



▶ AUTOMATED INSTRUMENTATION FOR ANALYSIS OF STABILITY SAMPLES.



▶ REACH-IN CHAMBERS, QUALIFIED, PROGRAMMABLE STABILITY CHAMBERS, MEETING ICH REQUIREMENTS.



▶ WE ALSO CARRY OUT NIST / NPL TRACEABLE, STABILITY CHAMBER MAPPING, CALIBRATION & QUALIFICATION FOR PHARMACEUTICAL CLIENTS

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# Stability studies

ADDRESSING THE STABILITY REQUIREMENTS OF PHARMACEUTICAL MANUFACTURERS

*Do you need to outsource stability storage, analysis, & qualification (of storage equipment)? **Look no further.** Choksi Laboratories provides ones stop solution for all your stability outsourcing.*

## Helping you achieve your regulatory

CLL provides stability testing and storage to support both generic products as well as for national/international regulatory submissions for new products.

CLL's stability storage facility maintains storage chambers with complete power backup and continuous monitoring of environment conditions & security.

Our Calibration staff periodically validates these stability chambers, apart from the initial IQ/OQ/PQ protocols to verify proper installation, operation, performance.



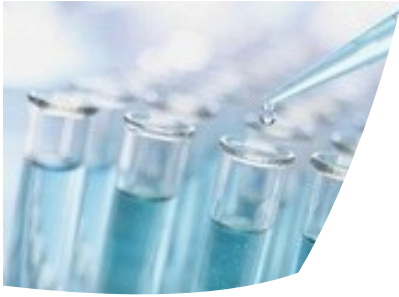
Temperature and humidity are calibrated on multiple points against NPL / NIST-traceable devices, and the storage units are fully mapped on full, half & complete loads.

Analytical data is recorded in our 21 CFR Part 11-compliant Laboratory Information Management System.



## CAPACITY AND CONFIDENCE

There is only one word to describe CLL's infrastructure in meeting your analytical requirements for stability samples - MASSIVE. With over 36+ HPLCs (Agilent, Waters, Shimadzu), LC-MS/MS, 20+ GCs, GC-MS, 8 USP-NF compliant Dissolution Systems, CLL can provide the speed and sample handling capacity that no other laboratory can match. Our central laboratory at Indore has a strategic tie-up with the largest USFDA approved pharmaceutical exporter from India for handling its complete requirements for outsourcing of stability samples.



# Getting the most from our experience

*Key Services: Stability Charging, Stability Samples Analysis, & Performance Qualification (calibration + validation) of Stability Chambers.*

**CLL Team:** Over 200 analytical scientists, microbiologists and engineers.

**CLL Infrastructure:** Four Labs in India (Indore, Baroda, Vapi, Panchkula) serviced by 15 regional offices.

*(Instruments: LC—MS/MS, GC -MS, HPLCs (UV / ECD/RI / FLD), GCs (FID/ TID/TCD/ PID/ ECD), GC - HS / Purge & Trap, Atomic Absorption Spectrometry, IC, ICP, FTIR, RAPID-Microbiology Autoreader, XRF, TOC Analyzer, Malvern Mastersizer, Dissolution Apparatus etc.)*

**CLL's USP:** Accuracy, Reliability, Fast Turn-around Time, Participation in International Proficiency Testing Programs, State-of-the-art-instruments, Audited by several foreign MNCs.

**CLL's Other Services:** Analytical Testing – QC Release, Method Development & Validation, Particle Size Analysis, Residual Solvents / OVI, Stability, TOC, Trace Element Analysis, Water Analysis (as per WHO / EPA / IS / EU norms), Microbiological Tests, Instrument Qualification & Calibrations.

## Approvals:

**FDCA (India),  
AYUSH (ISM),  
USFDA,  
NABL (ISO/IEC 17025),  
Export Inspection Council,  
Bureau of Indian Standards.**

**SMARTER  
OUTSOURCING!**

**Expertise  
&  
Discipline**



Audited & Trusted by the top pharmaceutical MNCs world-wide, CLL's analytical data has been used as a basis of regulatory submissions to USFDA, MHRA, & ANVISA.

For a strategic partnership, write to:  
pradipk@choksilab.com,  
himikav@choksilab.com



**YOUR PARTNERS IN QUALITY**

## CLL CORPORATE OFFICE AND CENTRAL LABORATORY:

6/3 Manoramaganj, Indore - 452001 (MP)  
Tel: +91-731-2493592/3, 2490592;  
Fax: +91-731-2490593;  
Email: info@choksilab.com

## BRANCH LABS:

### CLL Panchkula:

Plot No. 362, Industrial Area Phase 2, Panchkula - 134133, Haryana (India)  
Tel: (+91)-172-5048600/1; Fax: (+91)-172-5048602; Email: [panchkula@choksilab.com](mailto:panchkula@choksilab.com)

### CLL Baroda:

829, GIDC Makarpura, Baroda - 390010 (GJ)  
Tel: +91-265-2655955, 2657955, 2652955; Fax: +91-265-2631714; Email: [baroda@choksilab.com](mailto:baroda@choksilab.com)

### CLL Vapi:

II & III Floor, Gokul Complex, 101/8, GIDC Char Rasta, Behind GIDC Char Office, Vapi - 396195 (GJ)  
Tel: +91-260-2433488, 2432731, 2434061; Fax: +91-260-2432728; Email: [vapi@choksilab.com](mailto:vapi@choksilab.com)

## Regional Offices & Sample Collection Centers:

Ahemadabad, Bangalore, Chennai, Cochin, Calcutta, Cochin, Delhi, Goa, Gwalior, Hyderabad, Jaipur, Kolkatta, Kanpur, Mumbai, Nashik, Pune, Raipur, Rajkot, Roorkee, Surat