAL REFORMULATIONS**

**Providing speed, precision, and flexibility in product development**

- 3-hopper system: 1 capsule
  - » Add mini-tabs and granules with varying functional coatings
  - » Combine 2-3 different molecules
  - » Combine 2-3 different media (i.e., granules, powder)
- New product development
  - » Early-phase dose escalation and adaptive clinical studies
  - » Create patient-friendly and adjustable miniature tablet formulations
  - » Make quick adjustments in product dosing



- Generic product development
  - » Varying functional coats will help achieve extended-release profile
  - » Ability to use both mini-tablets and spheres interchangeably and to add as separate populations, reducing process development efforts
- Accuracy
  - » 100% visual inspection of mini-tab fills and sensitive onboard unit-dose weight verification





# Advatab<sup>®</sup>

ORALLY DISINTEGRATING TABLETS

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**Microcaps**<sup>®</sup>  
TASTE MASKING TECHNOLOGY

**Optimum**<sup>®</sup>  
ORAL DOSE MICROENCAPSULATION

**Diffucaps**<sup>®</sup>  
CUSTOMIZED RELEASE TECHNOLOGY

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MMTS<sup>™</sup> MULTI-MINI TABLET SYSTEM

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FLEXIBLE PARTICLE SIZING

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**Stratum**<sup>®</sup>  
INJECTABLE MICROENCAPSULATION

**Unisun**<sup>®</sup>  
OTIC INJECTABLE TECHNOLOGY

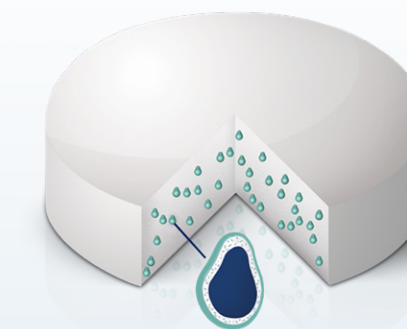
# SPECIALIZED TECHNOLOGIES

## Advatab<sup>®</sup> 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

## Patented formulations and manufacturing process

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



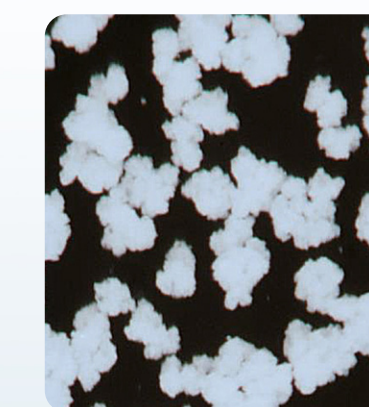
Advatab with embedded Microcaps Technology

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

CUSTOMIZED RELEASE  
**Diffucaps<sup>®</sup> | Microcaps<sup>®</sup>**



**API Granule**  
(Irregular Shape)



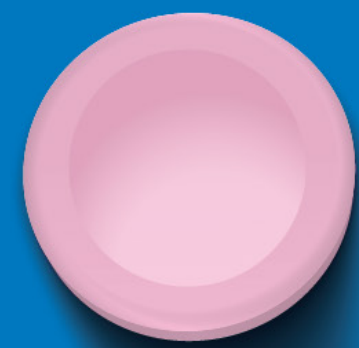
**Microcaps API**  
(Complete & Uniform Taste-masking)



**Advatab ODT**  
(Final Dosage Form)







# Parvulet<sup>®</sup>

PATIENT-CENTRIC DOSING SOLUTION

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**Parvulet**<sup>®</sup>  
PATIENT-CENTRIC DOSING SOLUTIONS

**Stratum**<sup>®</sup>  
INJECTABLE MICROENCAPSULATION

**Unisun**<sup>®</sup>  
OTIC INJECTABLE TECHNOLOGY

# SPECIALIZED TECHNOLOGIES

## Parvulet addresses multiple challenges

- Ideal for patients with swallowing difficulties
  - » Dysphagic patients
  - » Mucositis patients
  - » Pediatric and 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 a high percentage of patients in the geriatric and pediatric populations experience difficulty in swallowing.

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

- Easily administered in 30 seconds
- Swallowing aid built into formulation
- Mimics natural swallowing mechanism with no choking hazards
- Available in dispersible granules and tablets

*Parvulet provides the ideal solution for patients who have difficulty swallowing. For a video demonstration of Parvulet in action [click here](#).*



## COMBINE PARVULET WITH OTHER ADARE TECHNOLOGIES

TASTE MASKING  
**Microcaps**<sup>®</sup> | **Optimum**<sup>®</sup>

CUSTOMIZED RELEASE  
**Diffucaps**<sup>®</sup> | **MMTS<sup>™</sup> Minitabs**



# Stratum<sup>®</sup>

INJECTABLE MICROENCAPSULATION

# SPECIALIZED TECHNOLOGIES

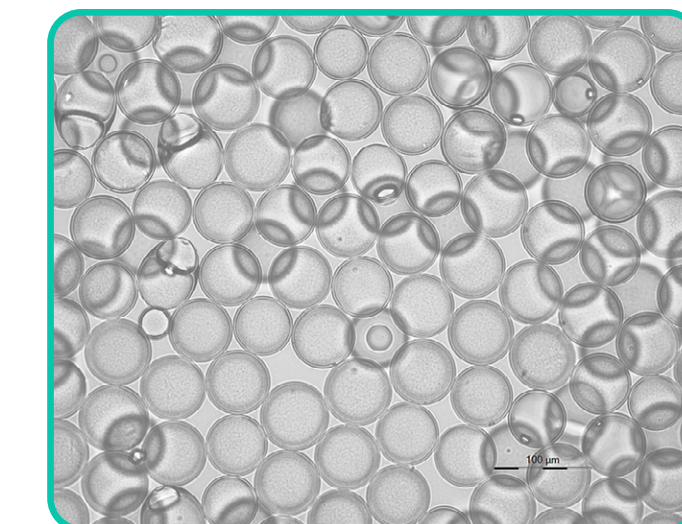
## Stratum<sup>®</sup> offers controlled and pulse release options in an injectable form

### Controlled Release

- Titrates drug release kinetics to enable novel long-acting injectable drug delivery products
- Creates uniform, monodisperse microspheres
- Offers sustained release for any desired length of time (days, weeks, months, up to year) via discrete control over release rate, including linear kinetics
- Perfect for pharmaceuticals where compliance is critical:
  - » contraception
  - » antipsychotic
  - » addiction and bacterial resistance medications

## Stratum microparticles open up a whole new world of possibilities

- Particle sizes down to 10 µm with ± 5% deviation from the mean diameter
- Uses a water "carrier" stream
- Analogous to emulsion processes
- Requires lyophilization
- Compatible with PLGAs, PLAs, PCLs, PCPHs, alginates, gelatins, and other biopolymers
- Good for injectable small molecules, proteins, peptides, vaccines, and heat stable molecules



Uniform 50 µm microspheres



### Pulse Release

- Delayed release of API for true pulse release
- Shell composition tuned to release API after a month or more
- Improves patient compliance by reducing number of injections, including self-boosting vaccines and long-acting ocular injections

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# Unisun<sup>®</sup>

OTIC INJECTABLE TECHNOLOGY

# SPECIALIZED TECHNOLOGIES



Unisun leverages enhanced Stratum<sup>®</sup> microparticles for treating the inner ear

- Combines Stratum microspheres with a film-forming agent, or a film-forming agent on its own
- Film-forming agent uses a non-irritating aqueous base
- Film-forming agent dries quickly on warm biological surfaces
- Can be used to inject and set up highly concentrated depots of a drug
- Good for small molecules, proteins, peptides, and vaccines

## Unisun<sup>®</sup>: A Breakthrough In Intratympanic Delivery

- Unisun combines the use of uniform drug-loaded microspheres with a fast film-forming agent.
- This innovative injectable technology provides both precise control of drug release and low cost, intratympanic delivery.
- In testing, uniform 30µm microspheres remained on the tympanic membrane after 35 days.
- Unisun can be used with many drugs that treat otic disorders, including:
  - » Meniere's disease
  - » Sudden sensorineural hearing loss
  - » Tinnitus
  - » Autoimmune inner ear disease



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<p><b>Microcaps</b><sup>®</sup> TASTE MASKING TECHNOLOGY</p>	<p><b>Optimum</b><sup>®</sup> ORAL DOSE MICROENCAPSULATION</p>	<p><b>Diffucaps</b><sup>®</sup> CUSTOMIZED RELEASE TECHNOLOGY</p>	<p><b>Minitabs</b><sup>™</sup> MMTS<sup>™</sup> MULTI MINI TABLET SYSTEM</p>	<p><b>Duragran</b><sup>™</sup> FLEXIBLE PARTICLE SIZING</p>
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