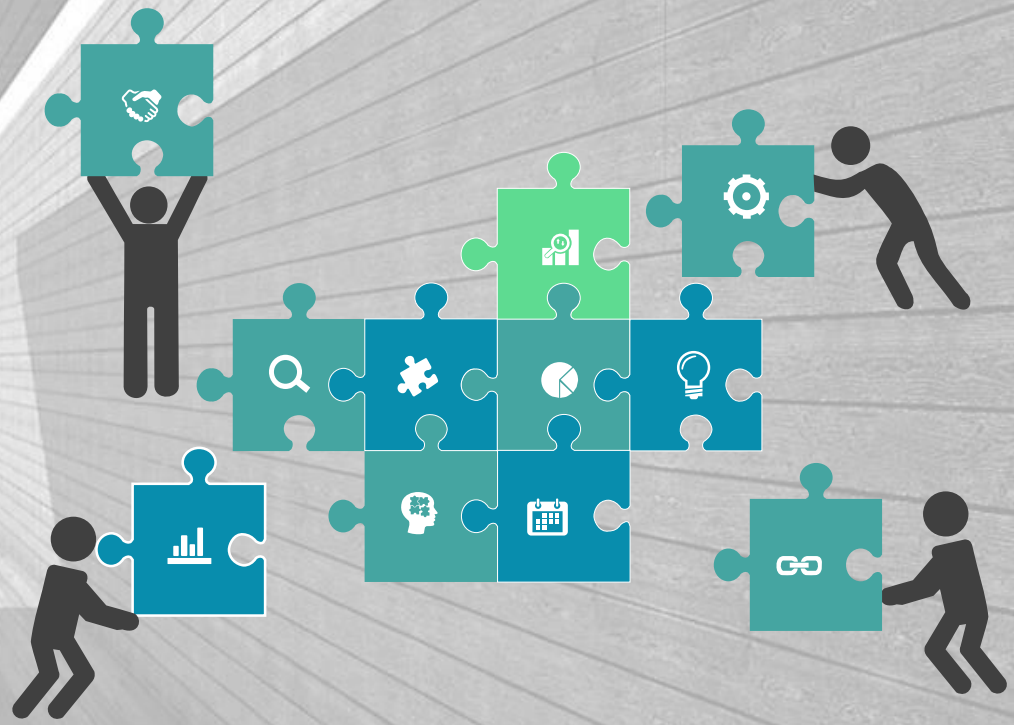
Stabicon

Incisive Solution Decisive Result



Overview

- Stabicon Life Sciences Pvt. Ltd., was established in the year 2010 with the intent to provide Innovations and Value Added Services to Consumer Healthcare and Pharmaceutical sectors
- Key capabilities comprise
  - Product development & Analytical Research of Innovative & differentiated OTC, Hygiene, Natural Products and Nutraceutical formulations
  - Stability studies, Analytical & Microbiological testing
- Team experience spans across “Concept to Commercialization” with competent technical expertise encompassing Innovations, IP & IPR, Regulatory and Technology Transfer

Regulatory Accreditations

01 Accredited by **ISO / IEC 17025:2005 (**NABL)

02 Approved by **FSSAI**

03 Approved by **FDA (India)**

04 Registered with **US FDA**

05 Registered with **DSIR**

06 Registered with **AYUSH**

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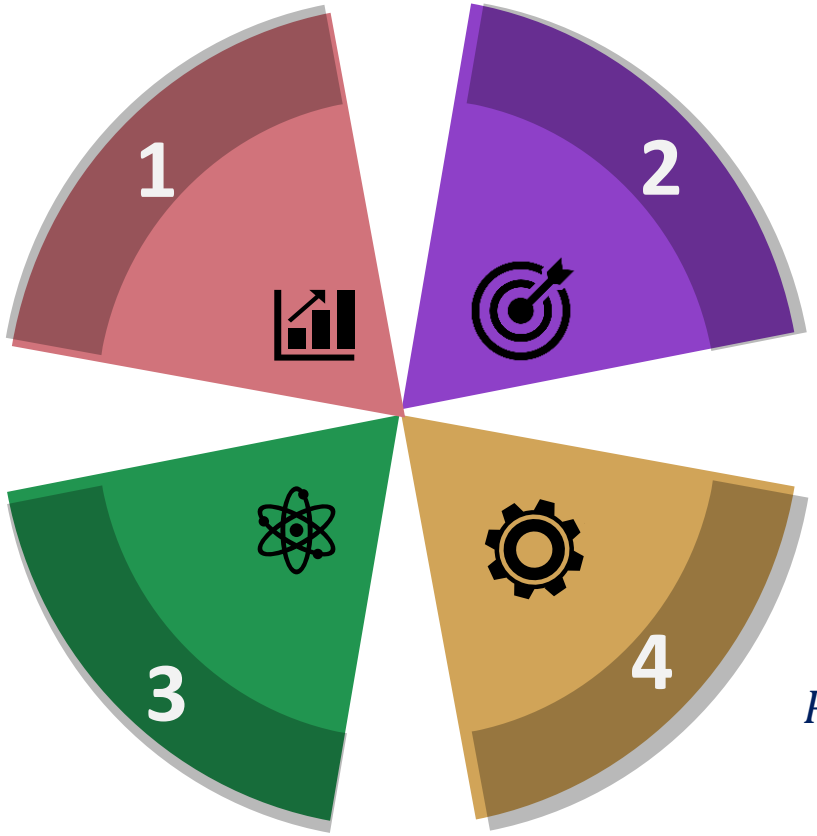
Capabilities

TRANSACTIONAL

Stability study as per ICH, Analytical Quality Control, Microbiology Studies and Integrated services

ANALYTICAL RESEARCH

Method development and validation for Rx, OTC, natural, Hygiene and Nutraceuticals



FORMULATION DEVELOPMENT

Development of Rx, OTC, Nutraceutical, natural products and Hygiene products for clients across the globe

Back up tools

Product scale up and Manufacturing TT documentation, Packaging and Regulatory support

One-stop Shop

Providing end to end solutions - from development until dossier submission, including in vitro bioequivalence, proof of concept studies.

Stability Testing Center

Quality control testing

- **Analytical testing (HPLC, GC, UPLC)**
- **Wet lab testing**
- **Stability studies**
- **Dissolution tests**

Microbiology

- **Microbial limit test**
- **Preservative efficacy test**
- **Antibiotic assay**
- **Bacterial endotoxin test**
- **Environmental monitoring**
- **Water analysis**

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Stability Capability

Support for early product development stage to its commercialization.

Stability chambers are qualified as per ICH conditions:

Global market support

Formulation Types

Solid, Semi solid, Liquid and Topical Readiness for Aerosols

Data Monitoring & Alert System

- 21CFR compliant software
- Alarm notification through SMS and hooter system.

Special stability studies

- Photo Stability Study
- Thermal Cycling Study
- In-Use Stability
- Freeze Thaw Stability
- Customized special Study

Storage Capacity
138 k Liters

8 Walk in
2 Reach in

Business continuity

- Standby chamber
- Fully automated DG back-up
- Engg team available 24 x 7

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AR&D and FSSAI Center

Analytical Research & Development

- Instrumentation labs
- Wet labs
- Chemical Assays
- Degradation analysis
- Method development and Validation
- Analytical method transfers
- Compendial Method verifications
- Cleaning validations

FSSAI / Liquid Manufacturing suite

- Nanonization Suite
- Mixing & Conditioning suites
- Packaging

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FR&D Center

Formulation Development Suites

- **Tablet Manufacturing Suite**
  - Granulation: Sifting, Milling, RMG, FBD
  - Compression
  - Coating
- **Capsuling**
- **Nanonization**
- **Liquid formulations**
- **Topicals**
- **Packaging**

FR&D Expertise

Our development expertise in Rx and OTC can cater global market exclusive needs including

- Oral solids- Tablets- Immediate Release, Sustained Release, Delayed- Release
- Capsules- Powders, Granules, Pellets
- Powders- Sachets, Mouth Melting/ ODT, powder for suspension
- Syrups, Solutions, Suspensions
- Liquid Sustained/ extended Release
- Topical-Creams, ointments, gels, lotions

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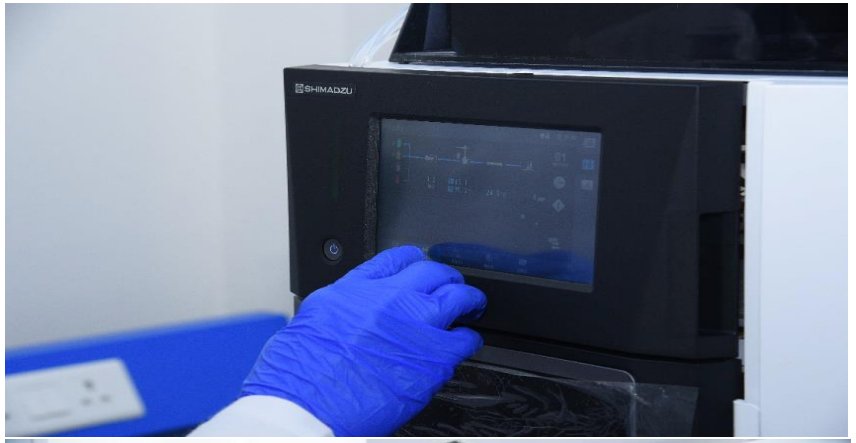
Platform Technology Innovations

- **Rapid Mouth Melt Granules (Sachets)**
  - Improving Solubility & Bioavailability for Class II & IV category drugs.
- **Liquid SR products**
  - Control Release using trigger such as time, pH, temp & moisture to deliver actives more specific profiles, such as pulsatile and delayed release
- **Formulating Poorly soluble API**
  - Improving delivery of sensory, taste & colour substance.
- **Arthritis Emulgel**
  - Gel product for Arthritis indication with Nano emulsion platform technology

Advanced Analytical Capabilities



Special analytical services in collaboration with our partner lab

- **Extractable & Leachable**
  ISO 10993, USP 1663, 1664, ICH, PQRI etc.
- **Nitrosamine impurities/TSNA**
  As per EU/USFDA guidelines
- **Chemical Characterization**
  Full Characterization as per ISO10993-18
- **Elemental Impurity Studies**
  ICHQ3D, Heavy Metals, Residues etc.
- **Genotoxic Impurities Evaluations**
  Nitrosamines, Phthalates, etc.
- **Residual Analysis for Medical Devices**
  ASTM Methods, EO Residue, ECH Residue etc.

Thank You

Stabicon Life Sciences Pvt. Ltd.

Corporate Office: #22, 7th Cross, Jaibharath Nagar, Bangalore – 560 033, Karnataka, India

Research & Development : #28, Bommasandra Industrial Area, 4th Phase, Jigani Hobli, Anekal Taluk, Bangalore-560 099

C P Bothra

Chairman – Stabicon Life Sciences Pvt Ltd

E mail: cpbothra@stabicon.com

Phone: +91 80 67640100