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CUTTING DRUG COSTS WITHOUT CUTTING CORNERS: A CDMO'S ROLE IN SMARTER MANUFACTURING

November 17th, 2025

Dave Miller, PhD.

Chief Scientific Officer, AustinPx

THE CHALLENGE: INNOVATION UNDER PRESSURE

Rising Costs

Escalating R&D and manufacturing expenses are tightening margins and heightening the need for efficiency.

Value Demands

Payers and regulators expect affordable innovation, measurable outcomes, and greater manufacturing accountability.

Global Strain

Inflation, capacity limits, and supply chain instability continue to raise costs and extend development timelines.

Evolving Expectations

The old cost-plus CDMO model no longer fits today's market. Sponsors now seek partners who deliver both innovation and value.

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THE OPPORTUNITY: TURNING PRESSURE INTO PROGRESS

Innovation Redefined

CDMOs are moving beyond capacity to creativi**ty, transforming complex science into scalable, manufacturable solutions that deliver real value.**

Collaborative Advantage

When CDMOs think with thei**r sponsors, innovation moves faster. Shared strategy and agility lead to stronger outcomes at every stage.**

Technology That Transforms

Platforms that combine speed, sustainabili**ty, and performance to deliver measurable impact where traditional methods can fall short.**

A New Standard

The leaders of today are setting new expectatio**ns for how science, strategy, and sustainability define the future of manufacturing and drug development.**

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SETTING THE STAGE:
REDEFINING HOW CDMOs CREATE VALUE

Leading with Purpose

Anticipating client challenges

Advancing performance and cost efficiency

Driving innovation with intent

Engineering Better Pathways

Smarter routes to clinical success

Integrated formulation and manufacturing

Simplified, scalable solutions

Creating Collaborative Impact

Transparent partnerships

Shared accountability

Measurable value creation

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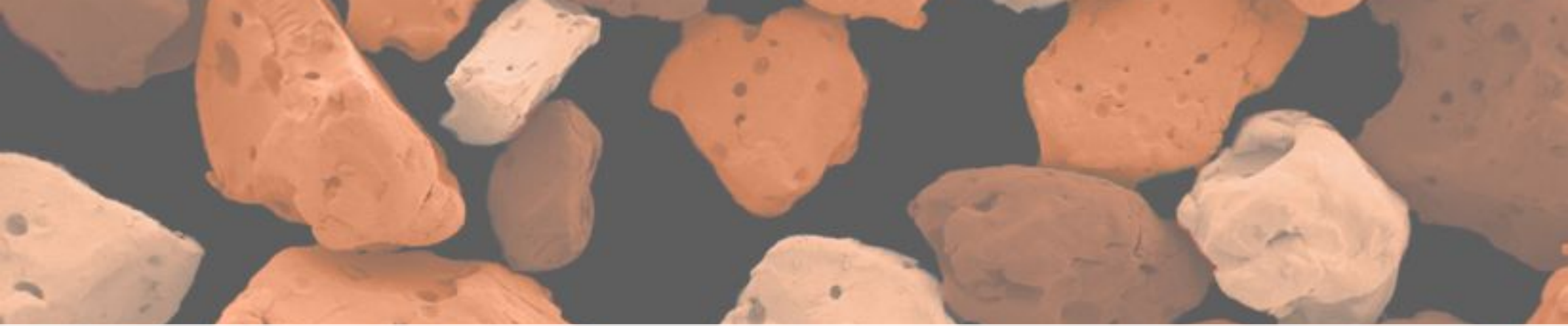
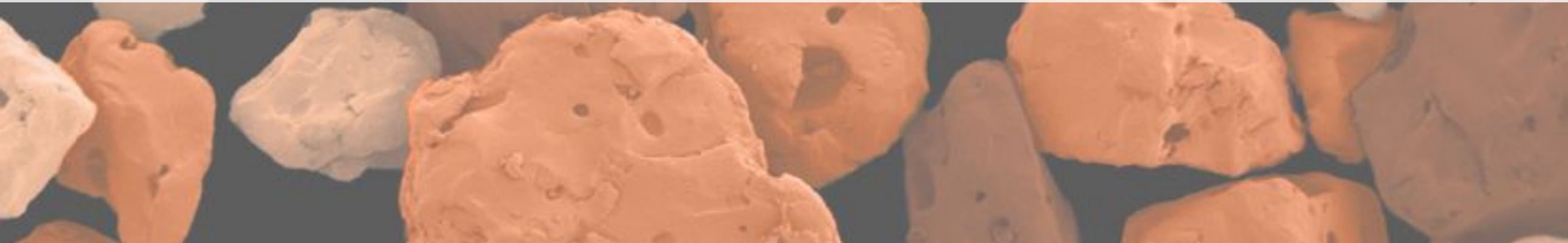
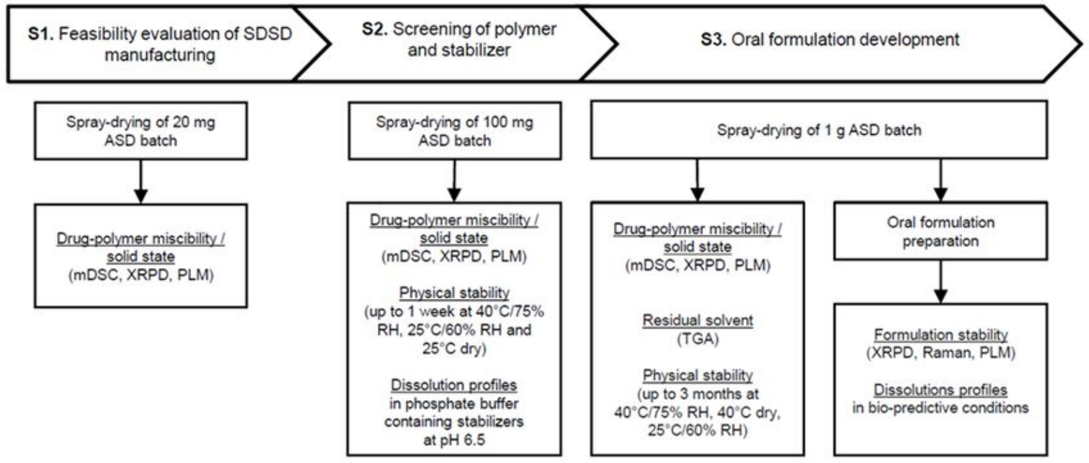


INEFFICIENCY MODEL: SPRAY DRYING FOR ASDs



BENEFITS OF SPRAY DRYING IN EARLY DEVELOPMENT

From: Ousset, Aymeric, et al. *Pharmaceuticals* 11.3 (2018): 81



Broad availability at small scale

Supports development

GMP manufacturing

Low API consumption

R**apid prototyping of binary ASDs**

Accelerates PoC and lead ASD selection

Established, template-driven workflows

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LIMITATIONS OF SPRAY DRYING ON SCALE UP

Suboptimal formulations: binary ASDs

High pill burden: low drug load, low ASD tablet load

SDD properties shift with scale

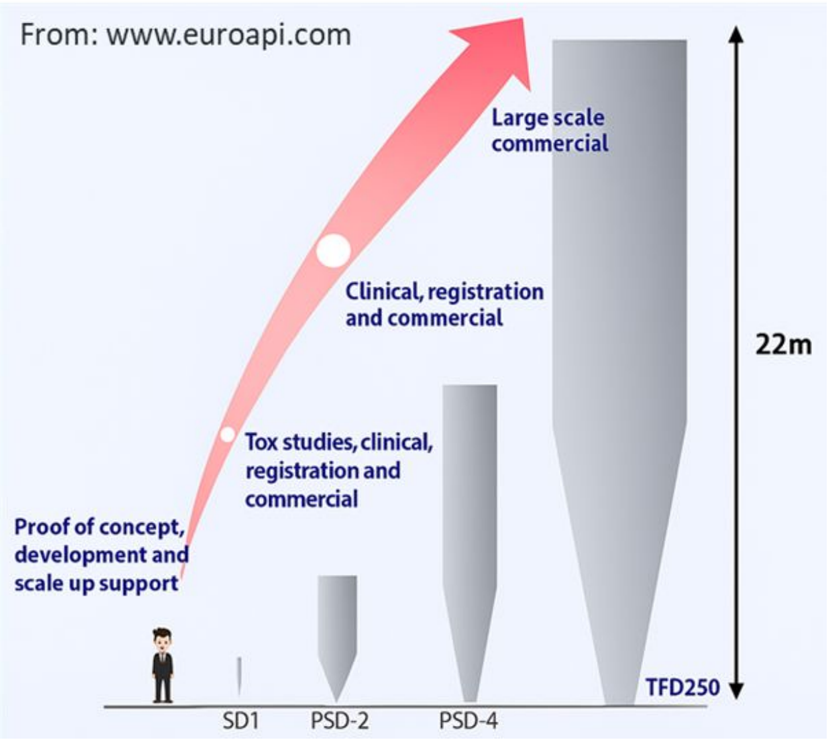
- Alters downstream processing
- Affects performance

Manufacturing inefficiencies

- Low feed solids
- Solvent and energy usage
- Energy usage
- Long processing times
- Added steps (secondary drying, roller compaction)

Solvent Handling Systems

Spray Drying Scale-Up



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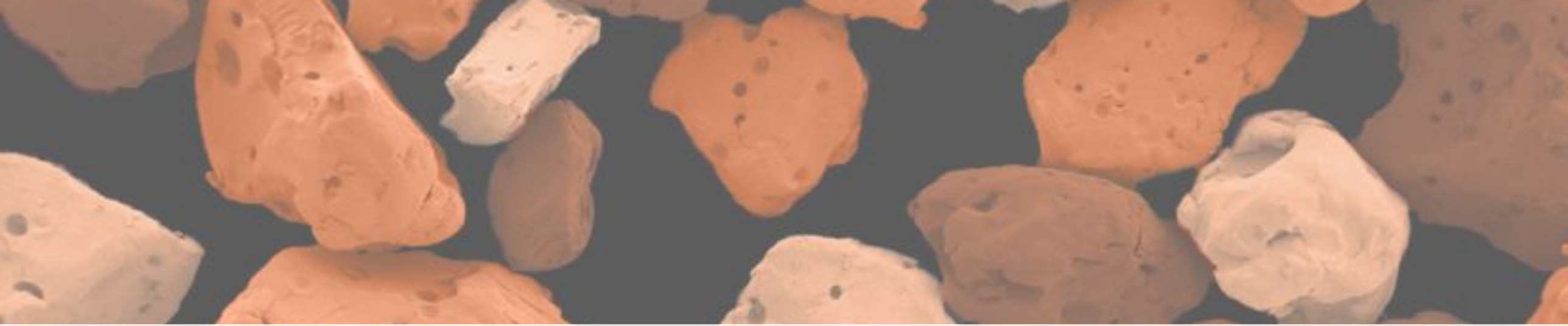
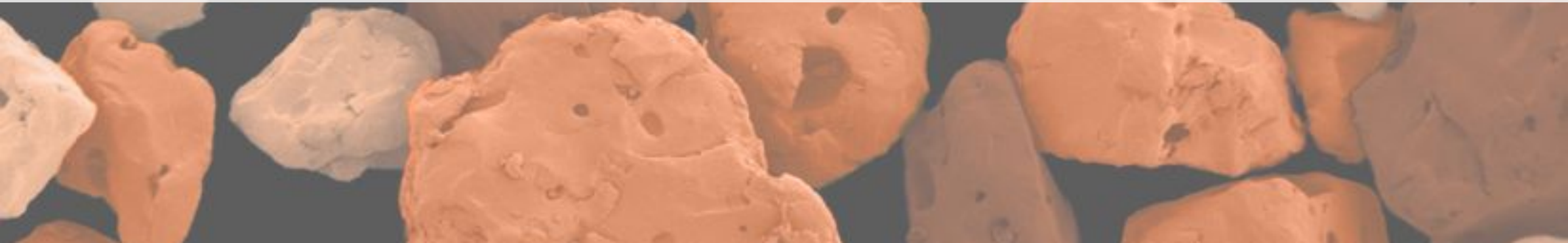


COMMERCIAL SPRAY DRYING EXAMPLE

Inefficient, wasteful, high pill burden



INTELENCE®

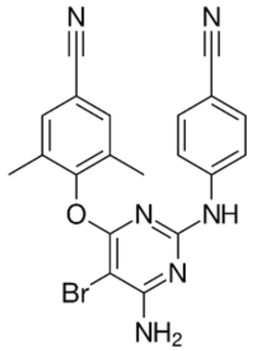
Spray Dried Etravirine

FDA approval: Jan 18, 2008

Indication: HIV type 1 (second line, in combination)

Insoluble, poorly-permeable BCS IV compound

Spray dried dispersion of etravirine in HPMC



Large tablets (1.4g, 22 x 11mm)

Dose: 200mg twice daily

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INTELENCE®

Spray Dried Etravirine

- ETV:HPMC (1:3) SDD
- Feed Solution: 8.64 kg ETV, 540 kg of dichloromethane, 60 kg of ethanol
- Post-processing: secondary drying, roller compaction
- 200mg tablet is 1.4g compression weight (40% external)
- High PK variability

EXAMPLE

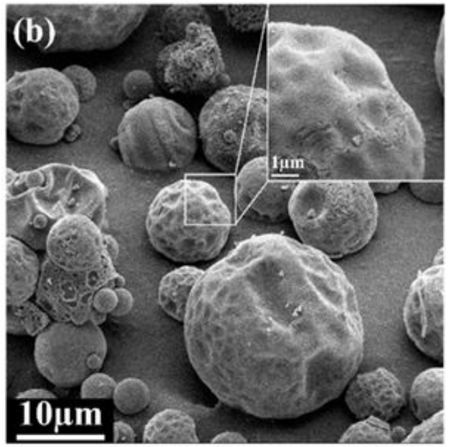
1) Manufacturing of Spray-Dried Powders with and without MCC

[0069] TMC125:HPMC (1:3)

[0070] The feed mixture of the formulation without MCC contained 8.64 kg TMC125, 25.0 kg HPMC 2910 5 mPa·s, in 540 kg dichloromethane and 60 kg ethanol absolute (99.9%).

[0071] This feed mixture was then admitted to a SD-12.5-N, closed cycle spray-drying chamber via a high-pressure nozzle in co-current mode under the conditions shown in table below.

Spray-drying parameters	
Drying gas	Nitrogen
Nozzle diameter (mm)	1.4 SF
Atomizing pressure (bar)	23
Feed rate (kg/h)	202
Drying gas flow rate (kg/h)	1250
Inlet temperature of drying gas (° C.)	115
Outlet temperature of drying gas (° C.)	49
Condenser temperature	−12° C.



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Spray Dried Etravirine

Intelence Commercial Spray Dying Data

Metric	Units	Spray drying
Total solids processed (ETV + HPMC)	kg	4,992
Total mass processed (ETV + HPMC + DCM + MeOH)	kg	91,659
DCM consumption	kg	78,000
EtOH consumption	kg	8,667
Total nitrogen conditioned (heat/cool/heat)	kg	567,195
ASD Processing time	hr	454
Secondary drying time	hr	25
Total ASD production time	hr	479

5 metric tons of SDD requires:

78 metric tons DCM

8.67 metric tons EtOH

567 metric tons of N2 conditioned

479 hours of production time

Translating to tablets requires:

Secondary drying

Roller compaction (excipient dilution)

Tableting (excipient dilution)

40% external phase, 1.4g total weight

Environmentally and Economically Costly Process

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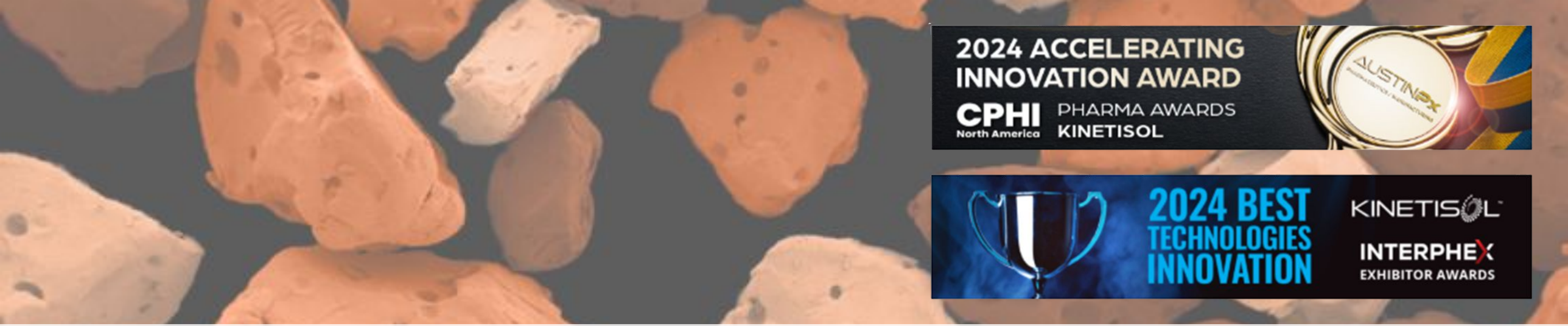

MODEL FOR EFFICIENCY: CDMO INNOVATION

KinetiSol™ Technology: The next generation ASD technology

ORIGIN OF KINETISOL™ TECHNOLOGY

Plastic recycling and pharmaceutics collide

1997

Innovative processing technology commercialized to solve plastic recycling challenges

2007

KinetiSol is born when plastics processing technology is applied to polymeric drug delivery challenges

2008 - present

World-class engineering and pharmaceutical science applied to perfect the technology and formulation platform

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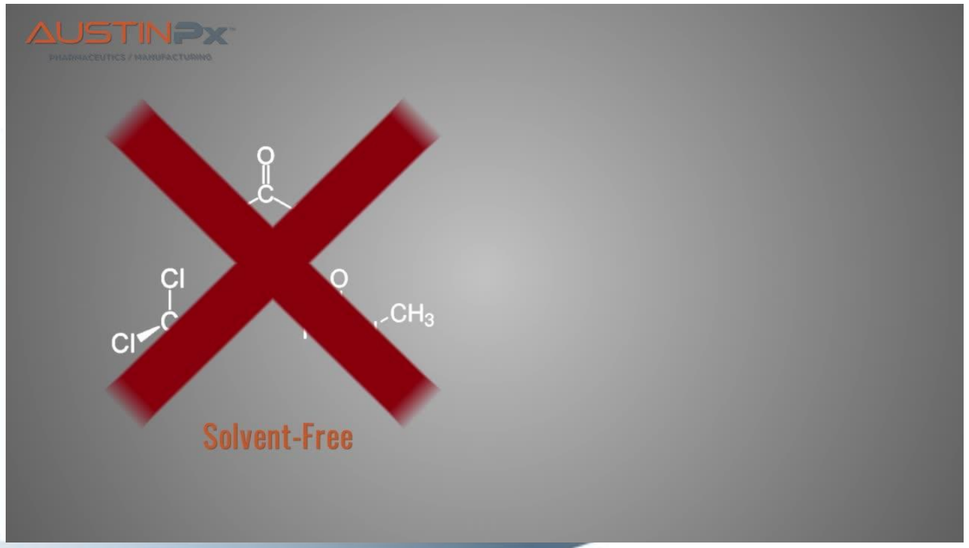
THE KINETISOL PROCESS

Ultra High Shear Mixing

- 10 – 20 seconds
- T_{max} < 200 °C
- No solvents
- Up to 40 kg/hr



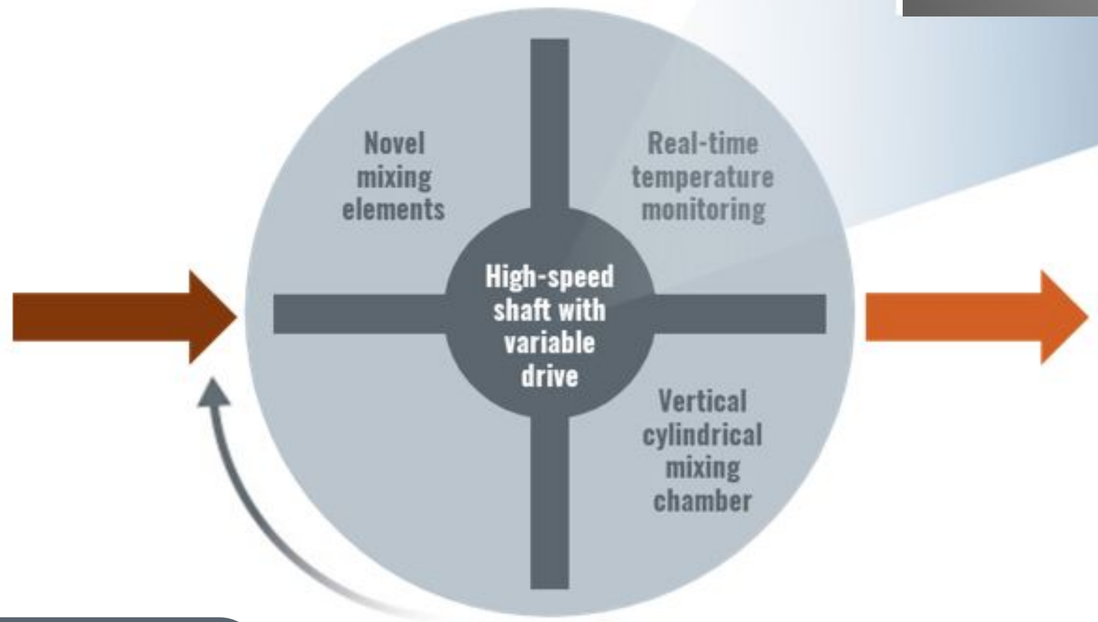
Input (blend)

Drug substance (API)

- Crystalline
- Insoluble
- Poorly bioavailable

Excipients

- Polymers
- Surfactants
- Stabilizers
- Solubilizers
- Innovative mixtures



Output

Amorphous Solid Dispersion Powder

- Soluble
- Bioavailable
- Stable
- Directly compressible
- Patentable

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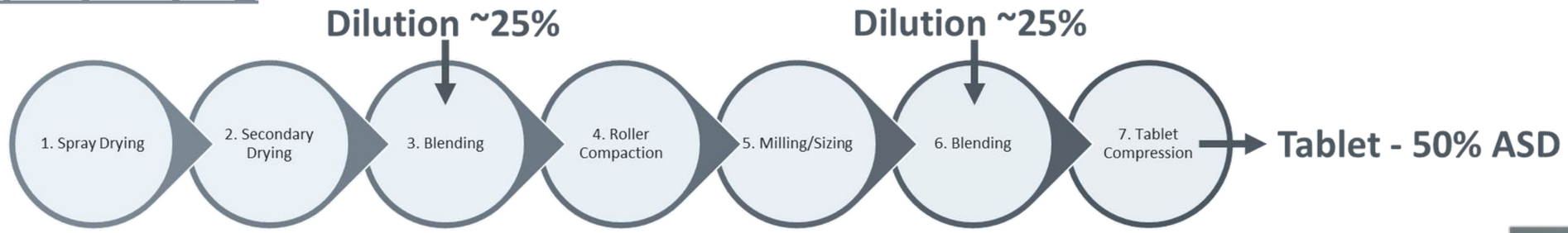
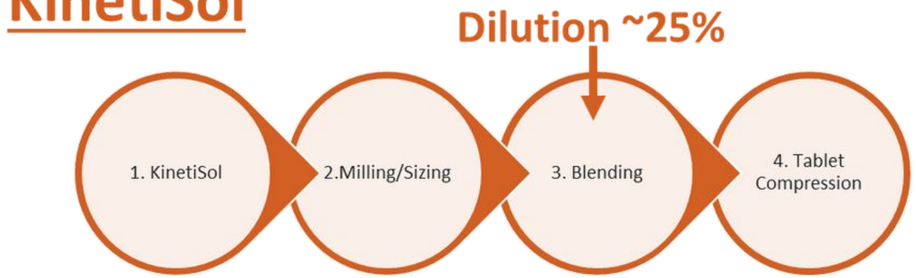
KINETISOL VS SPRAY DRYING

Tableting process flow diagrams

Spray Drying



KinetiSol



Tablet - 75% ASD

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KINETISOL TABLETING

High ASD loading per tablet

Pores created on melt quench

Become sites for particle:

Deformation

Fracture

Excellent compressibility

High tensile strength

Rapid disintegration

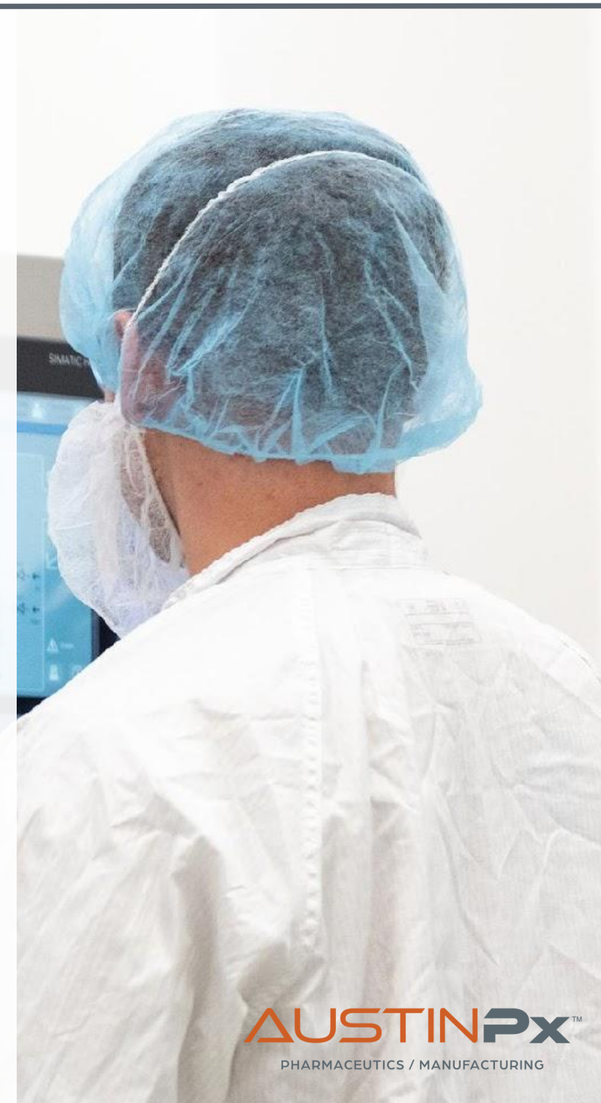
Minimal dilution

KDFX Tablet: P3/Com. Formulation

Component	KDFX IR Phase 2/3 Tablet	
	% w/w	mg/tablet
Internal Phase		
Deferasirox	40.0	360.0
Eudragit L100-55	19.8	178.2
Kollidon VA 64	19.8	178.2
Magnesium Stearate	0.4	3.6
External Phase		
Microcrystalline cellulose	13.0	117.0
Croscarmellose sodium	6.0	54.0
Colloidal silicon dioxide	0.5	4.5
Magnesium stearate	0.5	4.5
Total	**100.0**	**900.0**

Tableting Parameters/Results

Parameter	Units	30011
Bulk density of internal phase	g/ml	0.549
Tablet shape	--	Modified capsule
Cup depth	mm	1.47
Major axis	mm	19
Minor axis	mm	9.28
Avg. compression force	kN	17
Avg. tablet thickness	mm	6.76
Avg. fracture force	N	160.8
Tensile strength	MPa	**2.31**
Disintegration time	Min	< 5



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CLIENT CASE STUDY: LATE-STAGE REFORMULATION

Technology transition and formulation optimization for superior performance

Challenge: Phase I/II SDD Table

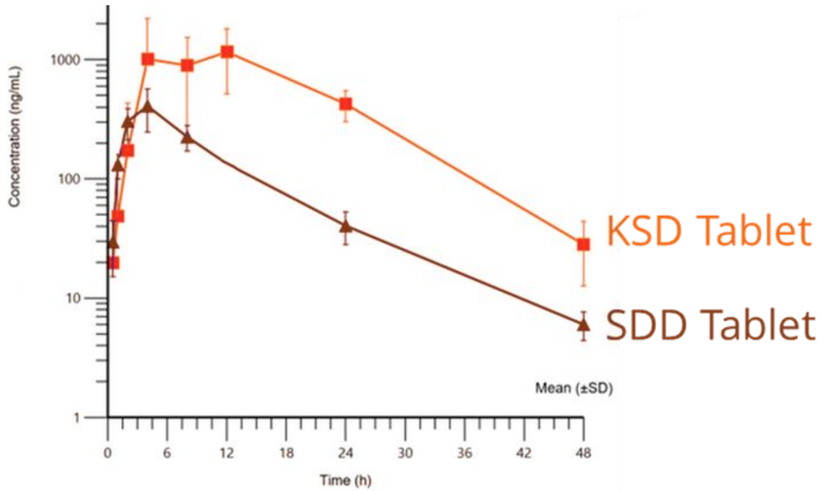
Suboptimal bioavailability
High pill burden
Manufacturing complexity

KinetiSol Outcomes

5x increase in AUC
Reduced dose to single tablet
Prototypes in 4 weeks, CTM in 4 months

Manufacturing Advantages

Eliminated solvents
67% reduction in total manufacturing time
Simplified scale-up to GMP and commercial scale



Primate PK Study: KSD vs SDD

Formulation		AUC_{last} (hr*ng/ml)	C_{max} (hr*ng/ml)
KinetiSol Tablet	Mean	21,205.0	1,609.3
	SD	7,382.4	1,016.0
SDD Tablet	Mean	4,262.9	407.5
	SD	949.6	162.4

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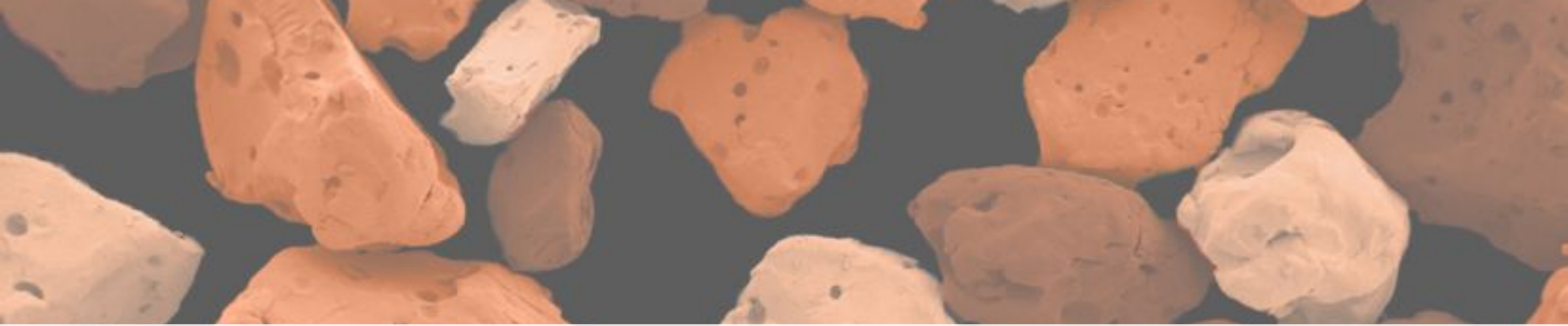
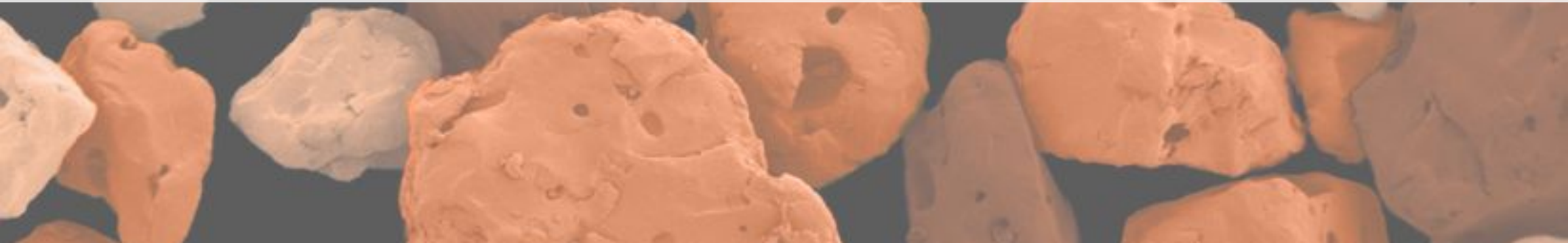


KINETISOL IMPROVES MANUFACTURABILITY

Non-solvent, energy sparing, small footprint, portable



KINETISOL PHASE SPECIFIC DEVELOPMENT OBJECTIVES

Preclinical	Formulation Development
Phase 1	Same Scale Transfer
Phase 2	Scale Step Change
Phase 3	Mode Change
Process Validation	Throughput Optimization

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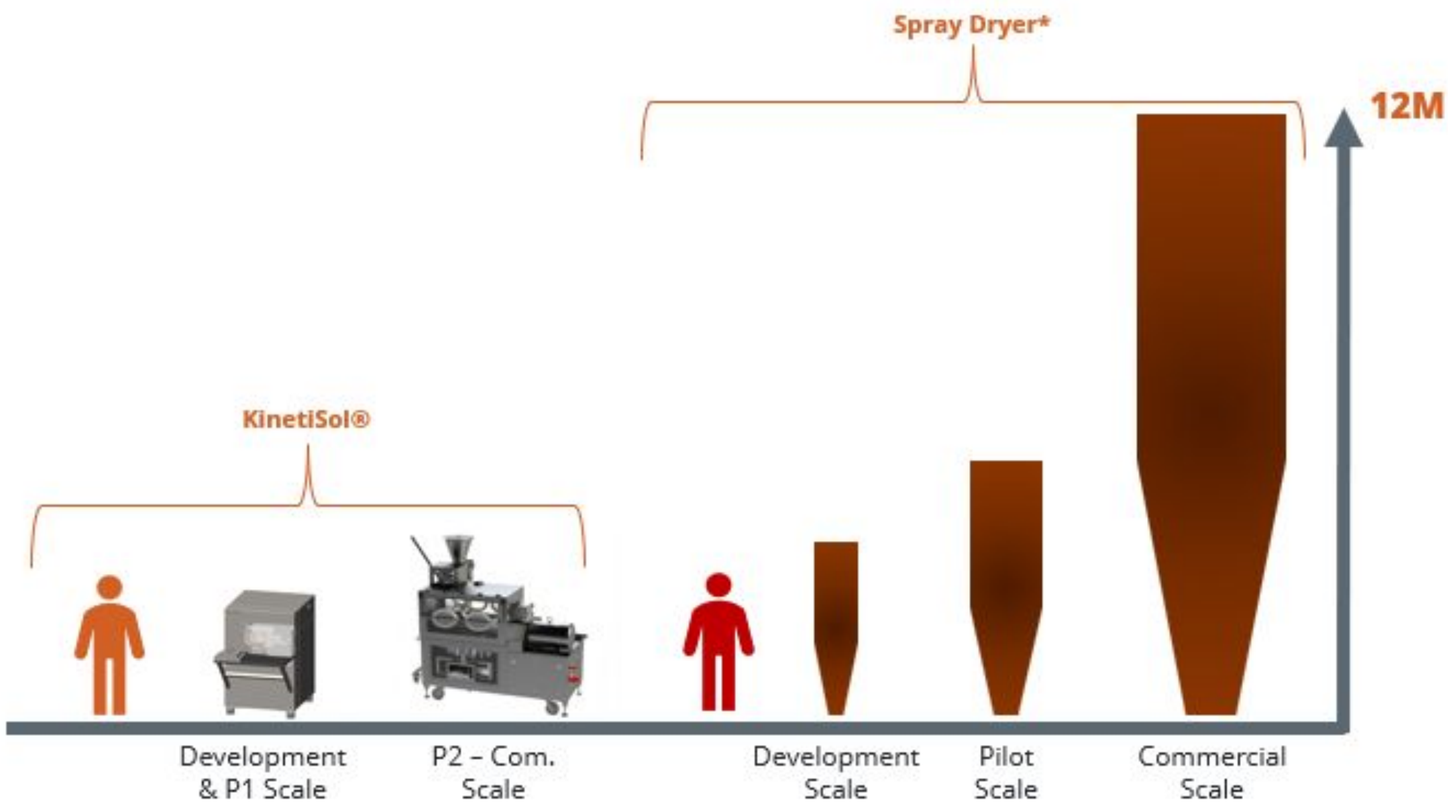
KINETISOL REQUIRES SIGNIFICANTLY SMALLER FOOTPRINT

From development to commercial, KinetiSol fits into a typical GMP facility



*Spray Drying Chambers Only. Does not represent full equipment requirements including solution and nitrogen feed, nitrogengenerator/tanks, cyclone separator, collection chamber and exhaust/scrubbers

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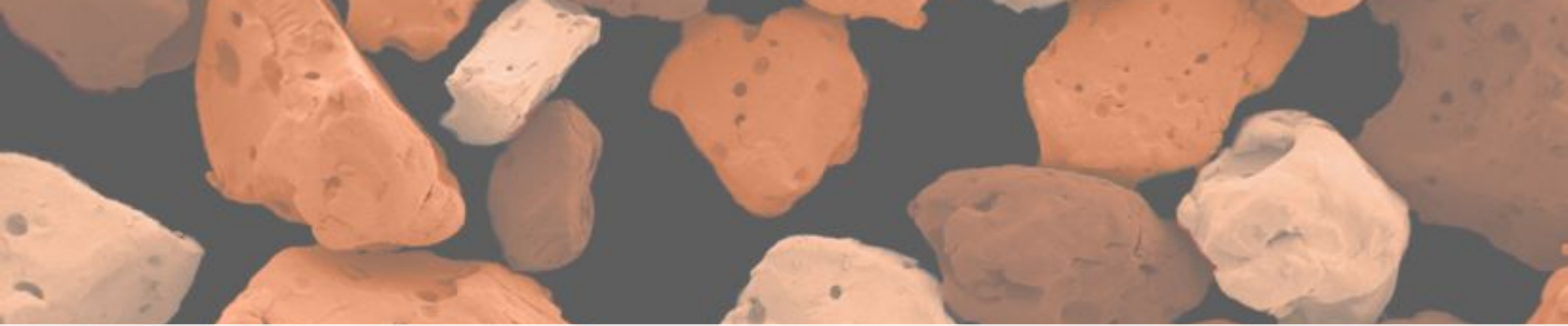
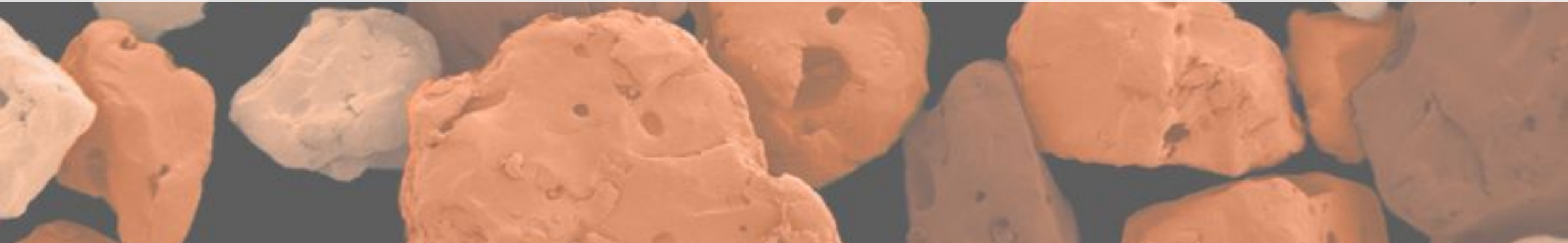


KINETISOL'S INTELENCE EQUIVALENT

Bioequivalence without solvents, streamlined manufactruing



ETRAVIRINE CHALLENGES

High TM compound - 270°C

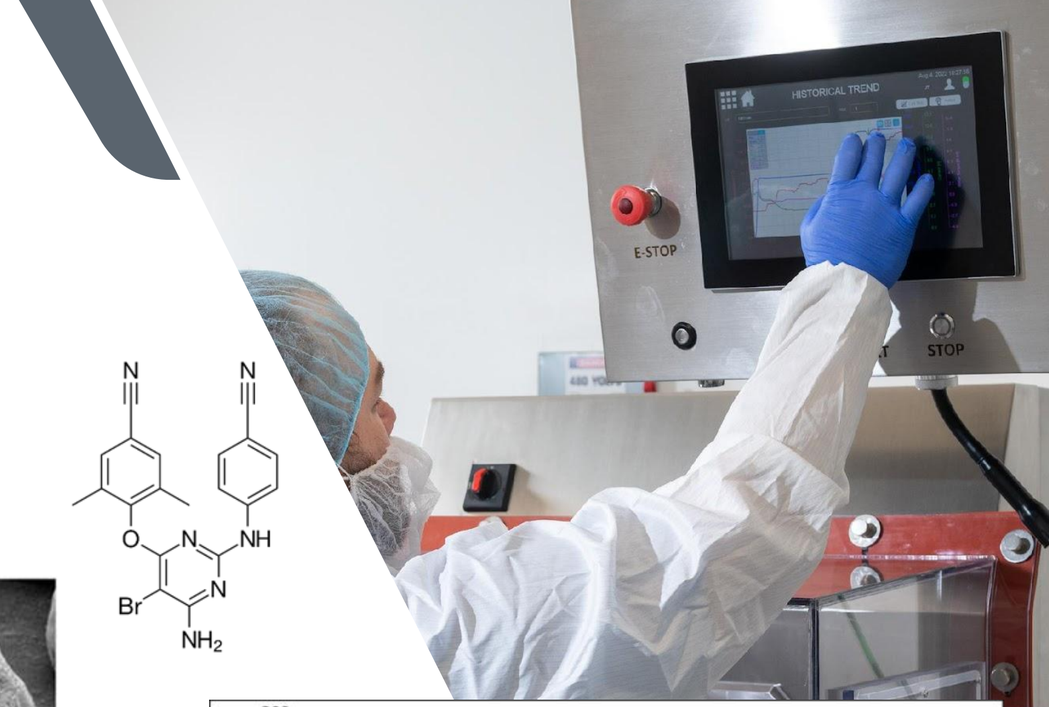
Highly thermally labile degrades before melt

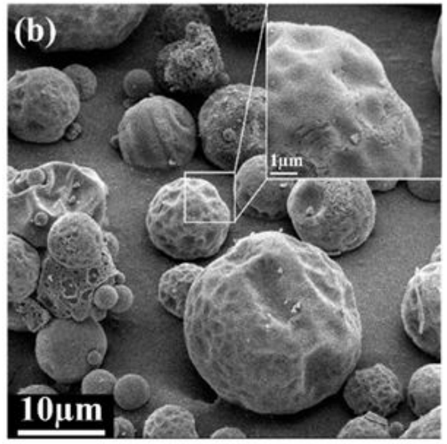
Highly insoluble - <<1 µg/mL

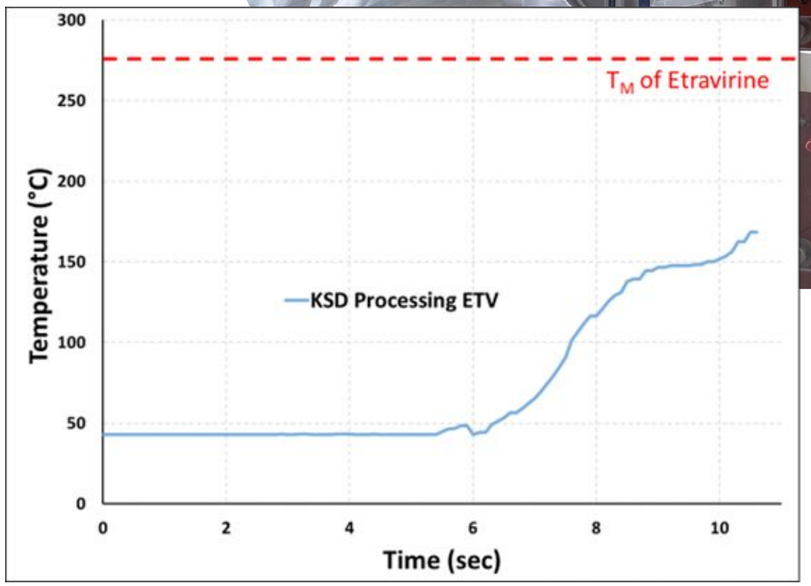
Poorly permeable – Caco-2 < 1x10-6

Unique SDD particle properties – MCC core

Minimally thermoplastic carrier polymer – HPMC







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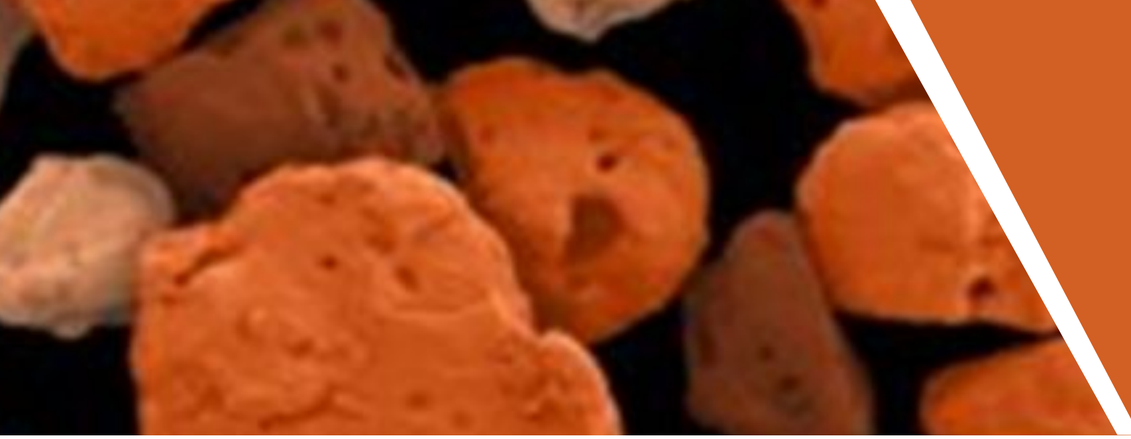
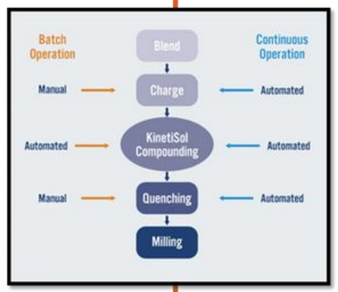


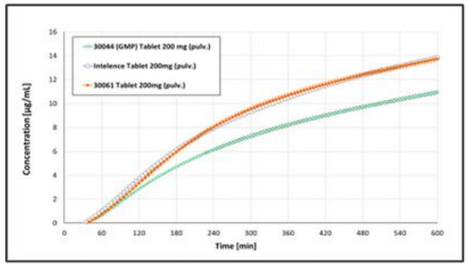
KETV: GRAMS TO KILOGRAMS TO METRIC TONS



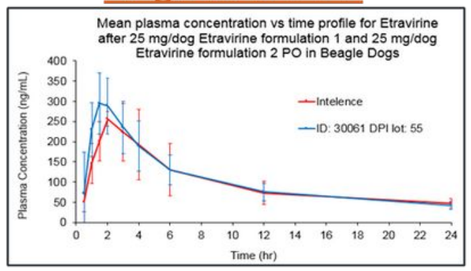
Development

Manufacturing

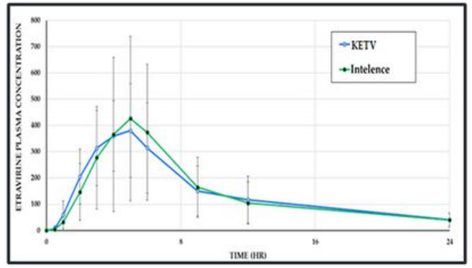
In-Vitro Flux



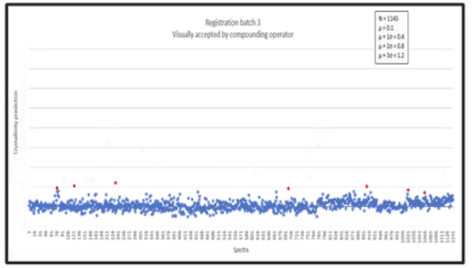
Dog PK Studies



Human PK Studies



Registration Manufacturing



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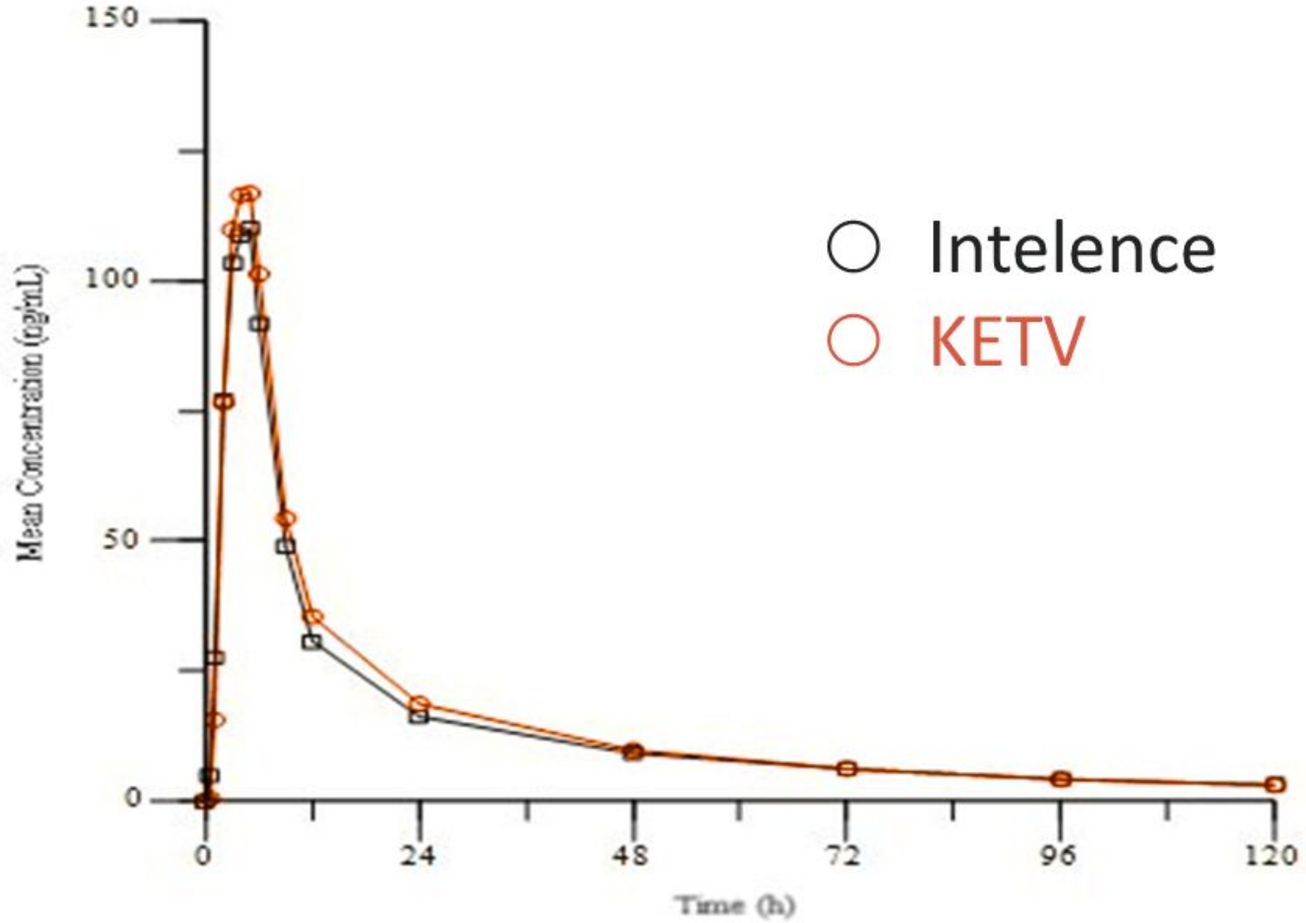
PIVOTAL HUMAN BE STUDY - FASTED

KETV vs. Intelence (n = 36)



Superimposable PK Profiles in the Fasted (true) Absorption State

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INTELENCE MANUFACTURING REVISITED

High ASD loading per tablet

Intelence Commercial Spray Dyring vs. KinetiSol

Metric	Units	Spray drying	KinetiSol
Total solids processed (ETV + HPMC)	kg	4,992	4,992
Total mass processed (ETV + HPMC + DCM + MeOH)	kg	91,659	4,992
DCM consumption	kg	78,000	0
MeOH consumption	kg	8,667	0
Total nitrogen conditioned (heat/cool/heat)	kg	567,195	0
ASD Processing time	hr	454	250
Secondary drying time	hr	25	0
Total ASD production time	hr	479	250

To produce 5 metric tons of KSD requires:

- ~~78~~ **0** metric tons DCM
- ~~8.67~~ **0** metric tons EtOH
- ~~567~~ **0** metric tons of N_2 conditioned
- ~~479~~ **250** hours of production time

Translating to tablets requires

- **No** Secondary drying
- **No** Roller compaction (**no** excipient dilution)
- Direct to tableting
- Only 25% external phase

Environmentally and Economically **Friendly** Process

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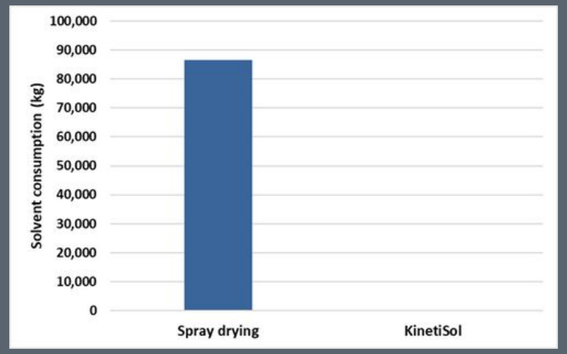
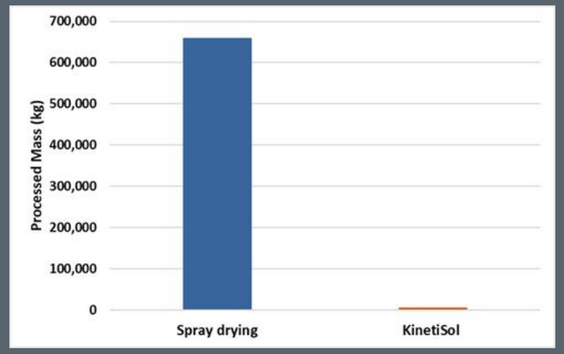
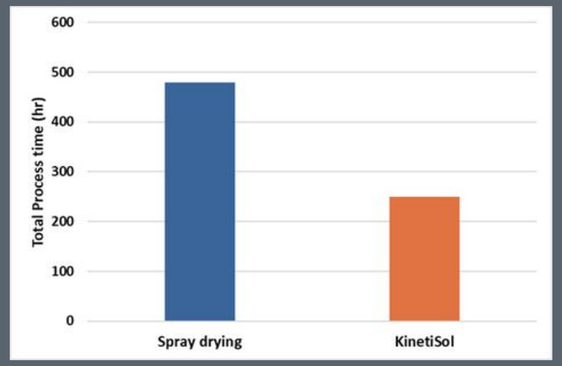
THE BOTTOM LINE....

Which would you rather???







Solvent Consumption

No Solvents - eliminates supply chain and regulatory risks

Total Process Mass

Dramatically reduced energy use and process time

Total Process Time

Together, these deliver a 30-50% reduction in COGS

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KINETISOL FOR LATE-STAGE ASD MANUFACTURING

Better, Simpler, Faster, Greener

KinetiSol in Action

Benefits

KinetiSol maximizes ASD performance

Lowers pill burden

Minimizes scale up risk

Eliminates solvents (literally tons)

Cuts manufacturing time and energy consumption

Portable, flexible, small-footprint – fits in common GMP suites

Standard utilities, not sophisticated solvent handling systems

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KINETISOL PROVIDES 30-50 % REDUCTION IN ASD COGS

BUILDING WHAT'S NEXT IN PHARMACEUTICAL MANUFACTURING

Critical Role of Strategic Outsourcing

Economic & environmental pressures are redefining what efficiency means in pharma

The CDMOs that lead through innovation, not just execution, will shape the next decade of development

KinetiSol proves that performance, affordability, and sustainability can work in harmony

The future of manufacturing is not just faster or cheaper.

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