

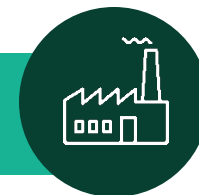


# Brio Pharmaceuticals Inc.



Partnering Formulation Development

Offering Custom / Contract Manufacturing



# VISION



To emerge as a leading player in Formulation  
Development and Manufacturing as CMO and CDMO  
for Global Pharmaceutical Companies



# Brio Genesis



Thirty-five (35) Years as a Quality CMO & CDMO



Founded in 1988 as a Privately Owned Company  
G&S Enterprises Doing Business as Great Southern  
Laboratories (GSL)



GSL assets were purchased in July 2012 by Pernix  
Manufacturing, LLC (PML), a wholly-owned subsidiary  
of Pernix Therapeutics



Pernix Manufacturing, LLC was purchased by  
Woodfield Pharmaceutical, LLC in April 2014



Brio Pharmaceuticals Inc. acquired assets of  
Woodfield Pharmaceuticals LLC in May 2023

## Relationships

NDA's / ANDA's and OTC Products of  
Leading Pharmaceutical Companies  
Manufactured from the Facility  
Are filed and / or Approved by FDA



# Facility

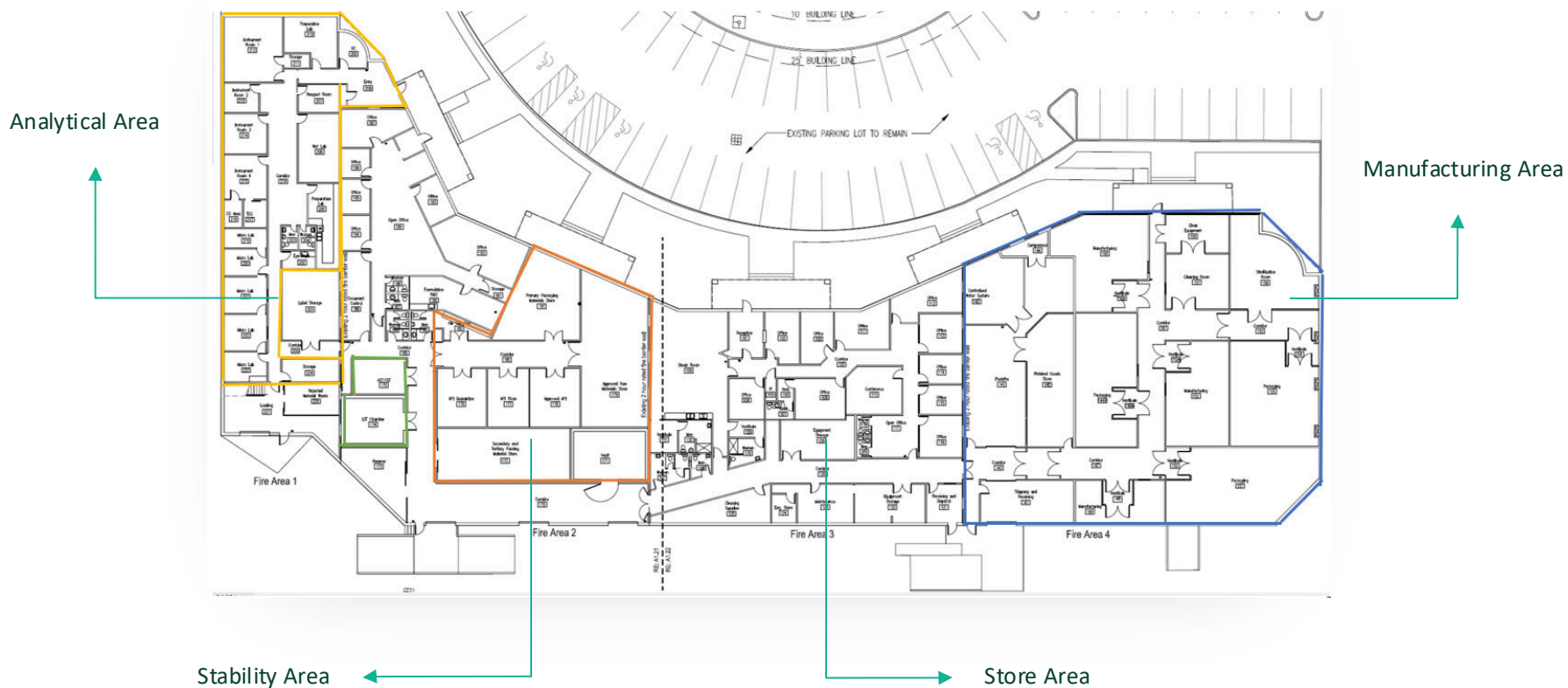
- Brio is built in an area of 3.4 acres on 10863 Rockley Road, Houston. Texas 77099.
- Built up area of the facility is 49,000 SFT.
- Facility has segregated areas for Materials Storage, Manufacture, Analytical and Stability activities

## Well monitored areas for:


- Receipt & Sampling of Materials
- Separate Warehousing of APIs/Excipients/Finished Products
- Manufacturing & Packing
- Label Control
- Quality Control
- Microbiology
- Documents Control


# Brio Layout


BRIO PHARMACEUTICALS INC.  
Activity Areas Layout




# Development Capabilities


 Solutions


 Suspensions

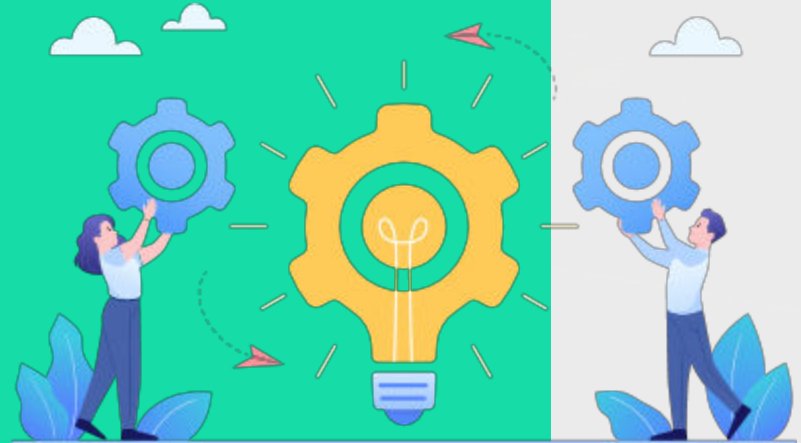
 Emulsions

 Creams

 Gels

 Injections

 Nasal Sprays



# Manufacturing Capabilities



Oral Solutions



Oral Suspensions



Nasal Sprays



Otic Drops



Gels & Creams for  
External Application

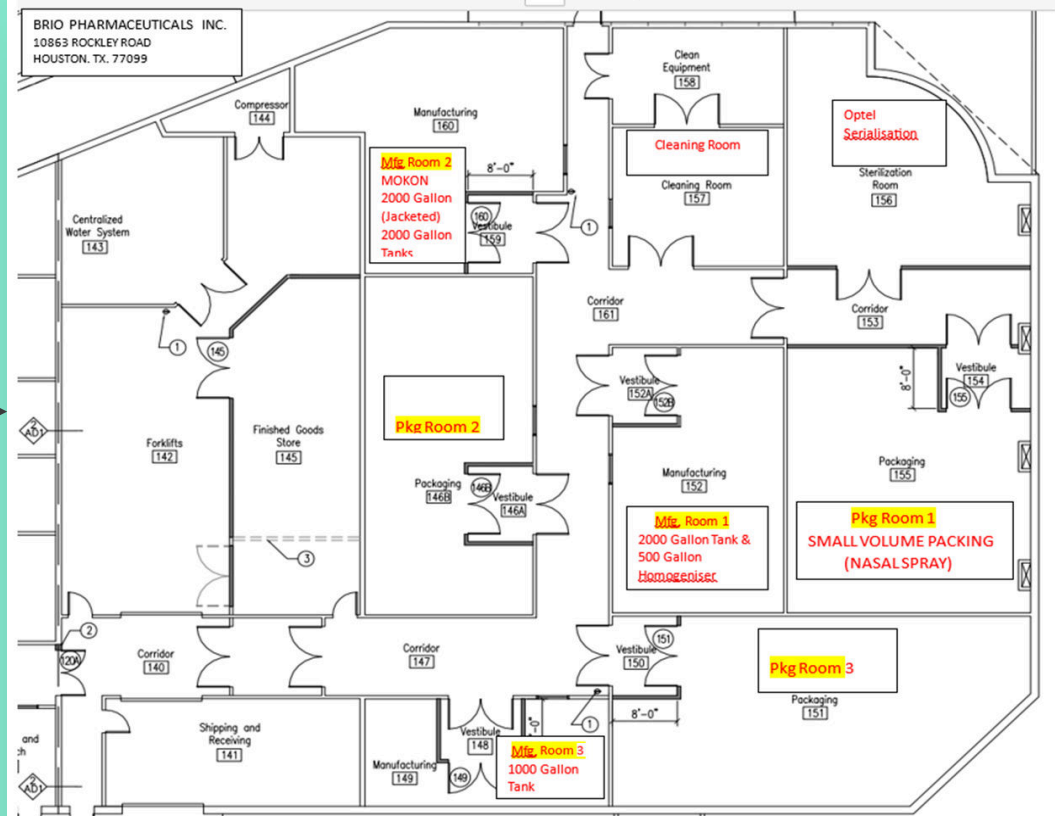


# Commercial Manufacturing Capabilities

Dosage Form	Minimum Batch Size	Maximum Batch Size
Solution (Gallons)	50	2000
Suspension (Gallons)	50	2000
Cream (Kg)	150	1500
Gel (Kg)	150	1500

Dosage Form	Minimum Package Size	Maximum Package Size
Bottles (oz)	0.25	16
Tube (g)	3	120

# Manufacturing Rooms Layout



# Purified Water System



State of the Art USP grade  
Purified Water generating system  
With  
Heat / UV / Ozone Sanitization

Capabilities And  
Closed Loop Circulation to the  
User Points

# Manufacturing Equipment



25 – 2000 Gallon Tanks with Load Cells

2000 Gallon Jacketed Tank with Load Cells

Movable & Stationary Mokon Heater Chillers

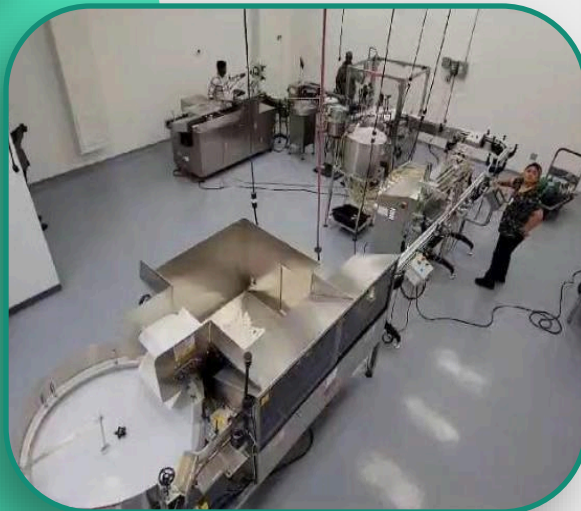
Lightening Mixers

Counter Rotating Mixers

500 Gallon Jacketed Homogenizer

Closed Loop Purified Water Connection

# Packaging Equipment



Gravity Filler for Round and Oblong Bottle

Orientainer, Capper, Retightener

Induction Sealer

Tube Filler

Spray pump Capper

Cartoner Closed Loop Purified  
Water Connection



Ensuring Compliance to  
DSCSA 2023 Requirements



Optel Serialization  
Hardware



Trace Link  
Numbering

## Analytical Capabilities



Method Development



Method Validation



Method Transfer

# Analytical Equipment



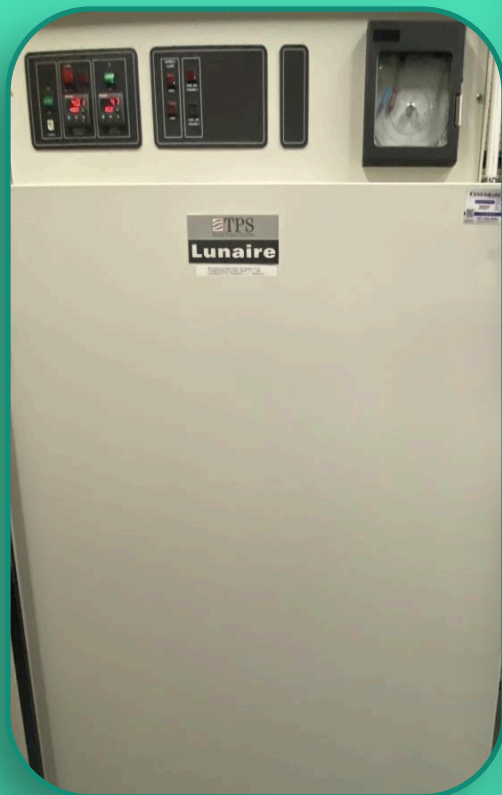
Instrument	Nos
IC	02
ICP-OES	01
HPLCs (DAD, UV & RI)	10
GC-MS & GC-Autosampler	02
Osmometer	02
TOC Analyzer	01
Viscometer	03
Densitometer	02
Polarimeter	01
FTIR	01
Dissolution (USP Type I & II)	02
UV-Vis Spectrophotometer	01

# Microbiology Equipment



- Biosafety Cabinets – 2 Separate
- Autoclaves – 3
- Colony Counter – 1
- Incubator (20-24°C) – 1
- Incubator (30-35°C) – 3
- Refrigerators (2-8°C) – 2

# Stability Chambers



- Accelerated (40/75) – 1
- Intermediate (30/60) – 1
- Long term Walkin (25/60) – 1

# Regulatory

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Texas State Drug Mfg. Lic. No. 1003715

FDA FEI No. 1628196

US FDA GDUFA Complied for 2025

In-house Capability to Review and File

Products for FDA Approval

# Thank you

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