AUSTINPx™
PHARMACEUTICS / MANUFACTURING

Tailoring Exposure for Efficacy:

Next Generation PK Optimization with KinetiSol™- Enabled BAE and CR Design

2026 CRBE Summit West
February 24th, 2026

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Chief Scientific Officer, AustinPx

KINETISOL™ TECHNOLOGY

20+ Years of Development and Clinical Testing

1997

Plastic Recycling Process

Innovative processing technology commercialized to solve plastic recycling challenges.

2007

Birth of KinetiSol

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

2008-Present

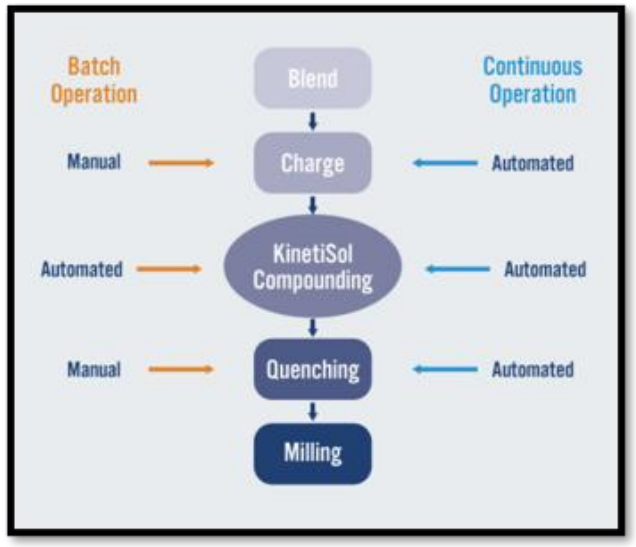
Advancing the Technology

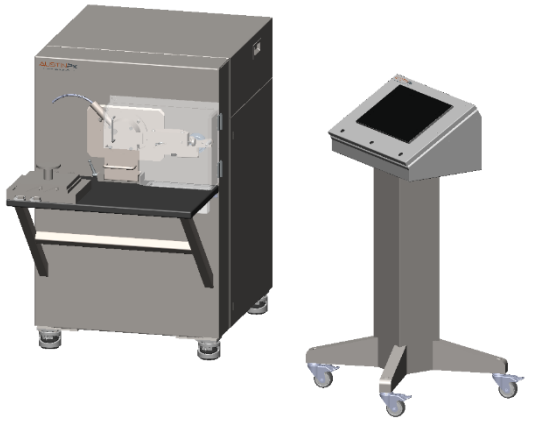
World-class engineering and pharmaceutical science applied to perfect the technology and formulation platform.

KINETISOL EQUIPMENT: RESEARCH TO COMMERCIAL SCALE

Small Footprint Translates to Lower Operational Cost

KINETISOL®





KinetiSol Formulator

- Lab Scale KinetiSol Equipment
- Preclinical to Phase I/II Scale
- Shot size range of 5-20g*
- Rate: 5-200 g/hr*

KinetiSol Compounder

- Large Scale Equipment
- Phase II to Commercial Scale
- PAT integration
- Shot size range 80-300g*
- Rate: Up to 20kg/hr*

*Shot size and rate of manufacturing are formulation dependent and established during process optimization.

THE KINETISOL PROCESS

Ultra High Shear Mixing

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

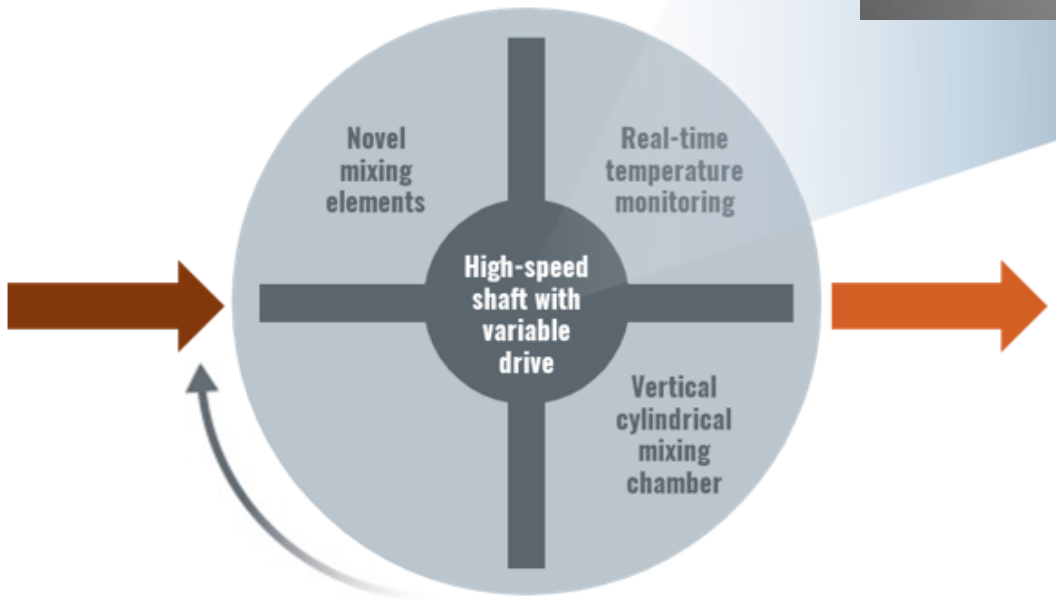
Input (blend)

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

KINETISOL FOR LATE-STAGE ASD MANUFACTURING

Scalable. Sustainable. Performance.

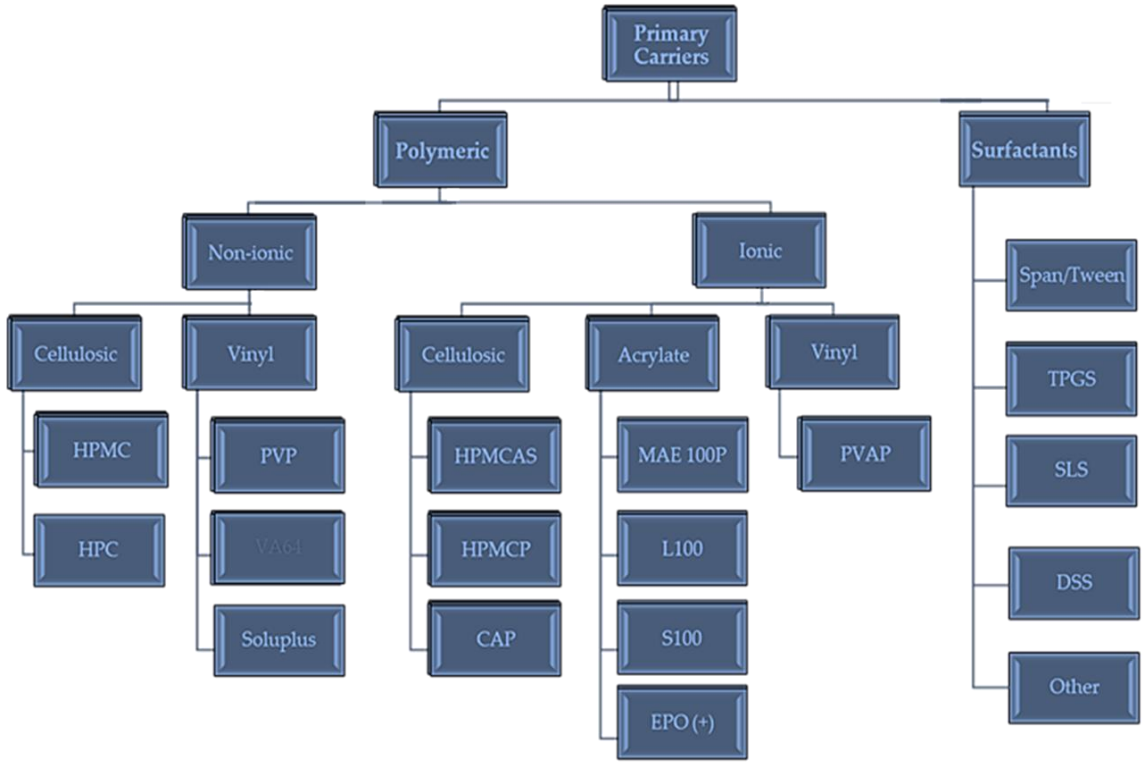
KinetiSol in Action

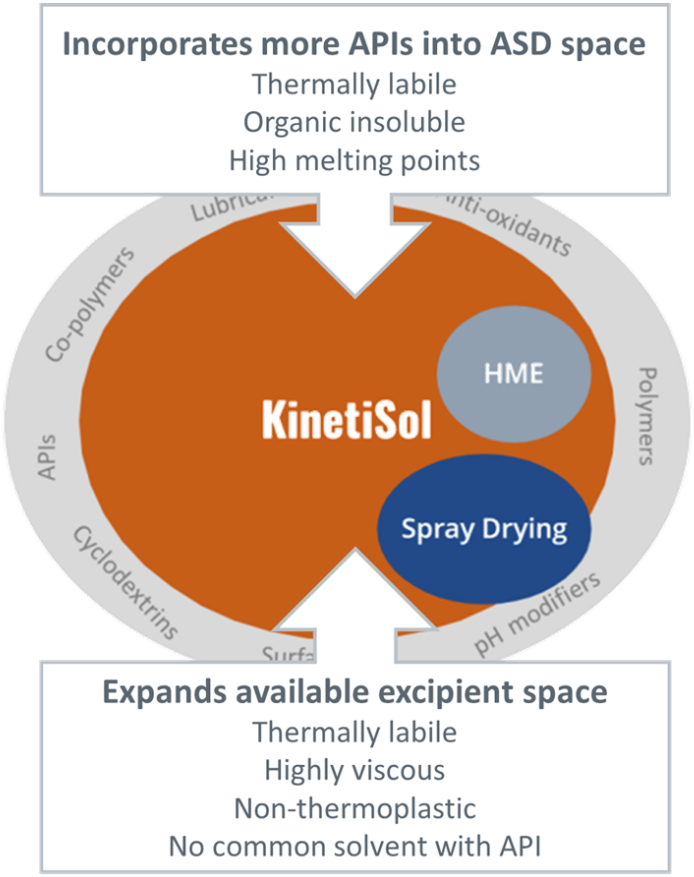
Benefits

- 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

KINETISOL: EXPANDING THE ASD DESIGN SPACE

Enabling broader API and excipient compatibility through alternative processing approaches





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KINETISOL: PARTICLE MORPHOLOGY

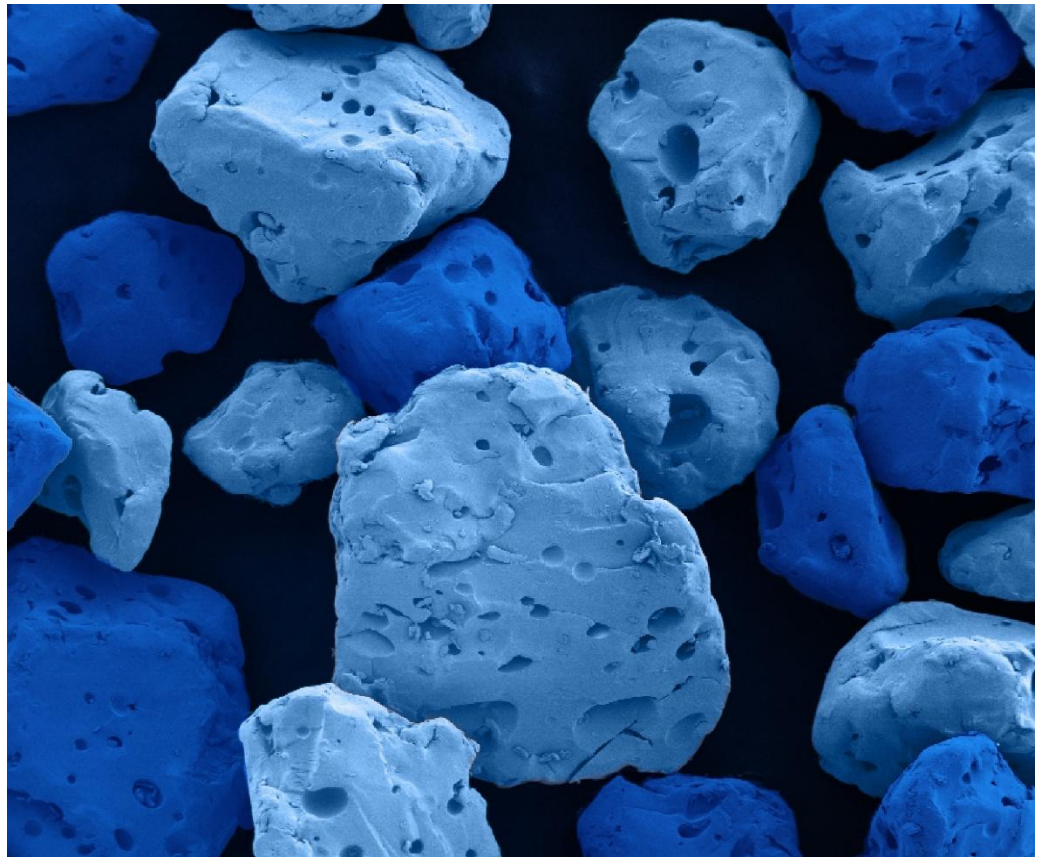
Porosity and density of particles leads to multiple ASD performance benefits

Tabletability Inherently porous, yet dense with excellent flow and compression properties

Excellent Compression properties with limited external phase excipients

Higher Exposure due to complete molecular mixing of drug in polymer and release mechanism from polymer

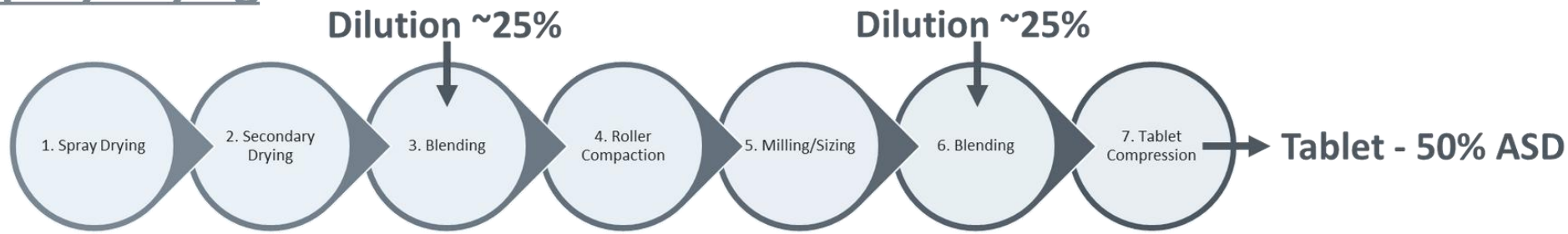
Reduced Pill Burden due to particle properties and higher ASD loading



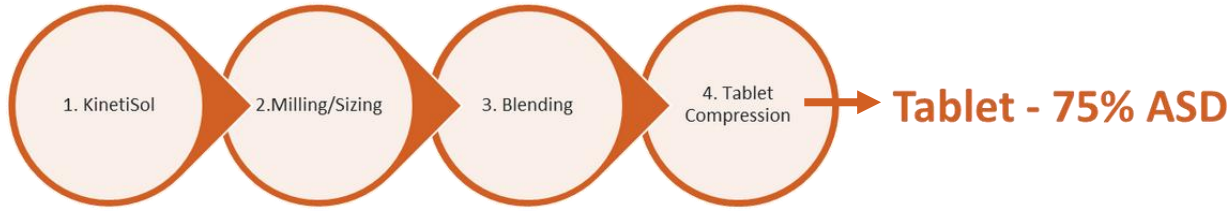
KINETISOL VS. SPRAY DRYING

Simplified Downstream Process Train Reduces Manufacturing Time, Costs and Risk

Spray Drying



KinetiSol



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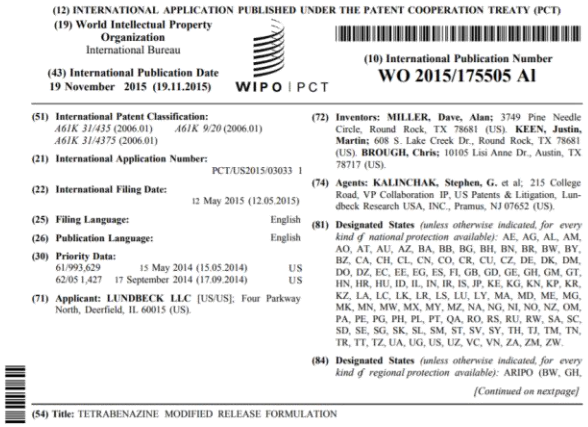
KINETISOL-ENABLED XENAZINE MR

PK Modification for Improved Patient Outcomes



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[Continued on nextpage]

(54) Title: TETRABENAZINE MODIFIED RELEASE FORMULATION

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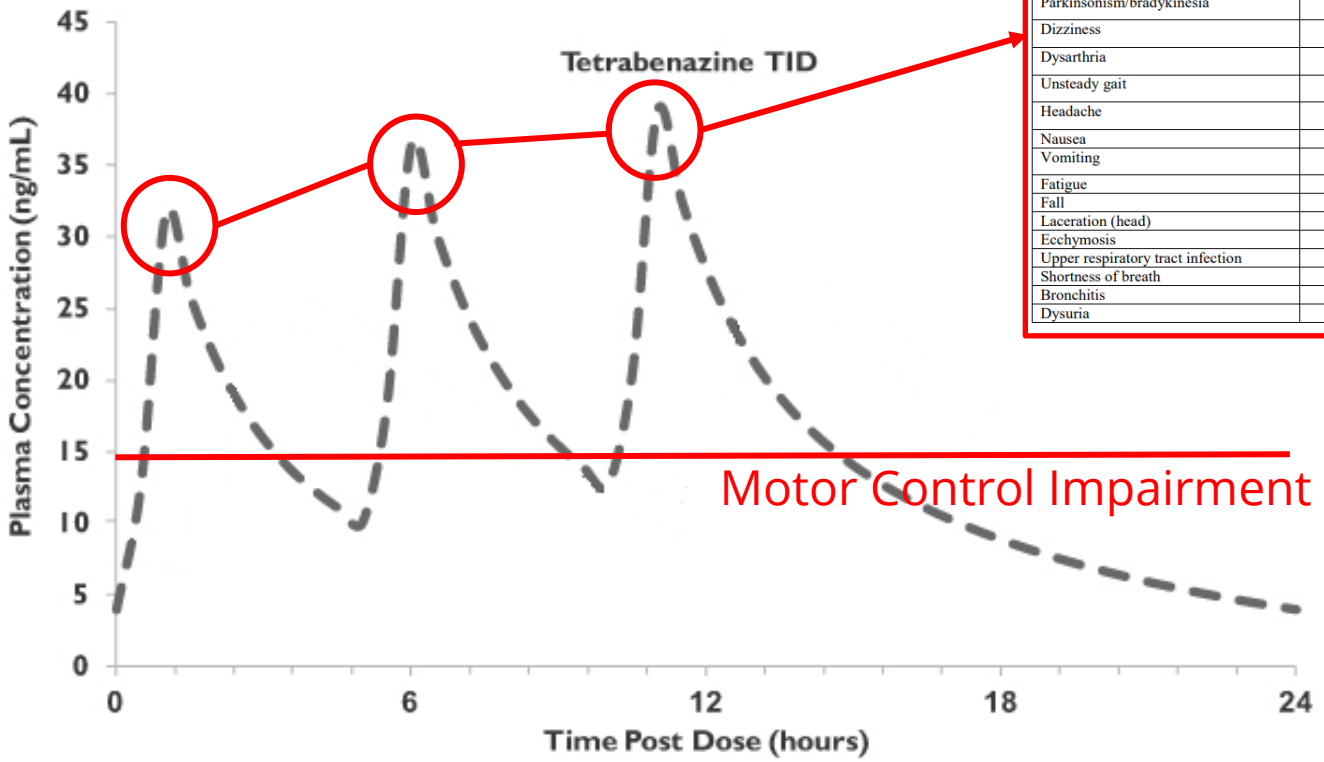
XENAZINE IR – SUBOPTIMAL FORMULATION

Frequent dosing, high side effects, limited efficacy

Adverse Reaction	XENAZINE n = 54 %	Placebo n = 30 %
Sedation/somnolence	31	3
Insomnia	22	0
Depression	19	0
Anxiety/anxiety aggravated	15	3
Irritability	9	3
Decreased appetite	4	0
Obsessive reaction	4	0
Akathisia	19	0
Balance difficulty	9	0
Parkinsonism/bradykinesia	9	0
Dizziness	4	0
Dysarthria	4	0
Unsteady gait	4	0
Headache	4	3
Nausea	13	7
Vomiting	6	3
Fatigue	22	13
Fall	15	13
Laceration (head)	6	0
Ecchymosis	6	0
Upper respiratory tract infection	11	7
Shortness of breath	4	0
Bronchitis	4	0
Dysuria	4	0



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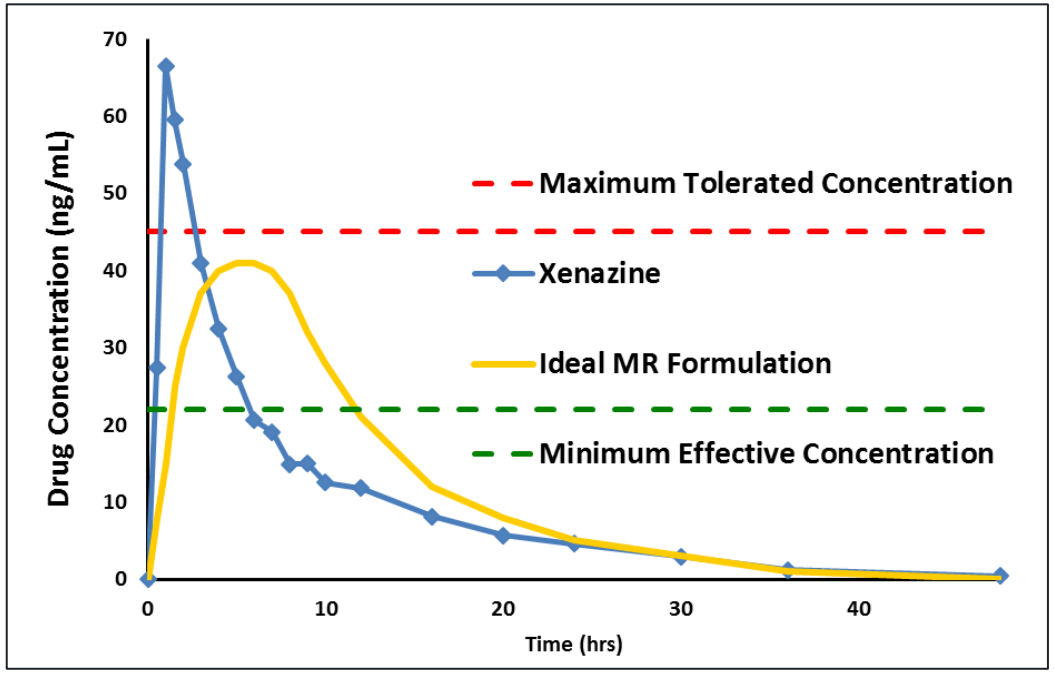
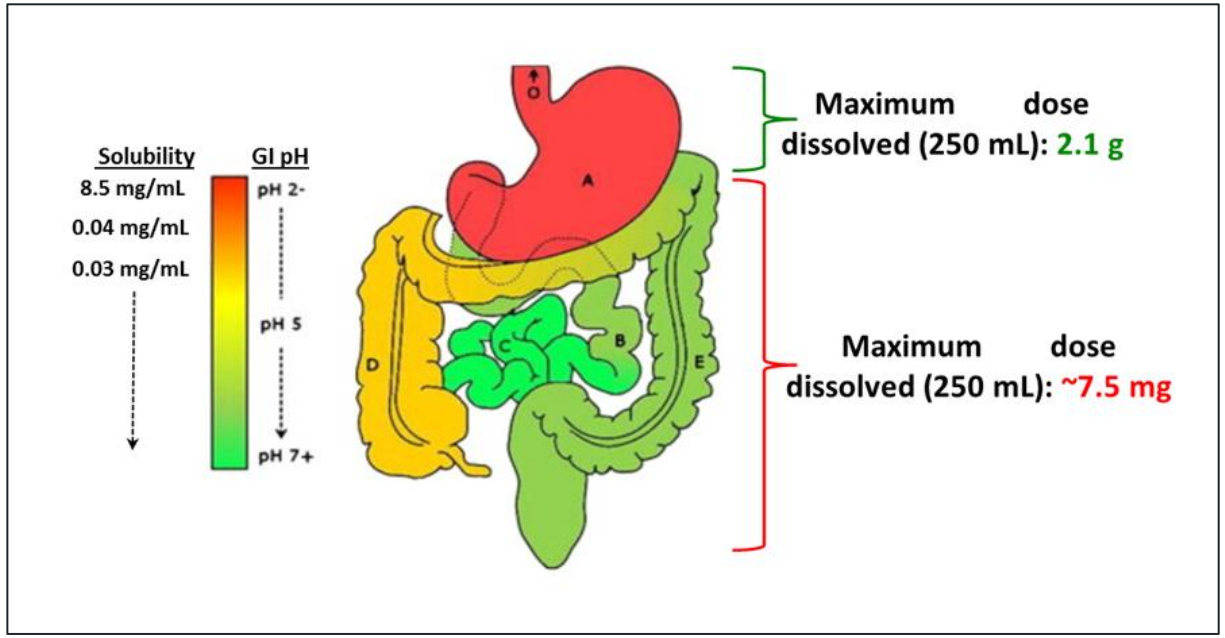
XENAZINE: DOSE LIMITING TOXICITY



- Dose titrated up to onset of AEs, then down to next lowest dose
- Most efficacious dose can't be administered
- Rapid elimination leads to frequent dosing and AEs
- Need MR formulation for:
  - **Reduced C_{max} with equivalent AUC**
  - **Reduced dosing frequency**
- Extensive prior efforts all failed

PH-DEPENDENT SOLUBILITY

PRIMARY BARRIER FOR MR DELIVERY



- Good solubility in gastric fluid
- Poor solubility in intestinal fluid
- Stomach-to-Small Intestine: near 300-fold decrease in solubility
- **How does one control release in stomach and enhance release in the intestinal tract?**

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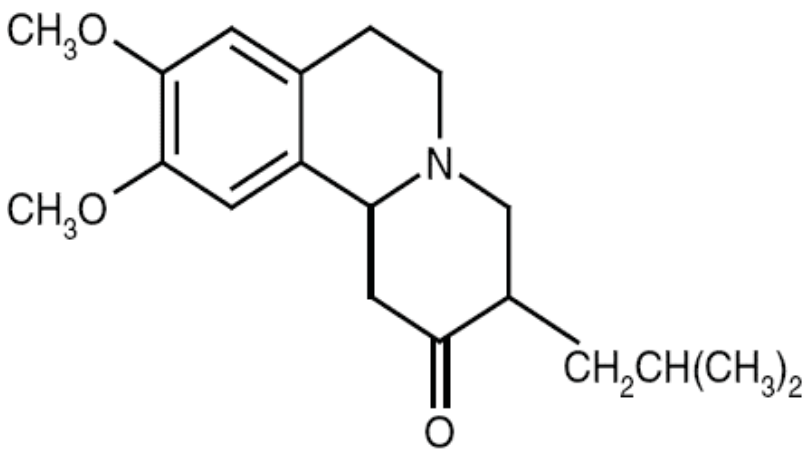
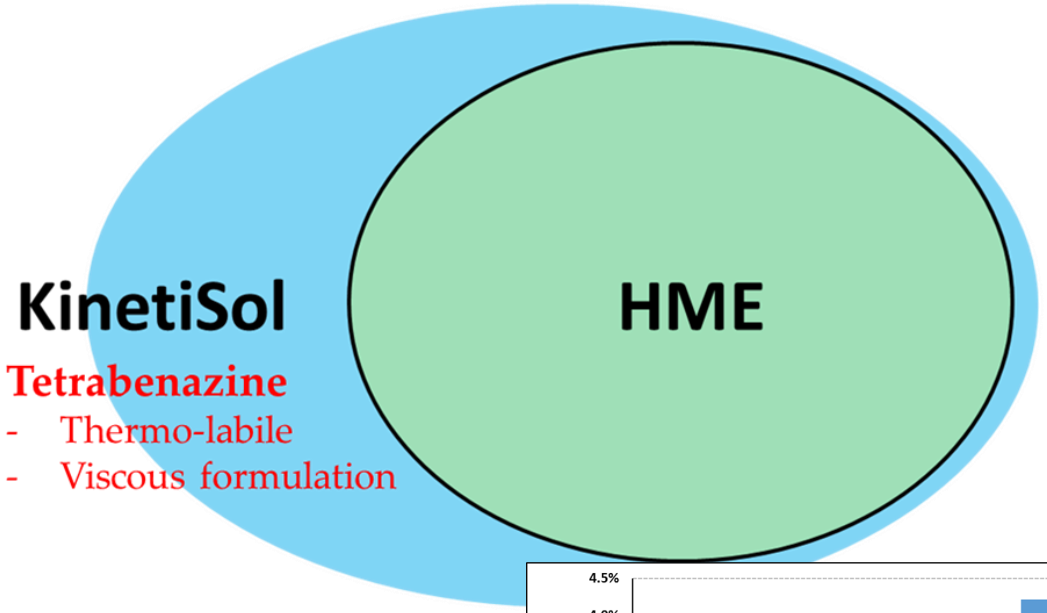
TETRABENAZINE: KEY PHYSICO-CHEMICAL PROPERTIES

TBZ: Physiochemical Properties	
Indication	CNS
Melting Point	130 °C
Solubility	< 30 µg/mL (pH > 3)
LogP	3.3
pKa	6.5
Key Issue	Very thermally sensitive, degrades in protic solvents
BCS Class	II

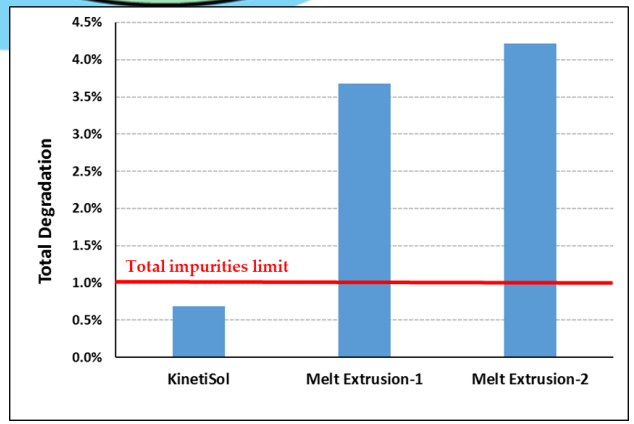


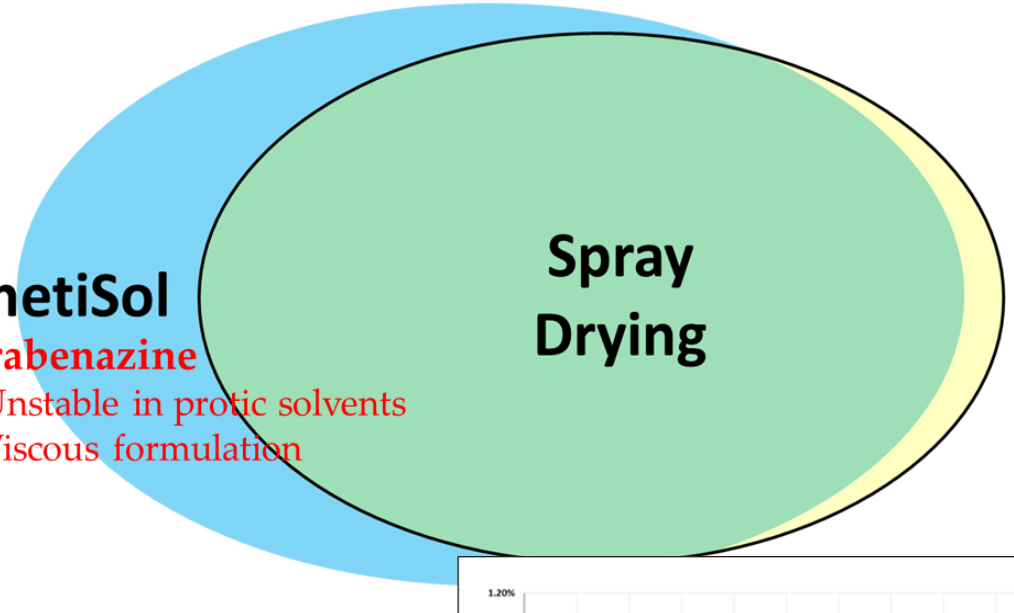
WHY KINETISOL FOR TETRABENAZINE?



Tetrabenazine

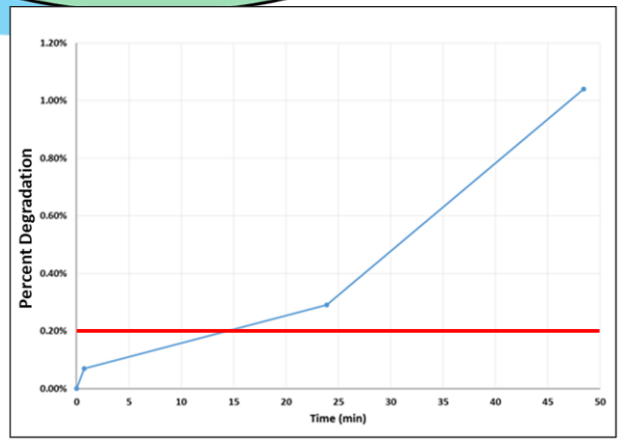
- Thermo-labile
- Viscous formulation





Tetrabenazine

- Unstable in protic solvents
- Viscous formulation



KINETISOL FORMULATION DESIGN SPACE

ENABLES XENAZINE MR

Unique Features

- Seven-component ASD formulation
  - 1 modified release polymer varied by MW
  - 1 IR polymer
  - 3 anti-oxidants acting synergistically
  - 1 lubricant/stabilizing agent
- 98% ASD in final tablet
- ASD tablet with MR profile
- Strong IP position

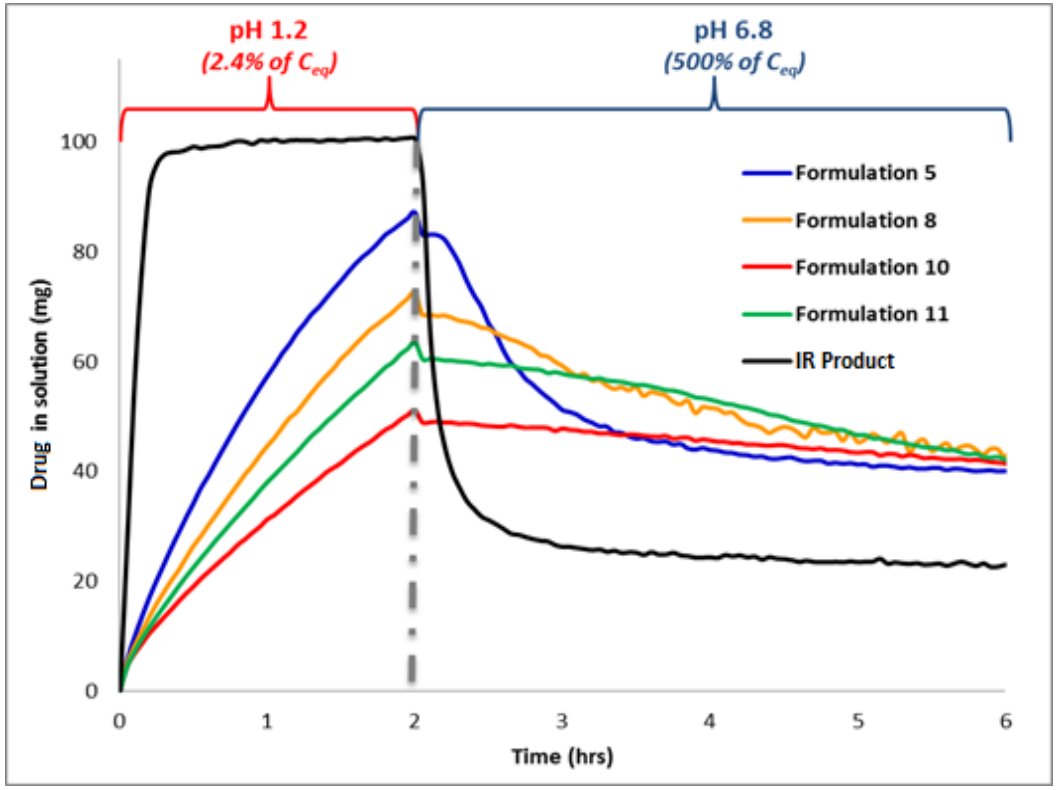
	Component	*% w/w*	*mg/tablet*
Amorphous Intermediate	Tetrabenazine	19.6	25.0
	Methocel E 15	54.2	69.1
	Kollidon VA 64	17.2	22.0
	Butylated Hydroxyanisole	0.8	1.0
	Butylated Hydroxytoluene	0.3	0.4
	Sodium Ascorbate	3.9	5.0
	Allubra-PG 100	2.0	2.5
External Phase	Aerosil 200	1.0	1.3
	Allubra-PG 100	1.0	1.3
	Totals	100.0	127.6

	Component	*% w/w*	*mg/tablet*
Amorphous Intermediate	Tetrabenazine	19.6	25.0
	Methocel E 50	35.7	45.6
	Kollidon VA 64	35.7	45.6
	Butylated Hydroxyanisole	0.8	1.0
	Butylated Hydroxytoluene	0.3	0.4
	Sodium Ascorbate	3.9	5.0
	Allubra-PG 100	2.0	2.5
External Phase	Aerosil 200	1.0	1.3
	Allubra-PG 100	1.0	1.3
	Totals	100.0	127.6

KINETISOL ENABLED REFORMULATION

LEVERAGING IN-VITRO AND IN-VIVO TOOLS

Non-Sink, Gastric Transfer Dissolution Testing



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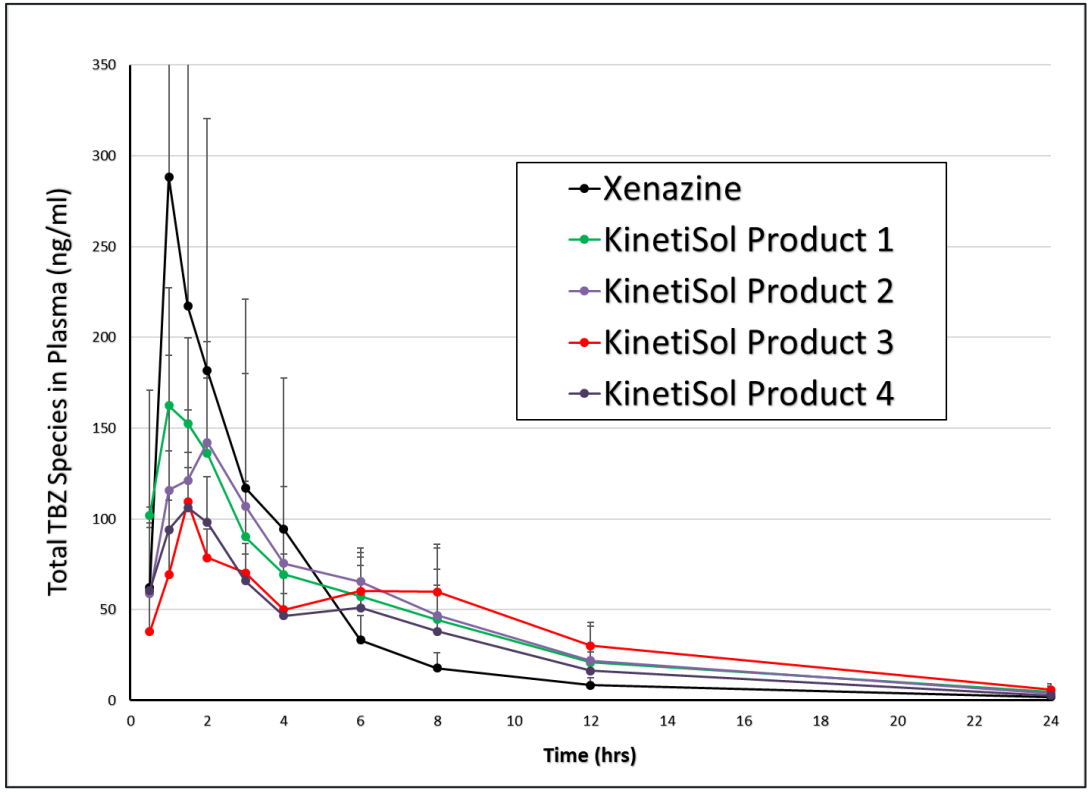
Pharmacokinetic Analysis in Dogs



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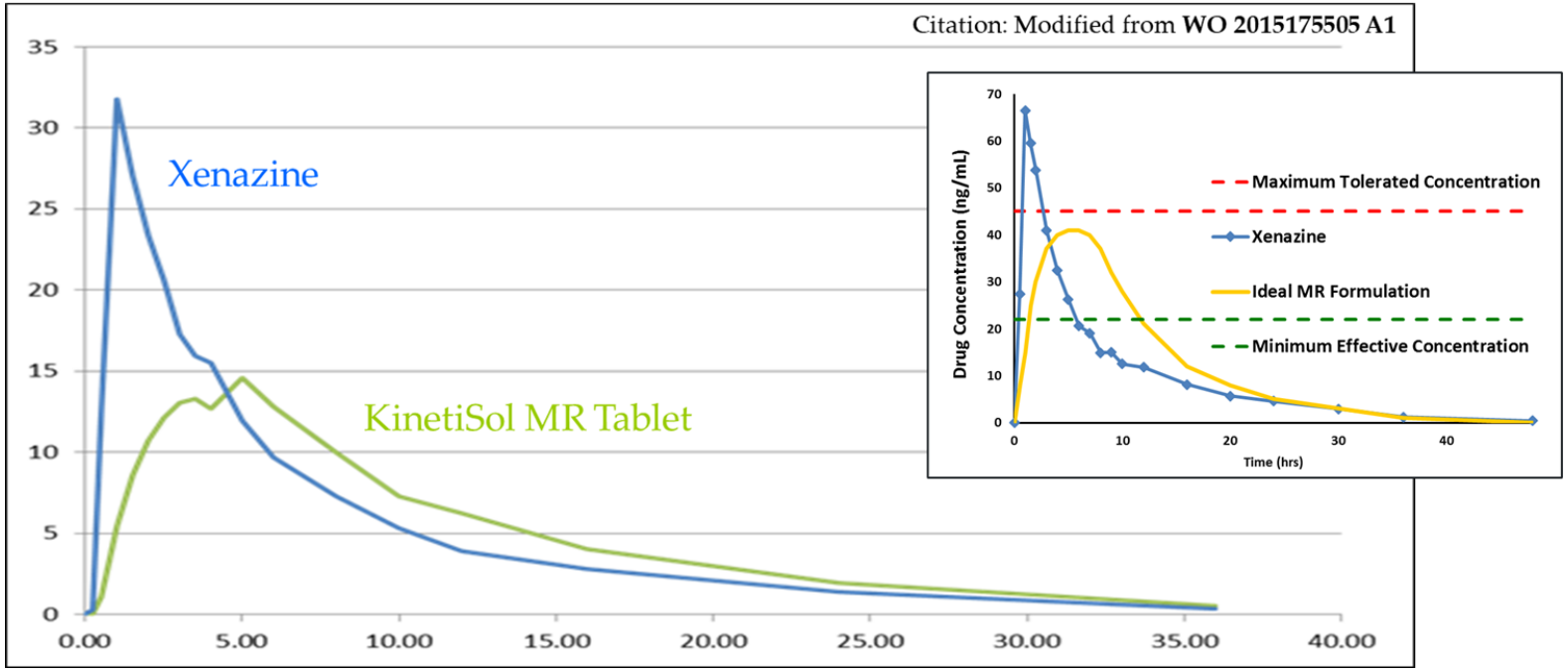
HUMAN PK COMPARISONS

KINETISOL MR VS. XENAZINE IR

KinetiSol achieved the unattainable MR profile



- The KinetiSol MR tablet blunted C_{max} by 50% with equal AUC to Xenazine
- Enables higher dose titration for **significantly improved efficacy and safety**

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Q&A SESSION

THANK YOU!!!

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