



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

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

- 40+ years experience in oral drug development
- 70+ contract development projects
- 65+ commercial products globally across multiple therapeutic areas
- 92% Right First Time rate
- 96% of customers would recommend us
- 750 global employees
- Facilities in the US and Europe
- 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
- Clinical Trial Materials
- Tech Transfer & Scale-Up
- Registration & Validation
- Manufacturing
- Packaging
- Post-Approval Services

ABOUT ADARE PHARMA SOLUTIONS	EARLY STAGE DEVELOPMENT	DEVELOPMENT SERVICES
NITROSAMINE MITIGATION	MANUFACTURING CAPABILITIES	3D SCREEN PRINTING
COMPREHENSIVE PACKAGING	OUR FACILITIES	SITE CAPABILITIES
SOLUBILITY ENHANCEMENT	PATIENT-CENTRIC SOLUTIONS	SOLUTIONS CENTER



WINNER
CPHI Leadership
Award 2025



TASTE MASKING

ENHANCED PALATABILITY

CUSTOMIZED DRUG RELEASE

OPTIMIZED PERFORMANCE

MULTIPARTICULATE SYSTEMS

IMPROVED FLEXIBILITY

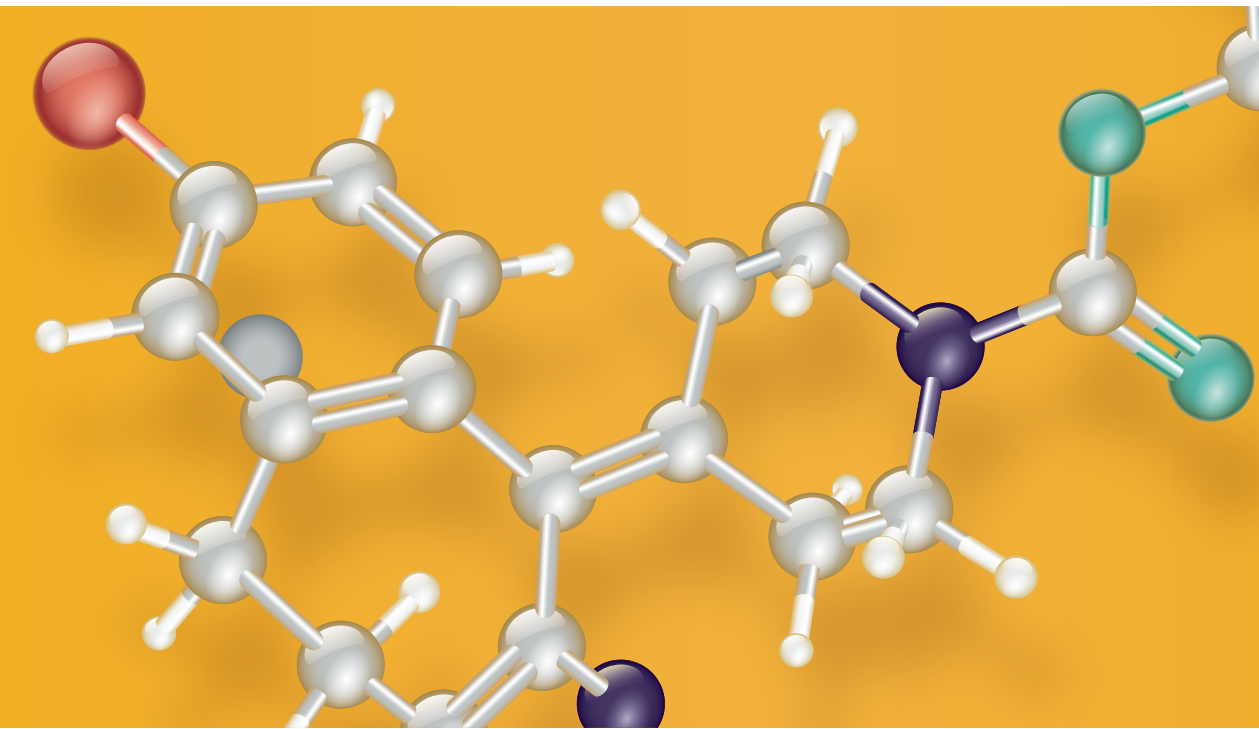
PATIENT-CENTRIC DOSING SOLUTIONS

INCREASED 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 screen 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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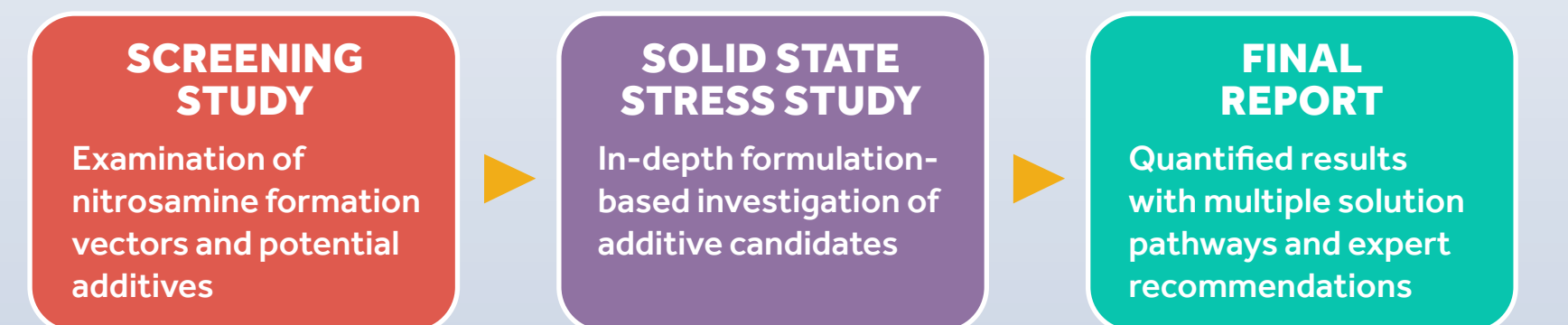


Very few CDMOs can claim Adare's level of experience in mitigating the presence of nitrosamine. We can employ our own in-house mitigation processes to develop the best long-term control strategies for your product.

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

- Global network of facilities
- Integrated regional supply chains
- Seamless scale-up & tech transfer
- Tableting
- Capsule filling
- Granulation & mixing
- Fluid bed processing
- Pan coating
- Blending
 - » Bin blending
 - » Static mixing
- Bilayer tablets
- Oven drying
- Small-scale GMP manufacturing



Specialized Services

- Microencapsulation of solids and liquids
- Modified release solutions (pulsatile delivery)
- Orally disintegrating tablets (ODT)
- Dry syrup/suspensions
- MMTS™ Minitabs
 - » Manufacturing License for Schedules II, 2N, III, 3N, IV, V, and L1
 - » Analytical Labs authorized for Schedules I–V
- Fixed-dose combination manufacturing
- Easy-to-swallow formats
- Solvent granulation and coating processes
- Food sprinkle dosage forms





3D SCREEN PRINTING

PIONEERING A NEW GENERATION OF ADVANCED PHARMACEUTICALS

Adare offers clinical scale GMP 3D screen printing capabilities from facilities in the US and Europe. This innovative technology empowers a wide range of enhanced dose flexibility capabilities:

- Complex multi-layered formulations
- IR, ER, and DR in a single tablet
- Near endless possibilities in dosage form shaping
- Tailored formulations for specific therapeutic needs

3D screen printing provides innovative formulation capabilities that are difficult or impossible to achieve with traditional methods.

Redefine what's possible in drug development and manufacturing with 3D screen printing



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COMPREHENSIVE PACKAGING



MULTILANE
STICKPACK
MACHINE

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Commercial Solid Dose Packaging Solutions in the US and Europe

- Bottle Filling
- Blister Packaging
 - » Commercial scale
 - » Available at US & EU facilities
 - » Thermoforming
 - » Up to four different drug products on a blister
- Stick Pack Filling
 - » Powder filling
- Flow Wrap Packaging
- Packaging of DEA Schedules II, 2N, III, 3N, IV, L1
- Serialization & aggregation
- Repackaging license

Expanded Packaging In Europe

- New 2,800 m² packaging hall in Milan, Italy
 - » Marchesini Integra Blister Line
 - » 50M+ blisters annually
 - » Tablets & capsules
- New 1,000 m² warehouse in Milan, Italy
 - » Capacity for 900 pallets
 - » Space for additional packaging lines



BLISTER PACKAGING LINE





OUR FACILITIES

A GLOBAL FOOTPRINT THAT ENSURES THE SECURITY OF YOUR SUPPLY

Development & manufacturing sites in the US and Europe

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<p>Vandalia, OH</p> <ul style="list-style-type: none"> • 179k sq ft (16.6k m²) • Research & development • Clinical & commercial scale manufacturing • Organic solvent capabilities • Manufacturing License for DEA Schedules II, 2N, III, IV, V 	<p>Pessano, IT</p> <ul style="list-style-type: none"> • 220k sq ft (20.4k m²) • Expanded R&D, packaging, and warehousing • Organic solvent formulation development • Clinical & commercial scale manufacturing • High potency (development scale) <10 µg/m³ • Controlled substances 	
<p>Lenexa, KS</p> <ul style="list-style-type: none"> • 5k sq ft (465 m²) • Research & development • Non-GMP development scale • Long-acting injectables 	<p>San Giuliano, IT</p> <ul style="list-style-type: none"> • 93k sq ft (8.6k m²) • Commercial scale manufacturing • Organic solvent capabilities • Customized release • Tableting & capsule filling 	<p>Philadelphia, PA</p> <ul style="list-style-type: none"> • 175k sq ft (16.2k m²) • Packaging & warehousing • 4 packaging lines & 1 powder filling line • Packaging of DEA Schedules 2N, III, 3N, IV





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SITE CAPABILITIES

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

DOSAGE FORMS	VANDALIA	LENEXA	PESSANO	SAN GIULIANO	DUNGAN
STANDARD ORAL SOLIDS (TABLETS & CAPSULES)	D C	D	D C	C	
MULTIPARTICULATES	D C	D	D C	C	
ORALLY DISINTEGRATING TABLETS & CHEWABLES	D C		D C	C	
LIQUID-FILLED HARD CAPSULES	D C				
BILAYER TABLETS	D C				
SUSPENSIONS (STANDARD & MICRO)	D	D			
SOLUTIONS & SYRUPS		D			
LONG-ACTING INJECTABLES		D			
LIPID FORMULATIONS		D			
EMULSIONS & MICROEMULSIONS		D			

SERVICES	VANDALIA	LENEXA	PESSANO	SAN GIULIANO	DUNGAN
MODIFIED RELEASE SYSTEMS	D C	D	D C	C	
PACKAGING	D		D C		D C
FLUID BED	D C		D C		
3D SCREEN PRINTING	D		D		
BIOAVAILABILITY/SOLUBILITY ENHANCEMENTS	D				

TECHNOLOGIES	VANDALIA	LENEXA	PESSANO	SAN GIULIANO	DUNGAN
ADAPTDOSTM	D C				
ADVATAB®	D C				
DIFFUCAPS®	D C		D C	C	
MICROCAPS®	D C		D C		
MINITABSTM	D C		D C	C	
OPTIMUM®	D	D			
PARVULET®	D C		D C		
STRATUM®		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[®]
- Bench-to-pilot scale Spray-drying
- Hot Melt (Leistritz ZSE 18)
- Conventional approaches using:
 - » Solubilizers
 - » Cyclodextrins
 - » Surfactants
 - » Super-disintegrants



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PATIENT-CENTRIC SOLUTIONS



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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



Microcaps
TASTE MASKING TECHNOLOGY

Optimum
ORAL DOSE MICROENCAPSULATION

Diffucaps
CUSTOMIZED RELEASE TECHNOLOGY

Minitabs
MMTS™ MULTI MINI TABLET SYSTEM

Adaptdose
MULTI-DELIVERY PLATFORM

AdvaTab
ORALLY DISINTEGRATING TABLETS

Parvulet
PATIENT-CENTRIC DOSING SOLUTIONS

Stratum
INJECTABLE MICROENCAPSULATION





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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®	MICROCAPS®	MINITABS™	OPTIMUM®	PARVULET®	STRATUM® (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[®]

TASTE MASKING TECHNOLOGY

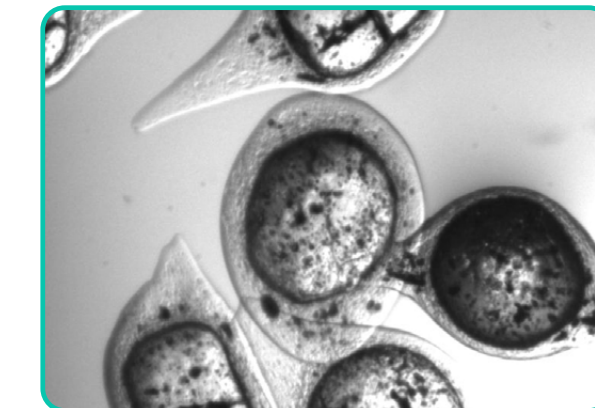
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SPECIALIZED TECHNOLOGIES

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[®] 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



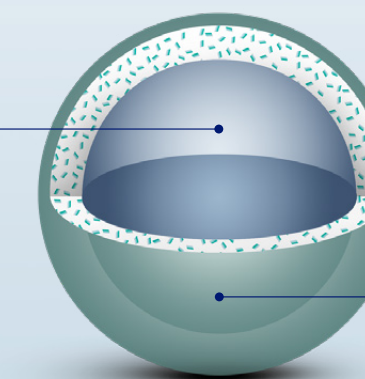
Microcapsule After Drying

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

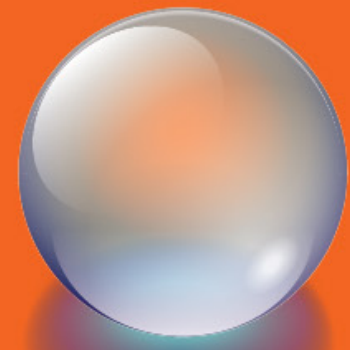
- crystal
- granulate
- liquid



Polymer Membrane



ADARE IS THE LEADER IN ORGANIC PHASE COACERVATION FOR PHARMACEUTICAL PRODUCTS



Optimum[®]

ORAL DOSE MICROENCAPSULATION

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SPECIALIZED TECHNOLOGIES

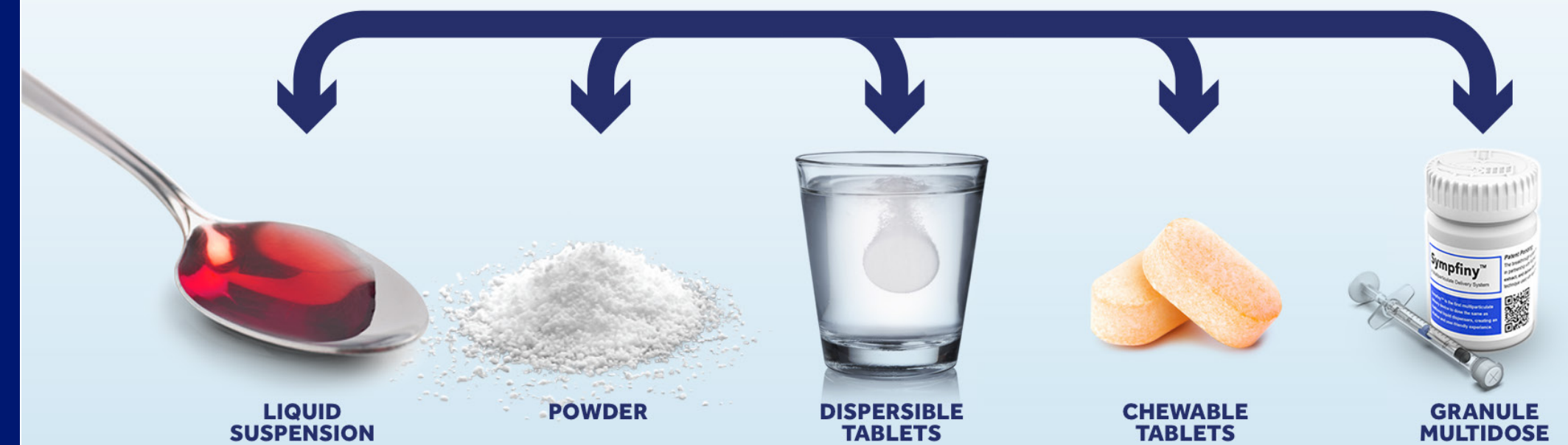
You don't have to sacrifice taste to achieve a dispersed solid oral dosage form

- 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[®]

CUSTOMIZED RELEASE TECHNOLOGY

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SPECIALIZED TECHNOLOGIES

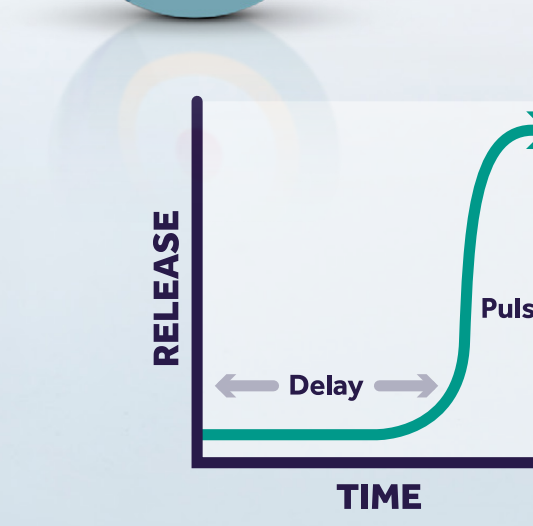
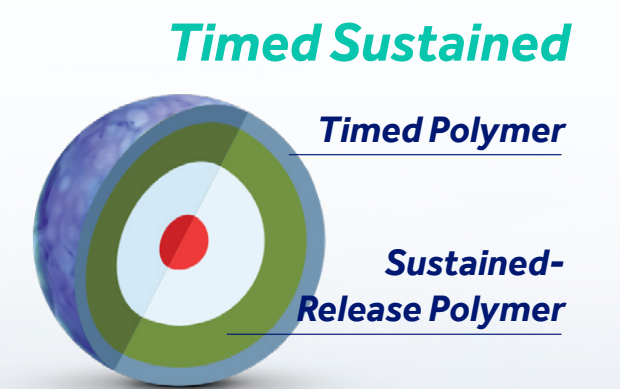
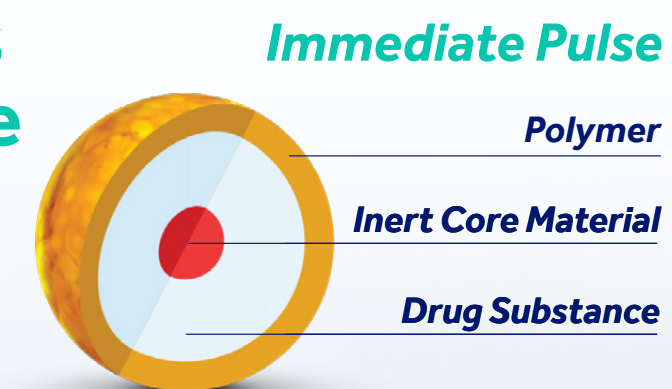
Diffucaps[®] controls drug delivery and optimizes release profiles

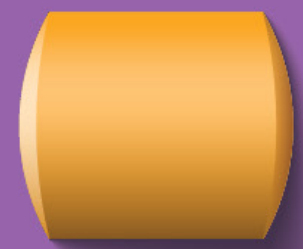
- Adjustable dosage strength and dissolution profile to achieve the desired in vivo pharmacokinetic profile
- Available as a capsule, orally disintegrating tablet, rapidly disintegrating tablet, or as a sprinkle
- Enhances drug solubility in sections of the gastrointestinal tract through combined use 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





Minitabs[™]

MMT[™] MULTI MINI TABLET SYSTEM

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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

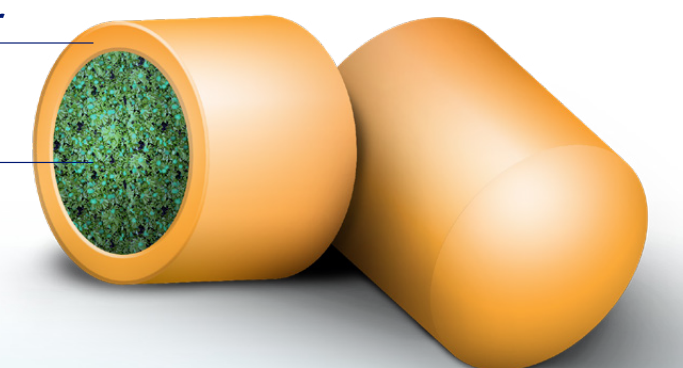


1.2 mm
Ultra Microtablets

Release Control Polymer

Minitablet

- high drug load
- granulation or hydrophilic matrix



MINITABS CAN BE COMBINED WITH

CUSTOMIZED RELEASE

Diffucaps[®]





Adaptdose[™]

MULTI-DELIVERY PLATFORM

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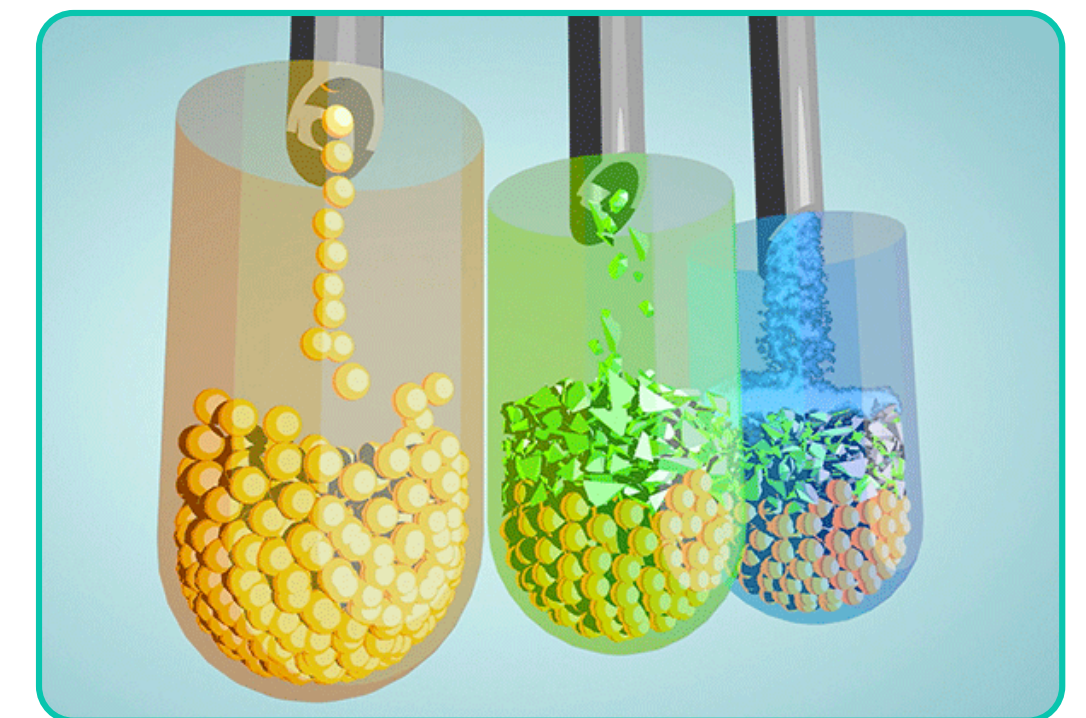


SPECIALIZED TECHNOLOGIES

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[®]

ORALLY DISINTEGRATING TABLETS

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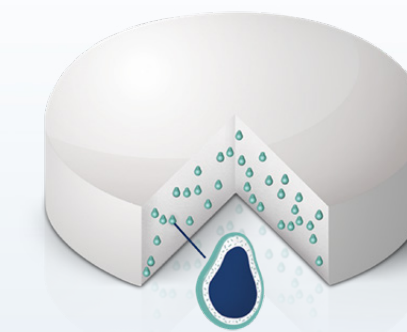
SPECIALIZED TECHNOLOGIES

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

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

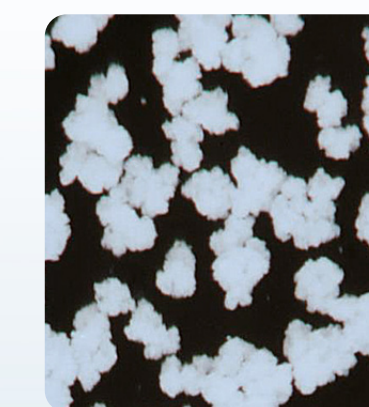
COMBINE ADVATAB WITH THESE ADARE TECHNOLOGIES FOR IMMEDIATE RELEASE OR CONTROLLED RELEASE OPTIONS



Micrographs of Formulation Stages



API Granule
(Irregular Shape)

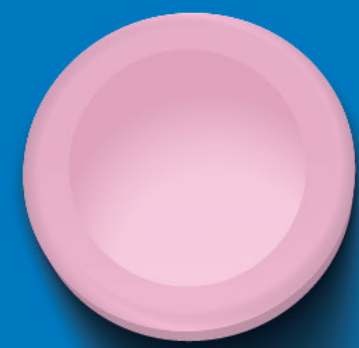


Microcaps API
(Complete & Uniform Taste-masking)



AdvaTab ODT
(Final Dosage Form)





Parvulet[®]

PATIENT-CENTRIC DOSING SOLUTION

ABOUT ADARE PHARMA SOLUTIONS	EARLY STAGE DEVELOPMENT	DEVELOPMENT SERVICES
NITROSAMINE MITIGATION	MANUFACTURING CAPABILITIES	3D SCREEN PRINTING
COMPREHENSIVE PACKAGING	OUR FACILITIES	SITE CAPABILITIES
SOLUBILITY ENHANCEMENT	PATIENT-CENTRIC SOLUTIONS	SOLUTIONS CENTER



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.



COMBINE PARVULET WITH OTHER ADARE TECHNOLOGIES



TASTE MASKING

Microcaps[®] | **Optimum**[®]



CUSTOMIZED RELEASE

Diffucaps[®] | **MMTS**[™] **Minitabs**

Stratum[®]

INJECTABLE MICROENCAPSULATION

SPECIALIZED TECHNOLOGIES

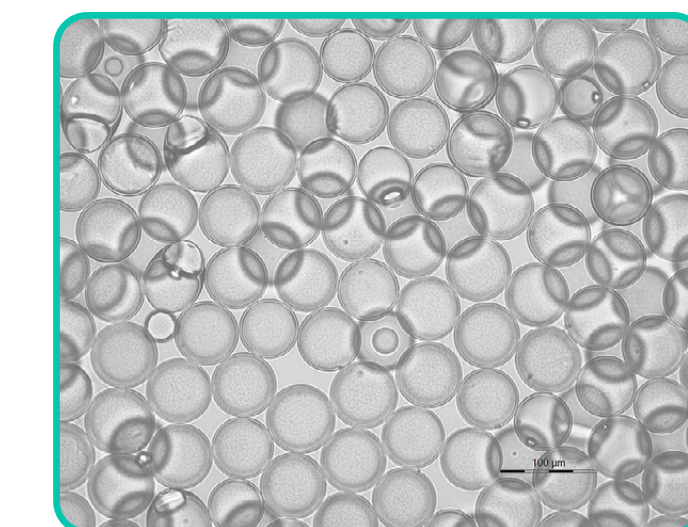
Stratum[®] offers controlled and pulse release options in an injectable form

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 $\pm 5\%$ 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

ABOUT ADARE PHARMA SOLUTIONS	EARLY STAGE DEVELOPMENT	DEVELOPMENT SERVICES
NITROSAMINE MITIGATION	MANUFACTURING CAPABILITIES	3D SCREEN PRINTING
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