



SAN DIEGO SITE

# Facility Facts



# San Diego, CA

**Potency Capability:** Up to Category 3A  
CDMO Footprint: 24,400 square feet

**DEA Controlled Substance Registrations:**

- Manufacturer: Schedules III, IV, V, List I
- Analytical Lab: Schedules II, IV, V, List I

**Specializations:** Sterile product manufacturer, solutions in vials, lyophilization, implants (compressed and molded), liposomes, micro and nano particulate suspension, liquid filled hard gelatin capsules, modified release technology, phase-appropriate formulation and analytical development, complex formulations, and controlled substances

# SD Site Potency Capability (SafeBridge ≤ 3a)

CRITERIA	CATEGORY 1	CATEGORY 2	CATEGORY 3A	CATEGORY 3B	CATEGORY 4
OEL Range	> 500 mcg/m <sup>3</sup>	500 mcg/m <sup>3</sup> - 10 mcg/m <sup>3</sup>	10 mcg/m <sup>3</sup> - 1 mcg/m <sup>3</sup>	1 mcg/m <sup>3</sup> - 0.1 mcg/m <sup>3</sup>	< 0.1 mcg/m <sup>3</sup>
Potency	>100 mg/day	10 mg - 100 mg/day	1 mg - 10 mg/day	0.1 mg - 1 mg/day	< 0.1 mg/day
Clinical Effects	none to minor	minor to moderate	moderate	moderate to severe	severe
Acute Toxicity	none to mild	moderate	moderate	moderate to severe	extreme
Skin or Eye Irritation	mild to moderate	moderate	moderate to severe	severe to corrosive	severe to corrosive
Sensitization Potential	none	weak to mild	moderate	moderate to severe	extreme
Chronic Toxicity	minimal	moderate	severe	severe	severe
Reversibility	reversible	reversible	irreversible	irreversible	irreversible
Mutagenicity / Genotoxicity	none	none - (+) Ames test	(+) in a battery of studies	(+) in a battery of studies	(+) in a battery of studies
Human Carcinogenicity Potential	negative	positive in animal studies not relevant to humans	probable - confirmed animal	probable - confirmed animal; suspected human	confirmed animal - human
Reproductive Toxicity	none	mild	moderate	severe	severe
Developmental Toxicity	none	some effects seen with maternal toxicity	moderate	moderate	severe
Absorption	minimal	moderate	significant	significant	significant
Warning Properties	good	fair to none	poor to none	poor to none	poor to none
Speed of Onset	immediate	immediate to delayed	immediate to delayed	immediate to delayed	immediate to delayed
Need for Medical Intervention	little to none	moderate (not life threatening)	Moderate to high	high (potentially life threatening)	high (potentially life threatening)
Other	none	none	Default band for materials of unknown toxicity*	Default band for materials of unknown toxicity and suspected highly hazardous*	may affect sensitive subpopulations

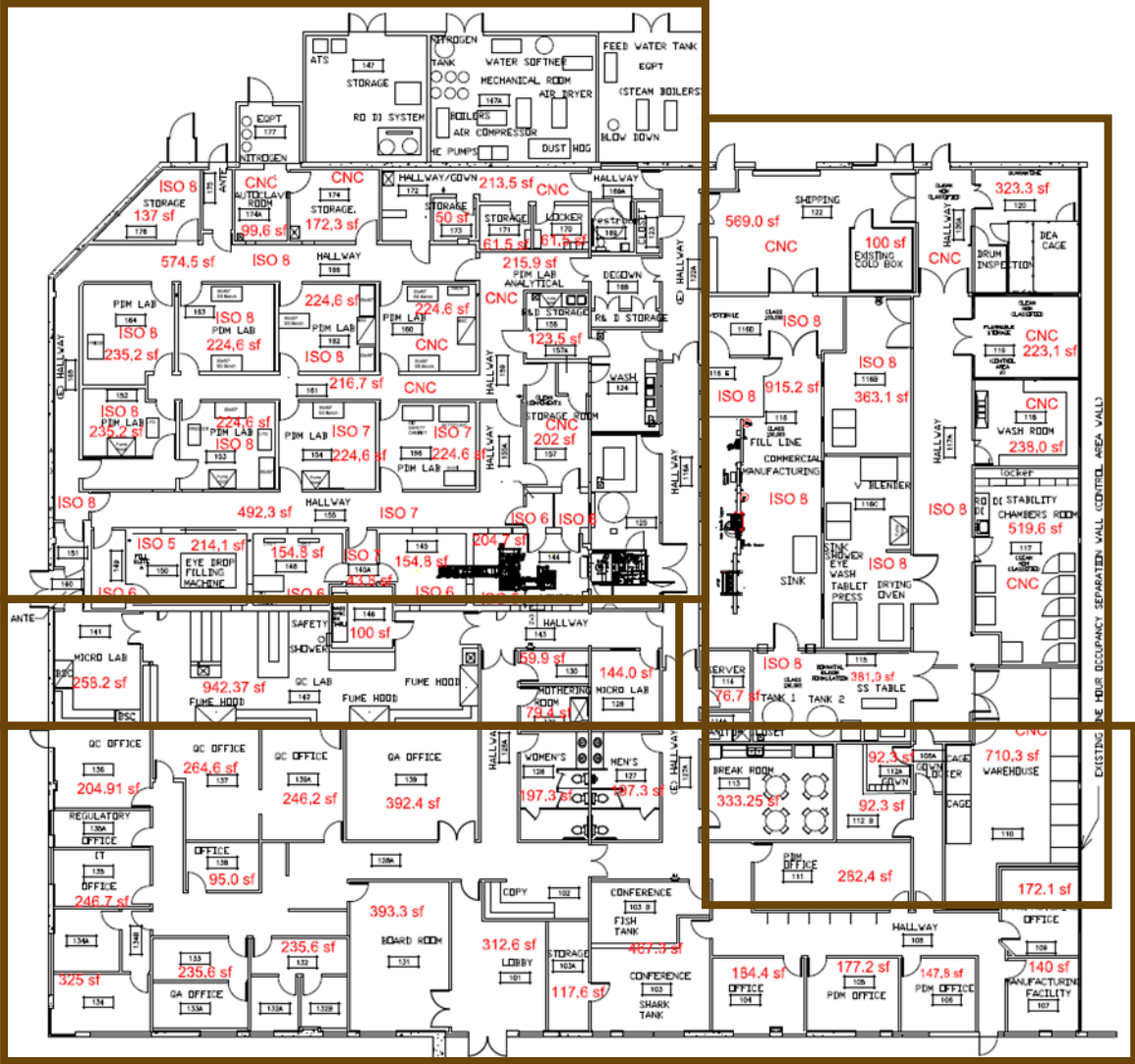


# Facility Footprint

Clinical Manufacturing  
Sterile Fill/Lyo  
Facilities/Utilities

QC Chemistry  
QC Microbiology

Office Area



Commercial Manufacturing  
Warehouse  
Stability Chambers

**Capabilities**



# Concept Through Commercialization

Formulation & Process Development	Analytical	Quality Assurance & Regulatory Compliance
Physicochemical characterization	Method development, verification & validation	Assistance with end-to-end filing strategies
Excipient compatibility	Raw material release	Early-stage regulatory guidance
Dosage form design	In-process testing	Late phase/NDA consultation
Solubility assessment	Finished product release testing	Preparation of regulatory documentation
Process design & optimization	Cleaning method development	eCTD submission ready
Scale-up & technology transfer	ICH stability & photostability	FDA meeting support
<b>Manufacturing &amp; Packaging</b>	Clinical through Commercial: sterile products, solutions in vials, lyophilization, suspensions/microparticles/nanoparticles, liposomes, oral solutions, topical gels, ointments, creams and lotions, liquid/powder filled capsules, functional/non-functional film coating, packaging (serialized bottles, blisters and sachets)	

# Production

Dosage Type	R&D	Phase 1 & Phase 2	Phase 3 & Commercial
Sterile Vial Filling	10s to 1000s with batch sizes of 10s of mL to 500 L	10,000 dosage units/day from 2 mL to 50 mL with batch sizes of 20 L to 500 L	
Sterile Lyophilization:	Small lyophilizer – 600 10 mL vials, Large lyophilizer – 9000 vials of 10 mL	Small lyophilizer – 600 10 mL vials, Large lyophilizer – 9000 vials of 10mL	
Sterile Liposomes and Nanoparticles:	250 mL to 1 or 2 L	250 mL to 1 or 2 L	
Sterile Ophthalmic Droppers:	50 mL to 30 L	1000s to 10,000s of 3 mL droppers (automatic filling machine)	
Oral Liquids (solutions, suspensions):	50 mL to 30 L	Up to 4000 L per batch packaged in round bottles from 10 mL to 500 mL	Up to 4000 L per batch packaged in round bottles from 10 mL to 500 mL, labeled and serialized
Liquid/semi-solid filled capsules (bioavailability enhancement) or powder filled capsules:	100s to 1000s of capsules	1000s to 10,000s of capsules (automatic filling machines for both liquids/semi-solids and powders)	
Topical Gels, Ointments, Creams, Lotions	50 mL to 30 L	Up to 30 L per batch packaged in jars, tubs, syringes, or sachets from 1 mL to 500 mL	
Single Layer Tablets	100s to 1000s of tablets	1000s to 10,000s of tablets (rotary tablet machine)	100,000s to 1,000,000s of tablets packaged in bottles, labeled and serialized



# Formulation Development

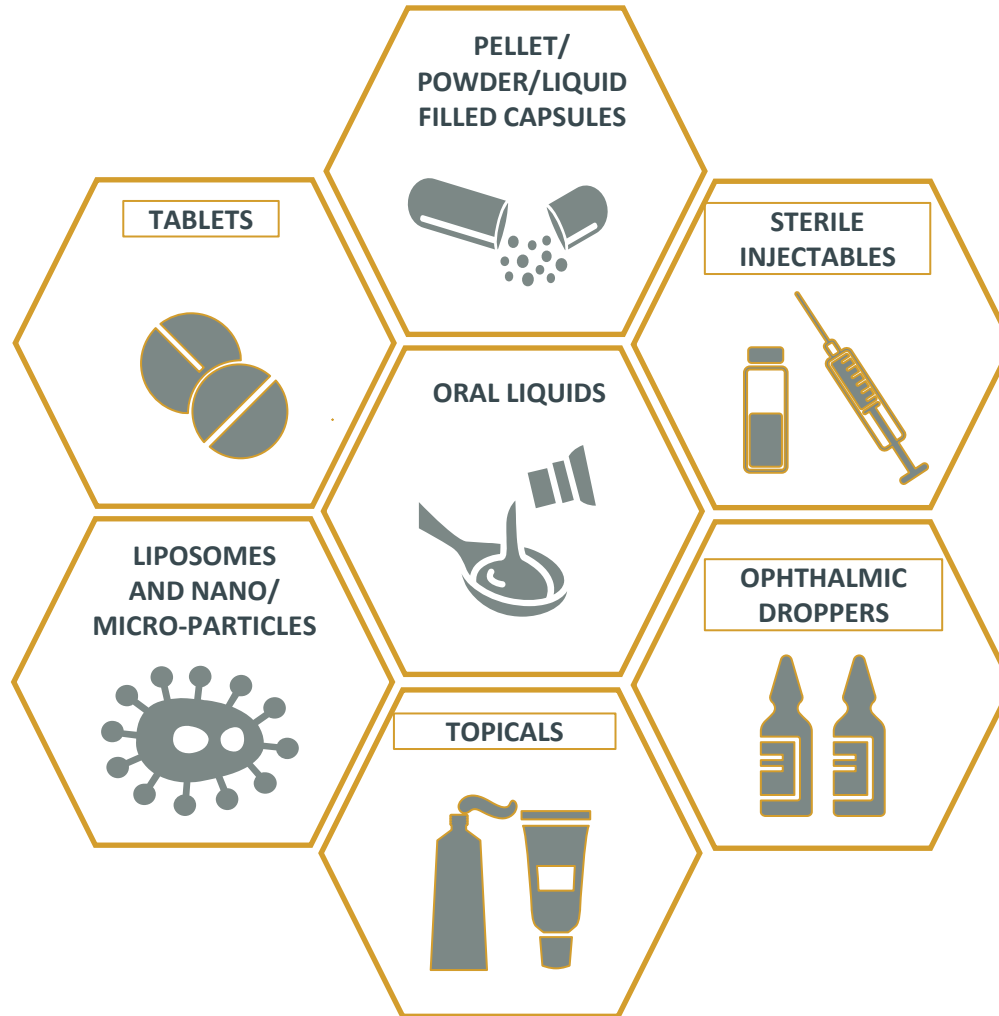
# Dosage Form Capabilities

## Development

Simple to complex formulation approaches

Modified Release (MR) technology

Phase-appropriate analytical approaches



## Manufacturing



DEA-regulated and high potency compounds

Regulatory guidance and support from concept through commercial

Flexible-scale clinical and commercial manufacturing and packaging

# Analytical Development



# Testing Capabilities



Waters U/HPLC with TUV,PDA, RI, MS, QDa, QTOF detectors



Titrator



GC/FID with Headspace



Dissolution



Malvern ZEN5600 Particle Size Analyzer

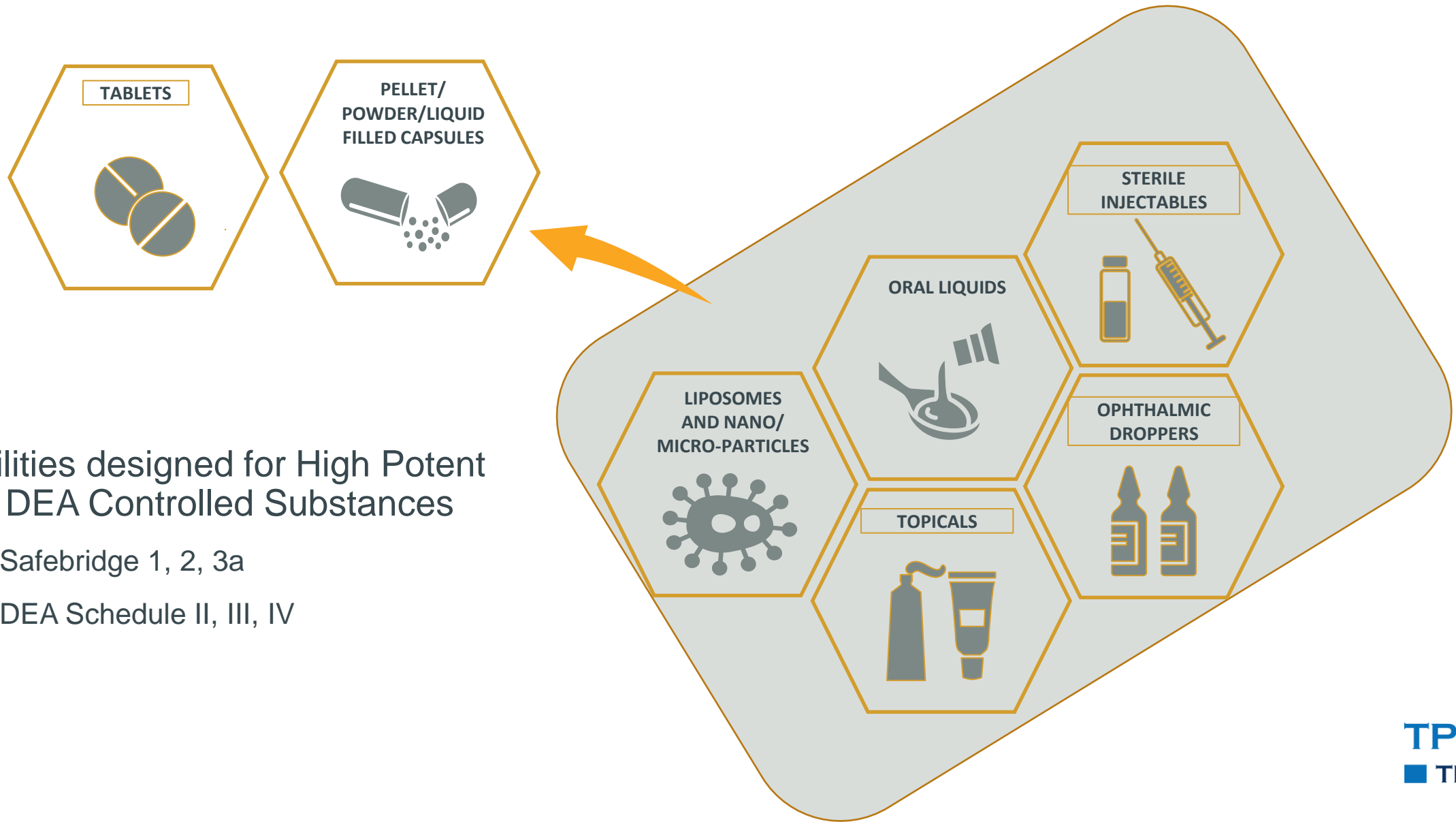
# Phase Appropriate Analytical Method Validation

Method Validation Parameter	Assay / Impurities / Dissolution		
	Phase I	Phase II	Phase III
System suitability	X	X	X
Accuracy	X	X	X
Precision – Repeatability	X	X	X
Intermediate precision - Reproducibility			X
Specificity	X	X	X
Detection limit			X
Quantitation limit			X
Linearity and range	X	X	X
Robustness			X
Forced degradation (drug product)			X
Solution stability	X	X	X

# Oral Solid Dosage



# Oral Solid Dose



- Facilities designed for High Potent and DEA Controlled Substances
  - Safebridge 1, 2, 3a
  - DEA Schedule II, III, IV

# Simple to Complex Formulations

- Single layer tablets
- Controlled/sustained release
- Multiparticulates
- Pellets
- Powder





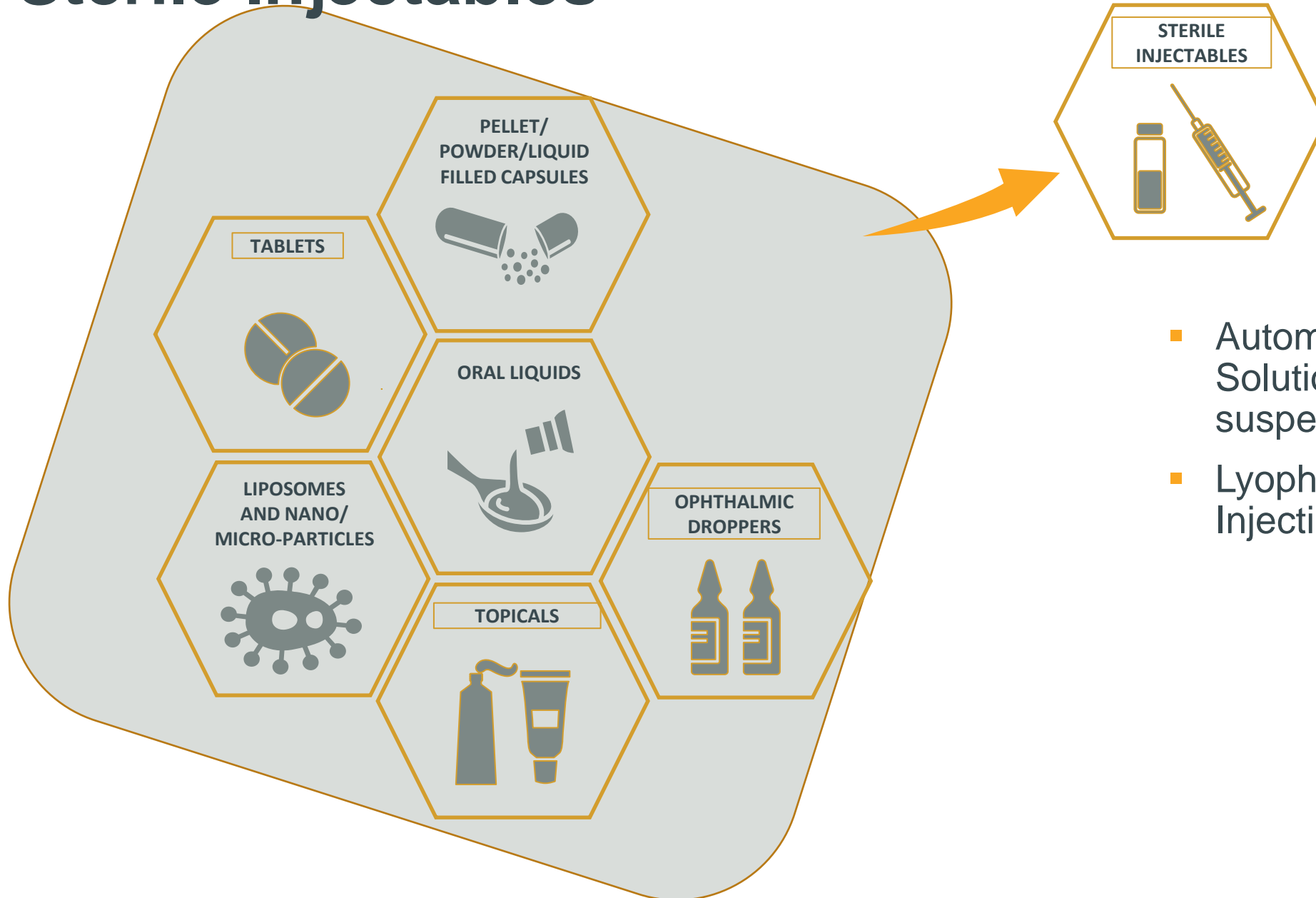
# Oral Solid Formulation Development

- Capabilities from bench top scale to pilot plant scale
  - Blending
  - Dry Granulation
  - Roller compaction
  - Milling
  - Tablet compression



# **Sterile Fill/Finish and Lyophilization**

# Sterile Injectables



- Automated Filling Line for Solutions and Nano-suspensions
- Lyophilized Powder for Injection

# Sterile Formulation

- Batch sizes from 30L to 500L
- Single use disposable systems using Pall Magnetic mixer
- Small and large molecules
- Safebridge 1, 2 and 3a

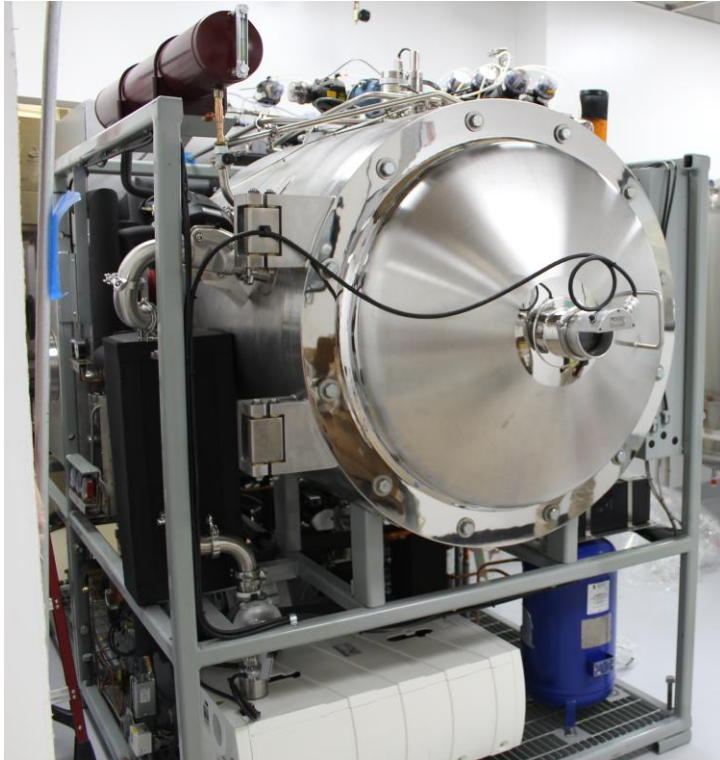


# Fill/Finish

- i-DOSiTECHNO automated vial filling up to 2,000 units per hour
- 100% checkweigh control of container fill volumes
- Automatic Tray Loader
- RABs
- Presterilized vials and stoppers
- Fills 2mL – 50mL vials
- Standard cap size 13mm and 20mm



# Lyophilization



- SP LyoGalaxy S50 Freeze Dryer
- Capable of holding ~9,000 10mL vials
- Typical freeze-drying cycles of 3-5 days
- Controlled nucleation technology

ControLyo® is a novel, patented approach to uniformly and instantaneously induces nucleation within a freeze-dryer via pressurization and depressurization

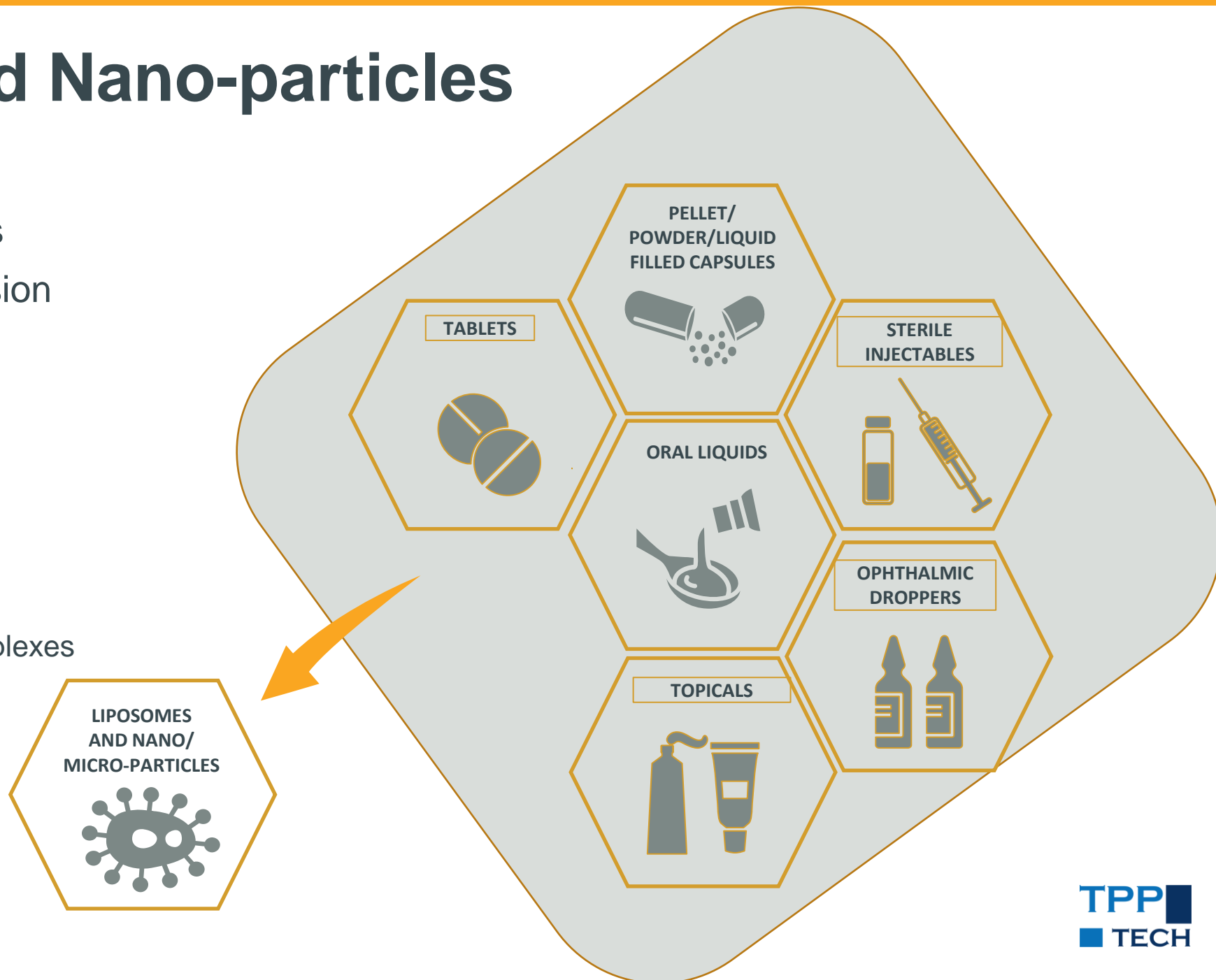
- Increase in cake pore size and subsequent reduction in dry layer resistance
- Faster Primary Drying
- Reduced freezing stress on biologicals
- Reduced reconstitution times
- Drying time optimization
- Improved cake appearance
- Reduced protein aggregations

# Other Formulations

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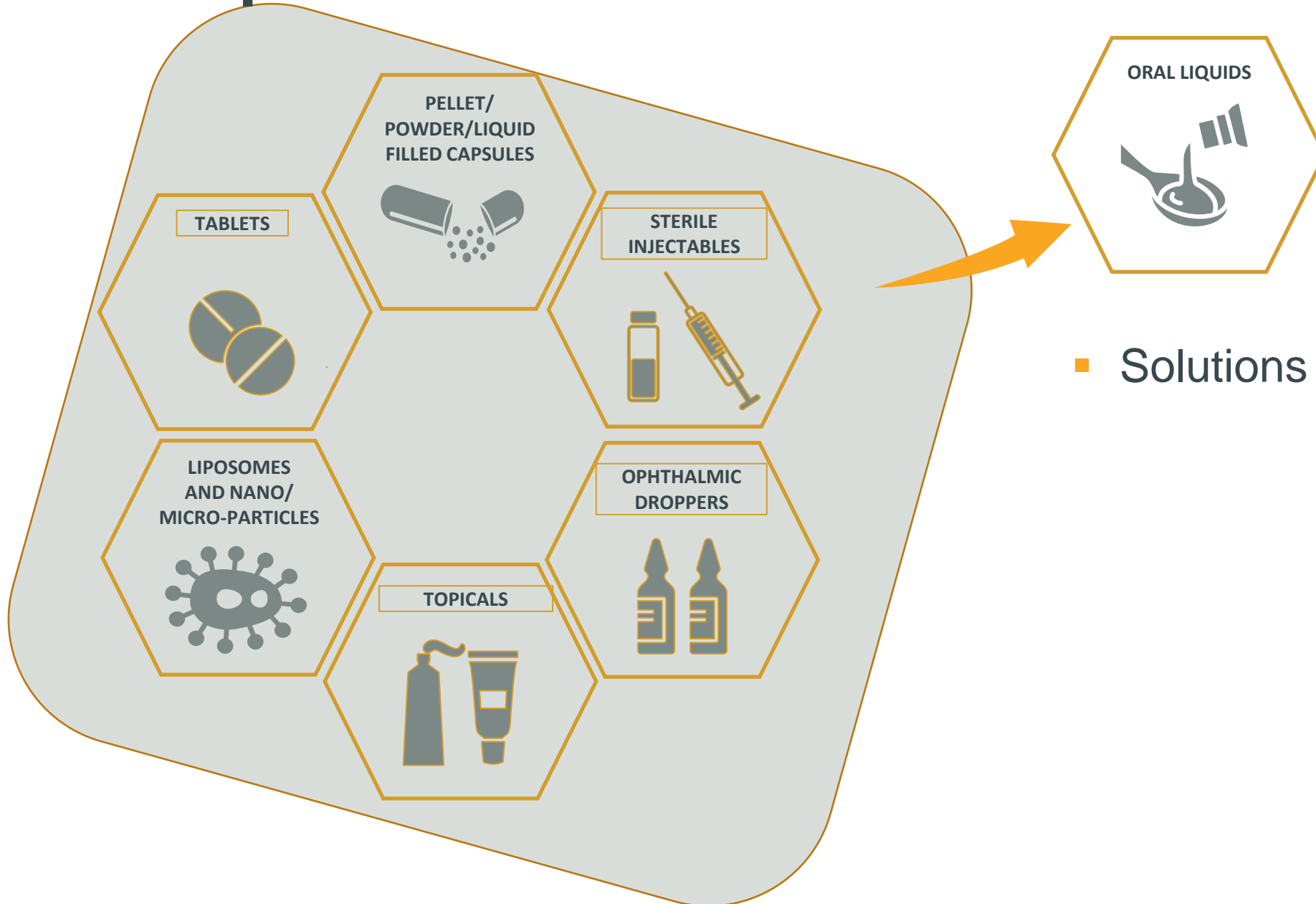
# Liposomes and Nano-particles

- Long-acting microspheres
- Long-acting nanosuspension
  - Ball milling
  - Aseptic manufacturing or terminal sterilization
- Liposomes
  - Small molecules
  - Peptides
  - Proteins
  - Small molecule-Protein complexes
  - Oligonucleotides
  - RNAs



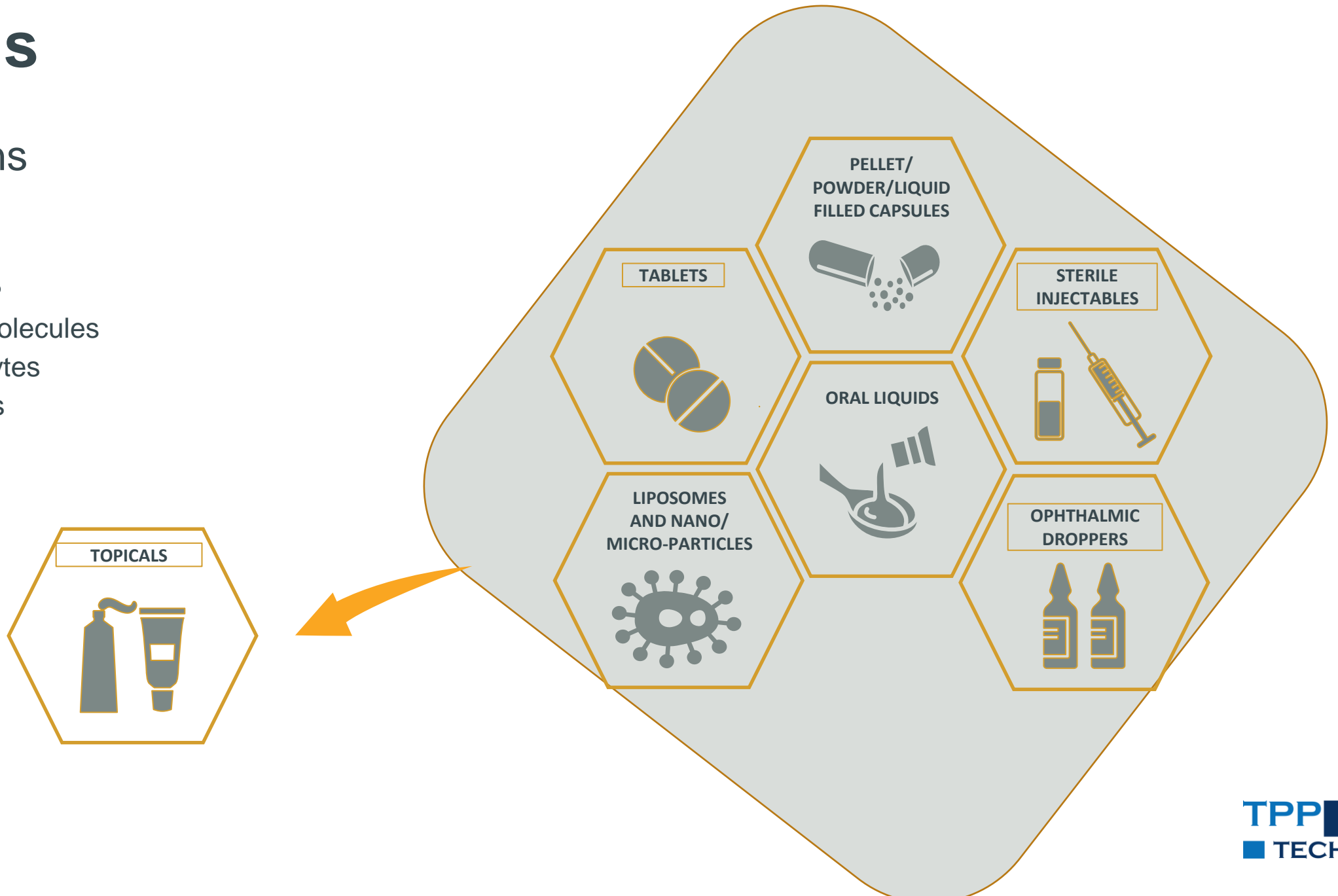


# Oral Liquids

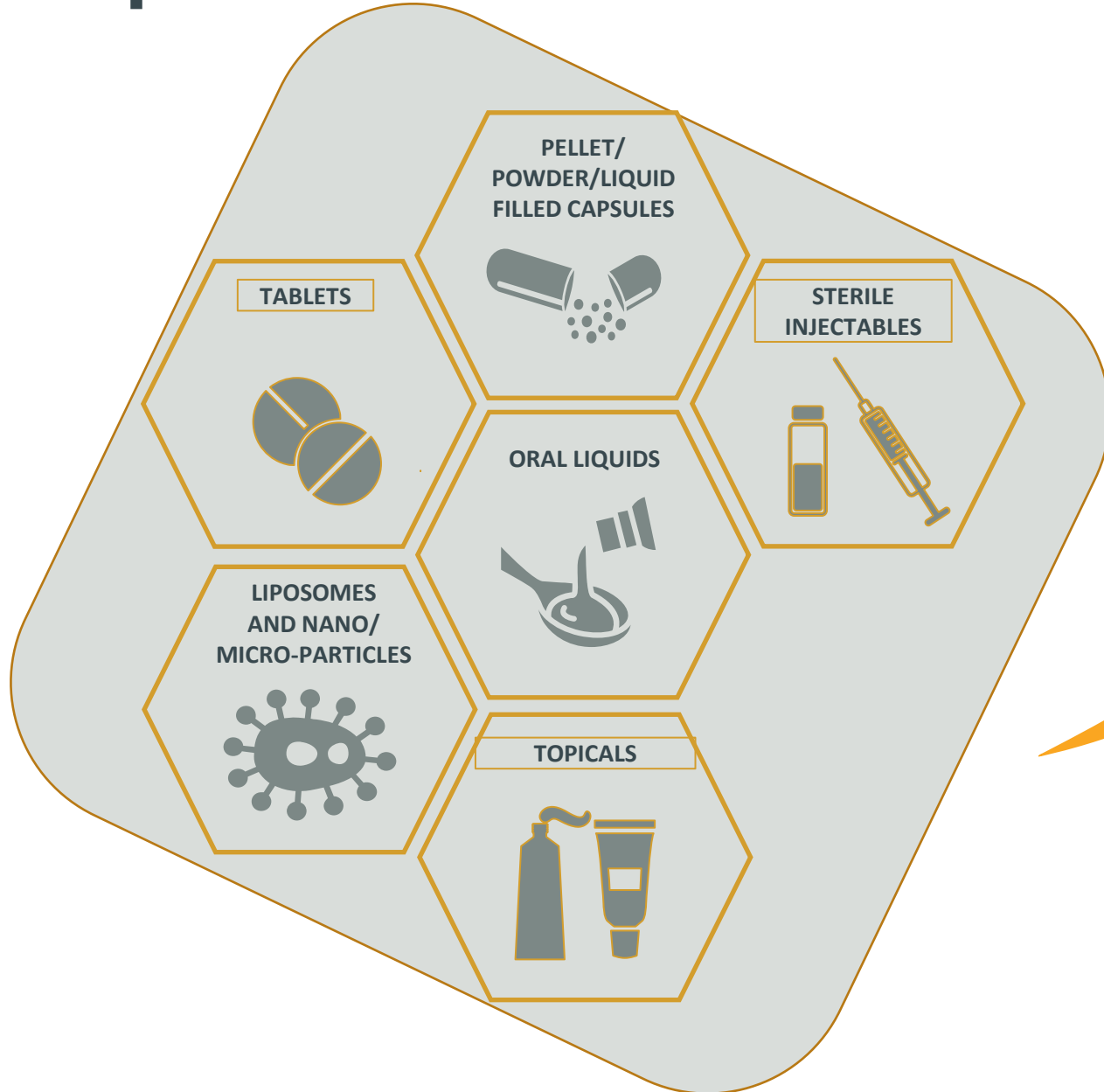


# Topicals

- Solutions
- Gels
- Creams
  - Small Molecules
  - Electrolytes
  - Peptides

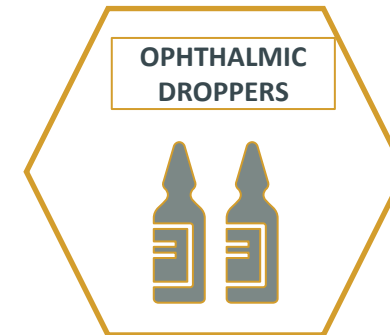


# Ophthalmic



## ■ Sterile Solutions

- Small molecules
- Peptides



# Commercial Manufacturing

# Commercial Capabilities

- Oral Solid Tablets
  - DEA License for Schedule II, III, IV, V, List I
  - Capable of handling solvents
- Oral Solutions and Suspensions
  - 2,000 L jacketed tanks
  - Manufacturing batch sizes up to 4,000 L



# Commercial Packaging

- Automated bottle packaging line for capsules and tablets
  - HDPE bottles 40cc – 500cc
  - Serialization, aggregation, track and trace
- Automated packaging line for oral solution and suspensions
  - HDPE bottles 20mL to 500mL
  - Serialization, aggregation, track and trace
- Controlled temperature warehouse
  - Vaults for Controlled Substances
- Global distribution



# Quality Assurance



# Quality Management System

## Quality Management System



**Quality Assurance**



**Quality Control**



**Employee Training**



**Documentation/  
SOPs**



# Equipment List

# Analytical Equipment

cGMP QC & Analytical Development	
Equipment	
<b>Spectrometers</b>	Agilent UV-Vis
	FT-IR – Thermo Scientific
	X-Ray Florescent Spectrometer - Shimadzu
<b>Liquid Chromatography</b>	HPLC / Agilent, G1322A0
	UPLC – Waters
	LC/MS – AB Sciex
<b>Gas Chromatography</b>	GC / MS - Agilent
	Agilent GC System with Headspace
	Agilent MSD
	GC – Agilent 7890B
<b>Titration</b>	Titration – Mettler Toledo
<b>Water</b>	Moisture Analyzer – Mettler Toledo
	Vacuum Oven – Shelo Lab
<b>Dissolution</b>	Dissolution Apparatus (USP Type 1 and 2) Agilent, Distek, Hanson, VanKel

# Analytical Equipment

cGMP QC & Analytical Development	
Equipment	
<b>Physical Testing</b>	Disintegration Tester – Hanson
	Tablet Hardness Tester – Vanguard, Vanderkemp VK200RC
	Friability Tester - Guoming
	Melting Point Analyzer - Stuart
<b>Particle Size</b>	Zetasizer Nano, ZEN5600 - Malvern
<b>Viscosity</b>	Viscometer - FungiLab
	Viscometer, DVEERVJTJ0 - Brookfield
<b>Microbiological</b>	Dispenser EFD 1500XL
	Steritest Symbio LFH Pump – Millipore
	Microbiological Sampler – Lighthouse
	Turbo Vap – Caliper Life Science
	Filter Integrity Tester – Sartorius Corporation
	Kinetix Flex – Pyros
	Pyros Kinetix Flex Tube Reader – Associates of Cape Cod

# Analytical Equipment

cGMP QC & Analytical Development	
Equipment	
<b>Microbiological</b>	Microplate Reader – VersaMax
	Molecular Devices – SpectraMax Gemini
	UV C Disinfection Chamber – Venex
	MIC Isolator – Containment Technologies, Inc.
	MIC Isolator (Micro) – Containment Technologies Group
<b>Environmental Testing</b>	TOC Analyzer – Shimadzu
	MetOne 3400 Particle Counter – Seiko
	SAS Pinocchio Super II Compressed Air Sampler – VWR / Dwyer

# Process Equipment

Process Equipment					
Category	Model & Equipment Type	Manufacturer	Scale	Development	GMP
Granulator	YK60, Oscillating Granulator	YK60	1-15 kg/h	•	
Spray Dryer	B-290, Mini Spray Dryer	Buchi	1 L/h		•
Compaction	TFC-220 Roller Compactor	Freund Vector	1-30 kg/h		•
Mixer-Powder	Blend Master, V Blender	Patterson Kelley	8 qt and 1 qt		•
	RSI10V13, RSI2V Robot Coupes	Robot Coupe	10L bowl and 2.5L bowl		•
	Ribbon Blender	Capplus Tech	5 cu ft.		•
	Vanguard, V-Blender	Vanguard	175 L		•
	Comminuting Mill	Fitz Mill	3550 rpm		•
Mixer-Liquid	Mag Mixer Tank	Pall Life Sciences	300 rpm		•
	L4RT, High Shear Mixer / Homogenizer	Silverson	NA		•
	25066 Mixing Vessel	JVNW	2000 L		•
	14.9 PSIG SW Mixing Tank (Jacketed)	JVNW	30 L		•

# Process Equipment

Process Equipment					
Category	Model & Equipment Type	Manufacturer	Scale	Development	GMP
Mixer-Liquid / Semi-Solid	Shaker Mixer	WAB	NA		•
	JVNW, 30L	JVNW	30 L		•
Mixer-Propeller	MM-3TC, Overhead Propeller Mixer	USA Labs	25 L Tank	•	•
Heater / Chiller	UHC-20/40, High Low Circulating Tank	USA Labs	6 L, (-40 – 200 °C)	•	
Solvent Tank	Stainless Steel Jacketed Tank	USA Labs	25 L and 100 L	•	
Filling Equipment - Powder	MF30, Manual Capsule Fillers	PAM	300 Capsules/Tray		•
	LM-14, Powder Filling Guns	M&O Perry Industries	3.2 mL, 0.25 in		•
	NIP-400, Automatic Capsule Filler	Huashili	30		•
Filling Equipment – Liquid	CFS1000, Gel Capsule Filler	Capsugel	1000 capsules/h		•
	BI-IX, SP i-DosiTecno Automatic Filling Machine	SP i-DosiTecno	1000 vials/h		•
	SGGSX, Dropper Filling Machine	SG	600 droppers/h		•
	Syringe Filler	Ingersoll-Rand	NA		•

# Process Equipment

Process Equipment					
Category	Model & Equipment Type	Manufacturer	Scale	Development	GMP
Filling Equipment – Liquid/Semi-Solid	11086, Piston Filler	REB Inc.	0.2-8.5 oz		•
Compression Equipment	OX100 Tablet Press	Korsch	29,000 tablets/20-60 rpm		
	Manesty Tablet Presser	IPR	NA		•
Coater	LDCS Tablet Coating System	Vector Freund	2.5 L	•	
Polisher	CPT200 – Capsule Polisher	CapPlus	300,000 capsules/h		•
Thin Film Freezing	TFF Roller GSD5-240-10NV + J21-03847	Iron House	1-2 L/h		•
	Thin Film Freeze Roller	CalFramo	1-2 L/h		•
	7555 RMV-115V Roller	US Stoneware	NA		•
Sealer	CB10693-4, BB10720-2, Induction Sealer	Pillar Technologies	300 bottles/h		•
	OPL-300-10, Heat Sealer	Van der Stahl	400 pouches/h		•

# Process Equipment

Process Equipment					
Category	Model & Equipment Type	Manufacturer	Scale	Development	GMP
<b>Weigher</b>	SADE Weight Sorter	Precision	1200 capsule/h		•
<b>Capper</b>	Semi-Automatic Capping Machine	Flexicon	600 capsules/h		•
<b>Welder</b>	USP750E, Ultrasonic Welder	Telsonic	NA		•
<b>Freeze Drier</b>	Lyophilizer, 323519	Virtus Genesis 25EL	NA		•
	Lyophilizer, 361017	Virtus Genesis 35EL	NA		•
	Lyophilizer, LyoGalaxy S50	Galaxy S50 SP Scientific	2-50 mL vials		•
<b>Microfluidization</b>	Microfluidizer MP-110	Microfluidics	NA	•	



