

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

CUSTOMIZED DRUG RELEASE

SOLUBILITY ENHANCEMENT

PATIENT-CENTRIC DOSING SOLUTIONS

IMPROVED PALATABILITY

OPTIMIZED PERFORMANCE

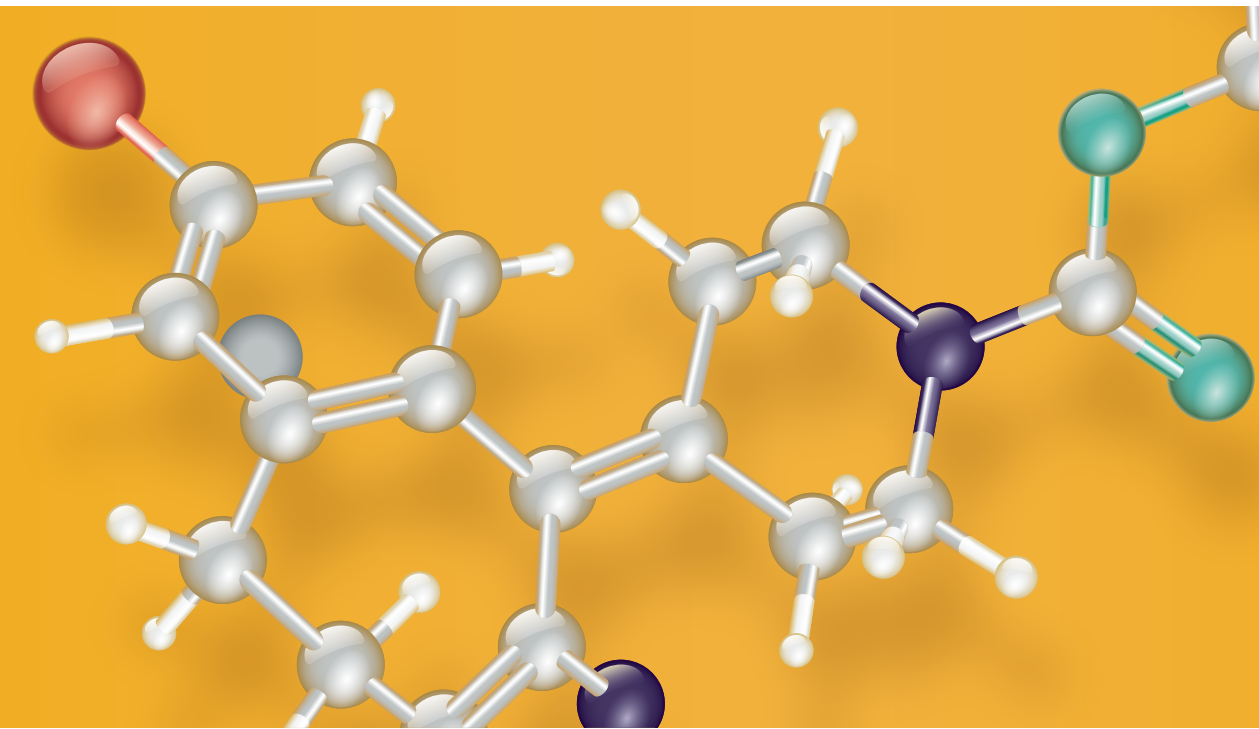
EFFECTIVE ORAL DOSING

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)
- 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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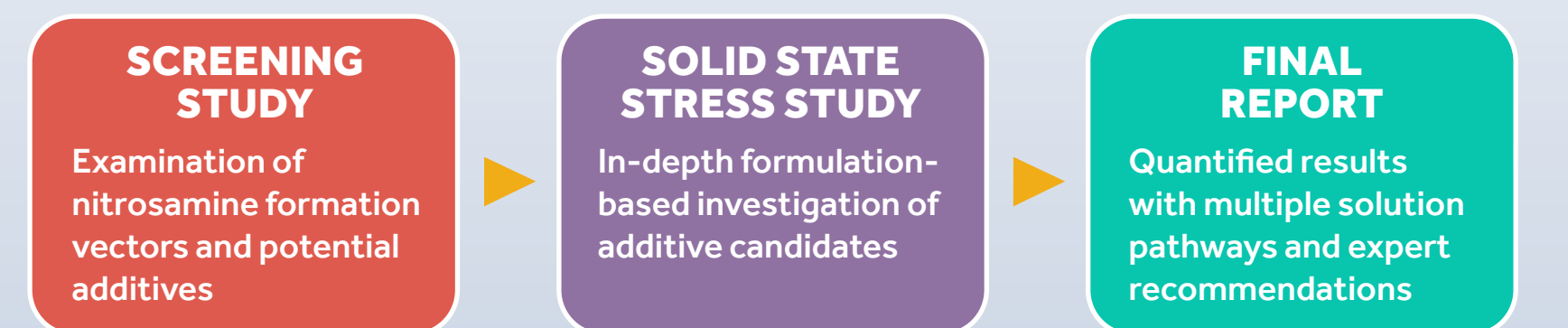


Very few CDMOs can claim Adare's level of experience in mitigating the presence of nitrosamine. We can employ our own in-house mitigation processes to develop the best long-term control strategies for your product.

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/m³ 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

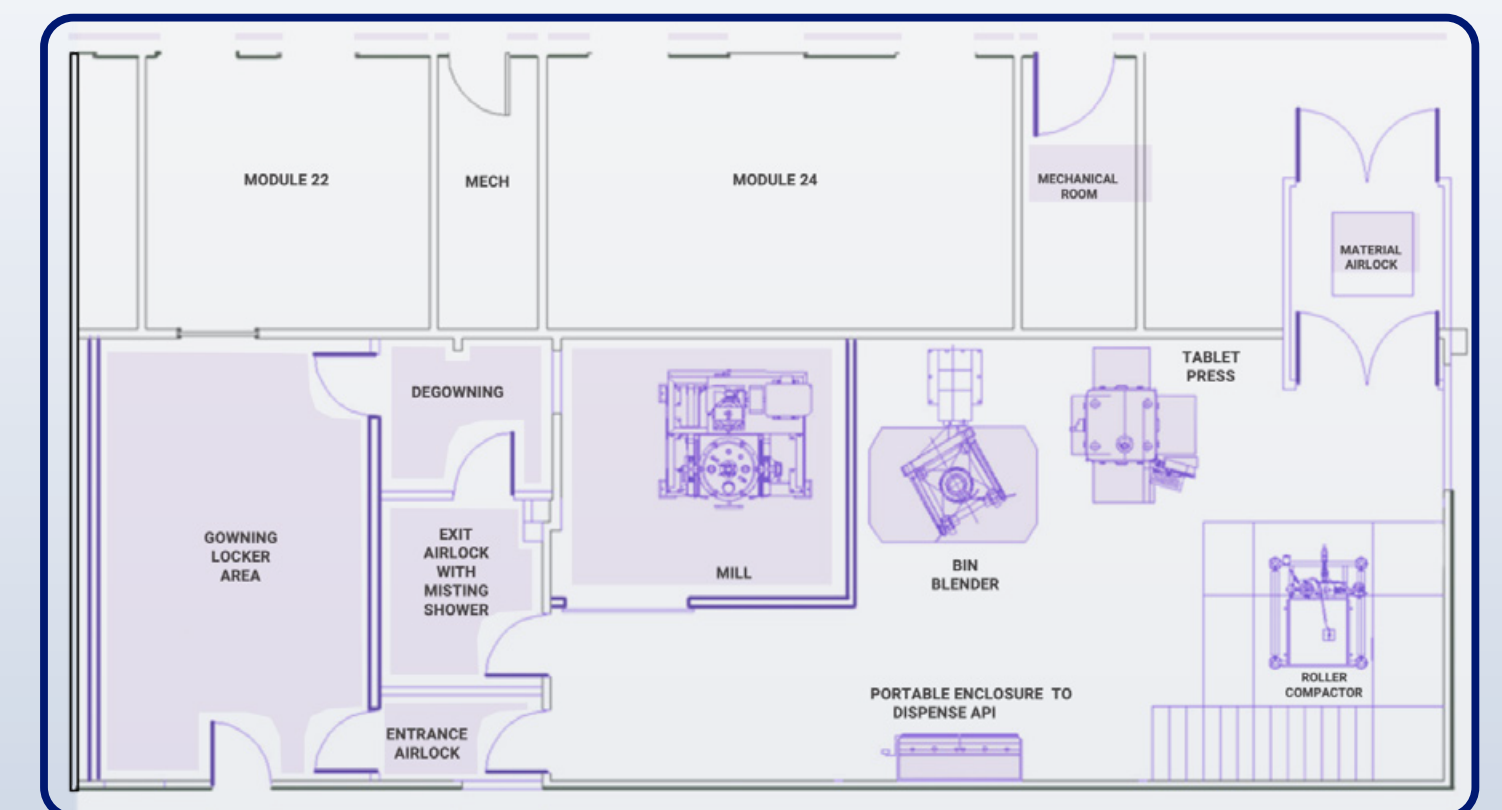
- Dedicated GMP manufacturing and development areas for dry blend high potency products
- Substances with occupational safety levels down to 1 mcg/m³, subject to safety/facility assessment
- Authorized to develop and produce pain management and CNS therapies

Potent Suites

- Milling Room
- Roller Compactor » Fitzpatrick
- Tablet Press » IMA Synthesis 500
- High Potent Airlocks, Locker Room, and Material Airlock
- Bin Blender
- MG2 encapsulator
- High shear granulation
- Capacity to offer:
 - » Portable blending
 - » Wet granulation
 - » Small fluid bed processing

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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

Expansions Coming 2024

- » 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>Lenexa, KS</p> <ul style="list-style-type: none"> • 5k sq ft (465 m²) • R&D center • Non-GMP development scale • Long-acting injectables 	<p>Vandalia, OH</p> <ul style="list-style-type: none"> • 179k sq ft (16.6k m²) • R&D center • Commercial scale manufacturing • Organic solvent capabilities • Manufacturing License for DEA Schedules II, 2N, III, IV, V 	<p>Philadelphia, PA (Orthodox St)</p> <ul style="list-style-type: none"> • 128k sq ft (12k m²) • R&D center • Commercial scale manufacturing • High potency development, manufacturing & packaging suites • Manufacturing & Packaging Licenses for DEA Schedules II, 2N, III, 3N, IV, L1 	<p>Philadelphia, PA (Dungan Rd)</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
<p>Aurora, IL</p> <ul style="list-style-type: none"> • 33k sq ft (3k m²) • R&D center • Commercial scale manufacturing • Fluid bed technology center • Manufacturing License for DEA Schedules II, 2N, III, 3N, IV, V, L1 	<p>San Giuliano, IT</p> <ul style="list-style-type: none"> • 93k sq ft (8.6k m²) • Commercial scale manufacturing • Organic solvent capabilities • Focused on customized release technologies • Tablet & capsule filling 	<p>Pessano, IT</p> <ul style="list-style-type: none"> • 220k sq ft (20.4k m²) • Expanded R&D capabilities • Clinical & commercial scale manufacturing • Packaging • Organic solvent capabilities • Controlled substances 	





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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							
ABUSE DETERRENT TESTING						D	
BIOAVAILABILITY/SOLUBILITY ENHANCEMENTS	D					D	
CAPSULE BANDING						D C	
FLUID BED	D C	D C		D C			
HIGH POTENCY (from 1 mcg/m ³)						D C	
MODIFIED RELEASE SYSTEMS	D C	D C	D	D C	C	D C	
PACKAGING	D			D		D	C
TABLET PRINTING						D C	
TECHNOLOGIES							
ADAPTDOSSE™	D C					D C	
ADVATAB®	D C			D C			
DIFFUCAPS®	D C	D C		D C	C		
DURAGRAN™		D C					
MICROCAPS®	D C			D C			
MINITABS™	D C	D C		D C	C	D C	
OPTIMUM®	D		D				
PARVULET®	D C			D C		D C	
STRATUM™			D				
UNISUN®			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)
- Dyno-mill
- Conventional approaches using:
 - » Solubilizers
 - » Cyclodextrins
 - » Surfactants
 - » Super-disintegrants



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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[®]

TASTE MASKING TECHNOLOGY

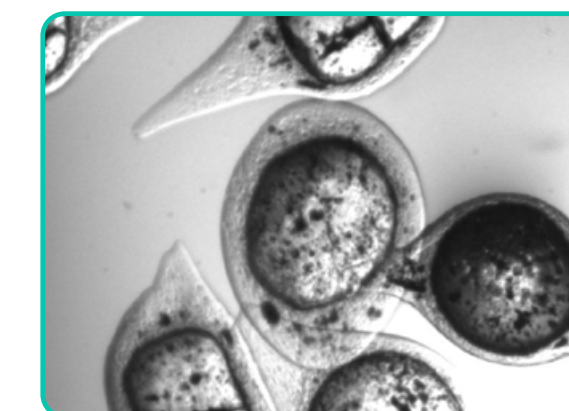
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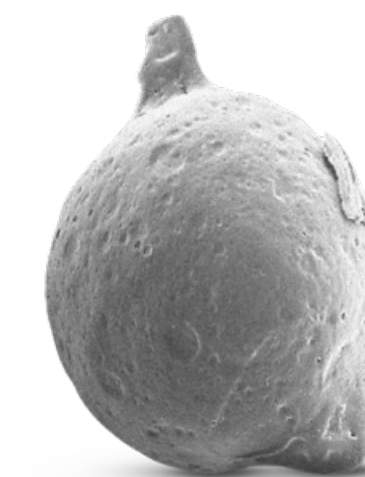
SPECIALIZED TECHNOLOGIES

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



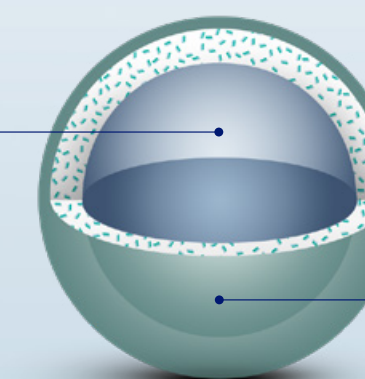
Microcapsule After Drying

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

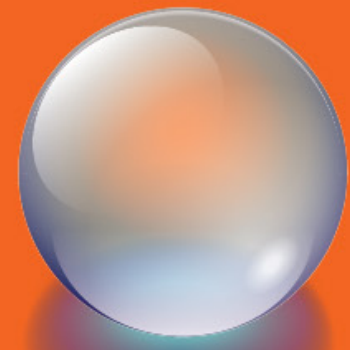
- crystal
- granulate
- liquid



Polymer Membrane



ADARE IS THE LEADER IN ORGANIC PHASE COACERVATION FOR PHARMACEUTICAL PRODUCTS



Optimum[®]

ORAL DOSE MICROENCAPSULATION

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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

SPECIALIZED TECHNOLOGIES

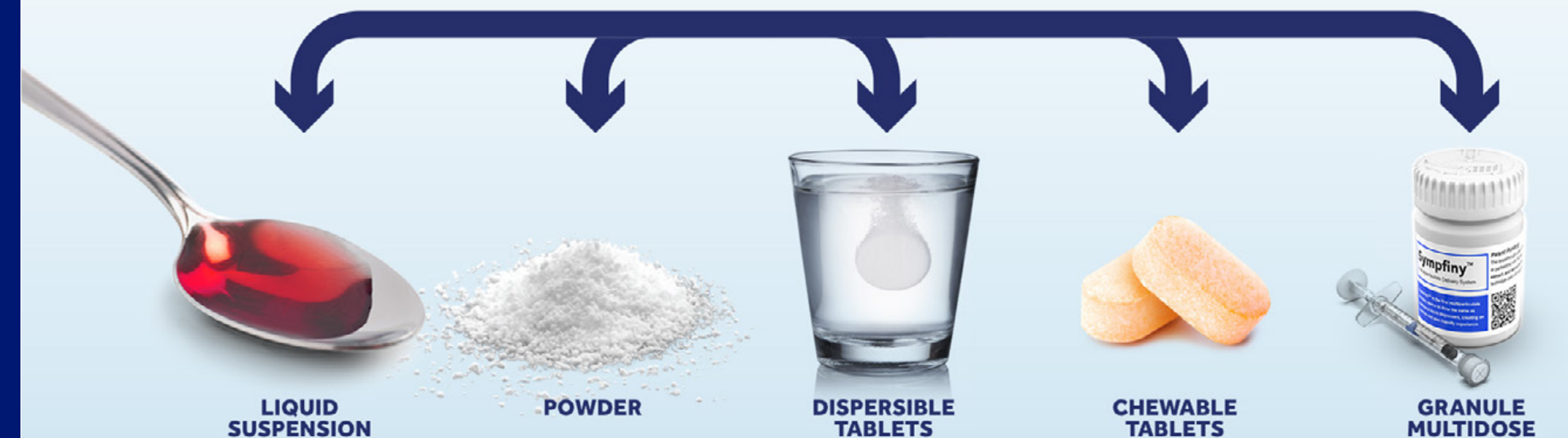
You don't have to sacrifice taste to achieve a dispersed solid oral dosage form

- 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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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

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


Immediate Pulse

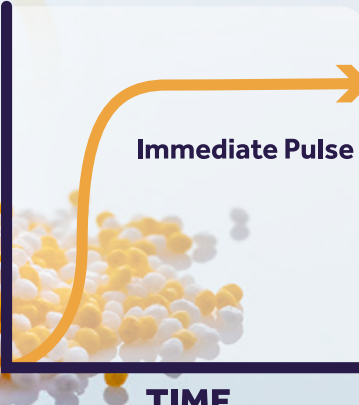


Timed Pulsatile

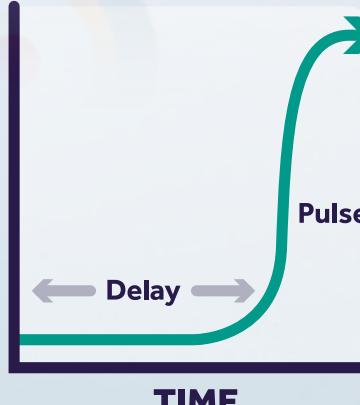


Timed Sustained






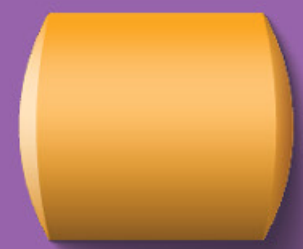
Immediate Pulse



Pulse



Sustained



Minitabs[™]

MMTST[™] 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

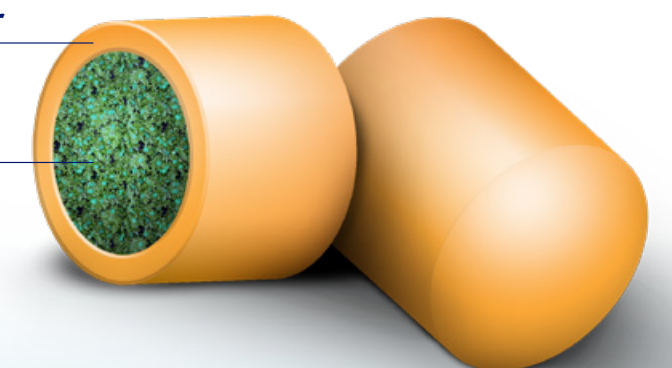


1.2 mm
Ultra Microtablets

Release Control Polymer

Minitablet

- high drug load
- granulation or hydrophilic matrix



MINITABS CAN BE COMBINED WITH

CUSTOMIZED RELEASE

Diffucaps[®]





Duragran[™]

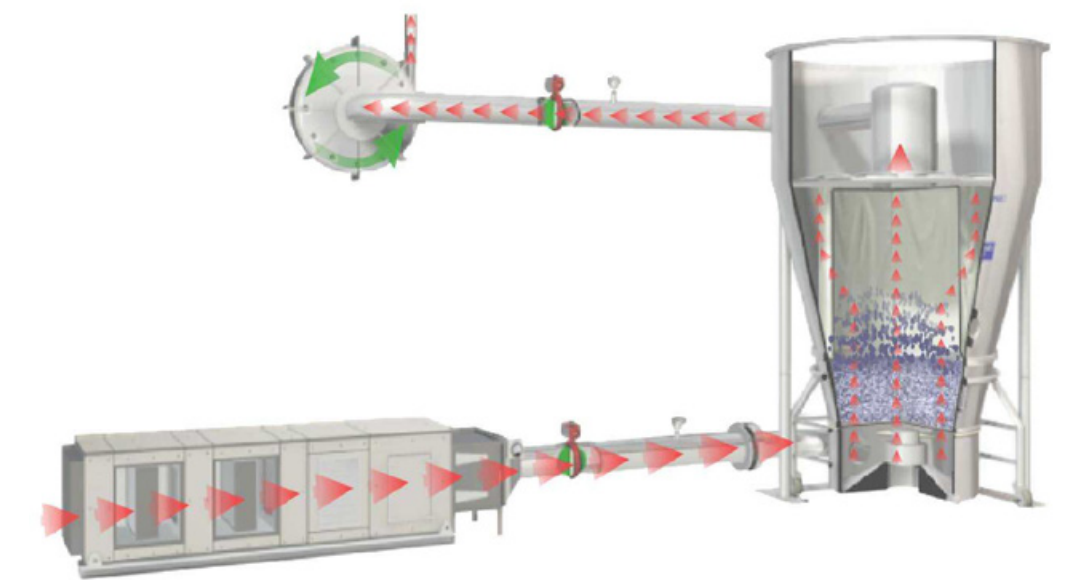
FLEXIBLE PARTICLE SIZING

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[™] 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

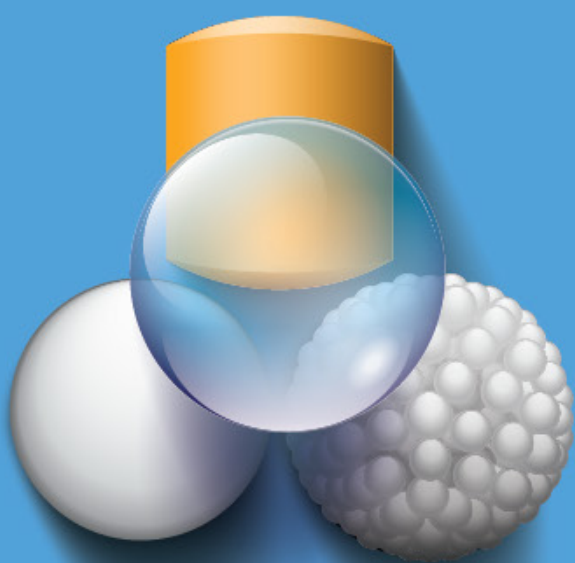


- Formulations with API loading as high as 90% or more
 - » As an alternative to the extrusion/spheronization process
- Larger granules can be formed and then coated in a subsequent process to provide the desired targeted release profile
- Granules can provide a unique product look
 - » Large, colored 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



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





Adaptdose[™]

MULTI-DELIVERY PLATFORM

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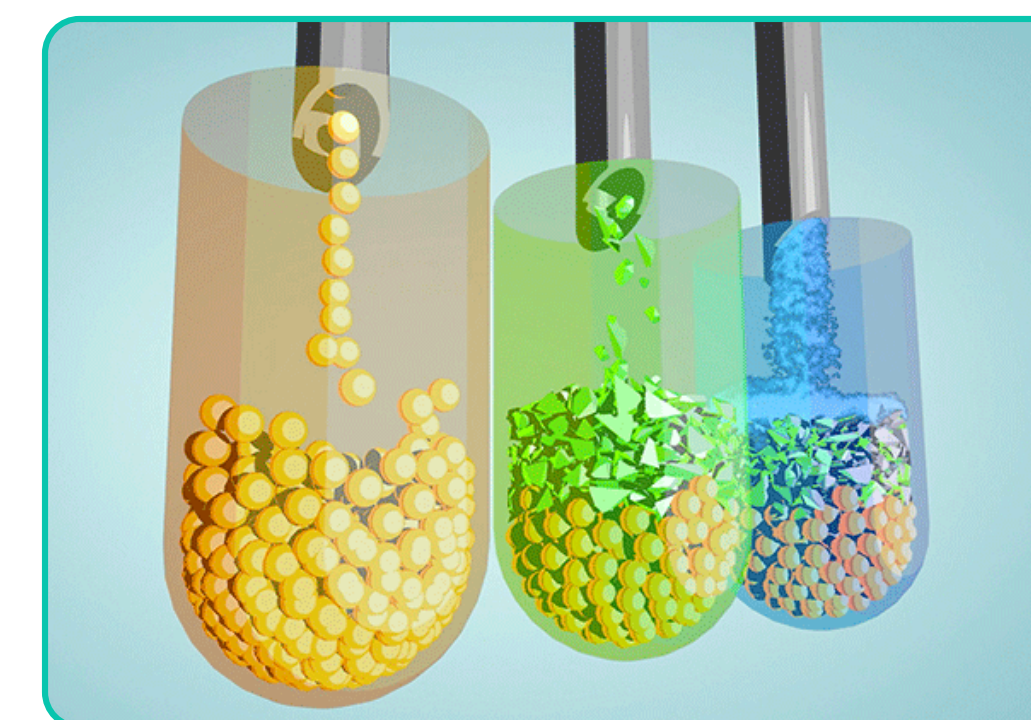


SPECIALIZED TECHNOLOGIES

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

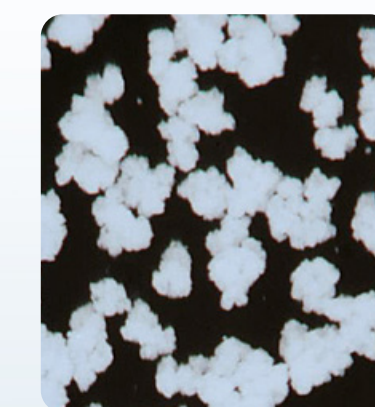
Patented formulations and manufacturing process

- 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

Micrographs of Formulation Stages



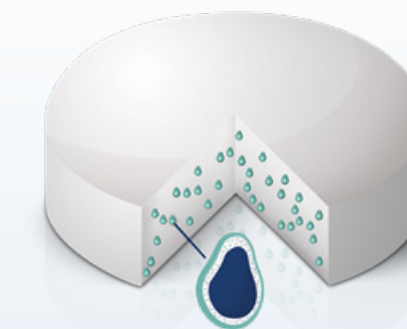
API Granule
(Irregular Shape)



Microcaps API
(Complete & Uniform Taste-masking)



AdvaTab ODT
(Final Dosage Form)



AdvaTab with embedded Microcaps Technology

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





Parvulet[®]

PATIENT-CENTRIC DOSING SOLUTION

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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





Stratum[™]

INJECTABLE MICROENCAPSULATION

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SPECIALIZED TECHNOLOGIES

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

Controlled Release

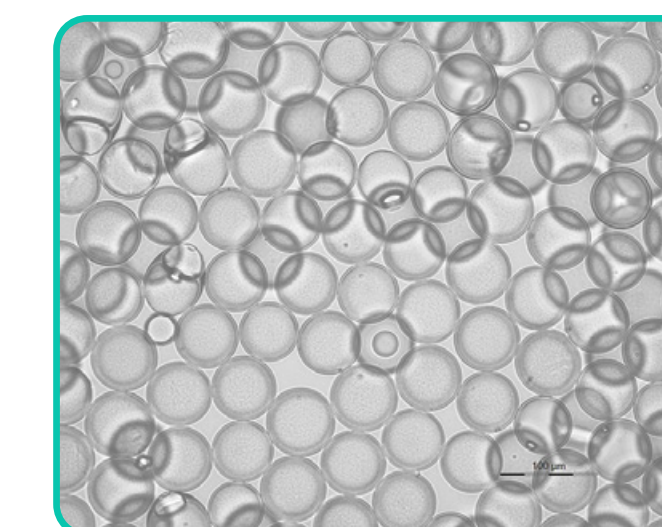
- Titrates drug release kinetics to enable novel long-acting injectable drug delivery products
- Creates uniform, monodisperse microspheres
- Offers sustained release for any desired length of time (days, weeks, months, up to year) via discrete control over release rate, including linear kinetics
- Perfect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

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

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



Unisun[®]

OTIC INJECTABLE TECHNOLOGY

SPECIALIZED TECHNOLOGIES



Unisun leverages enhanced Stratum[™] 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[®]: 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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