INFINITY®

Infinity Automation Systems Pvt. Ltd.

Container Closure Integrity Tester

LT-5000 CCIT

Electronic+Compliance+ Equivalence

SINCE 2 DECADES

150+ EMPLOYEES

PAN India

ASTM | FDA 21 CFR Part 11 | USP 1207 | NABL | CE | ISO 9001:2008 CERTIFIED COMPANY | EMA ANNEX 11

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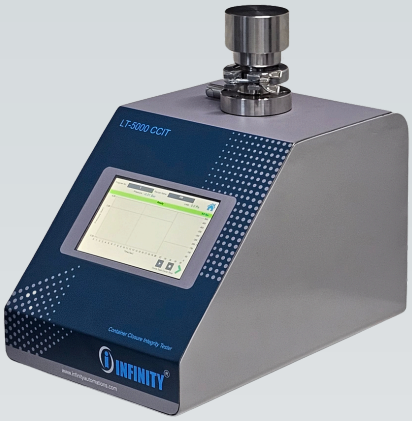
The LT-5000 CCIT is a highly precise leak detection system designed to verify the seal integrity of containers used for injectable drugs & other rigid packaging. It reliably detects even the smallest leaks, ensuring consistent quality & safety st&ards.

As per ***ASTM, FDA 21CFR Part11, USP 1207, NABL, CE, ISO 9001:2008, EMA ANNEX 11*** *guidelines*



ADVANTAGES

- No sample damage or preparation required; zero operator bias
- Detects defects as small as 0.005 ccm
- Identifies leaks as small as 0.5 µm
- More sensitive & consistent than dye ingress testing
- Provides quantitative & deterministic results
- Fast & reliable for both rigid & flexible packaging; test time is adjustable
- Easy-to-use touch screen interface with a compact design
- Modular system with quick-change components & custom-fit chambers
- Supports remote upload & instant access to reports & logs

APPLICABILITY

Vacuum decay leak testing is a non-destructive method for verifying container closure integrity (CCI) by detecting leaks from large to micron-sized in pharma, medical device, & food packaging. Recognized by ASTM F2338-09 & PDA as a st&ard for non-destructive leak detection.

Compatible With:

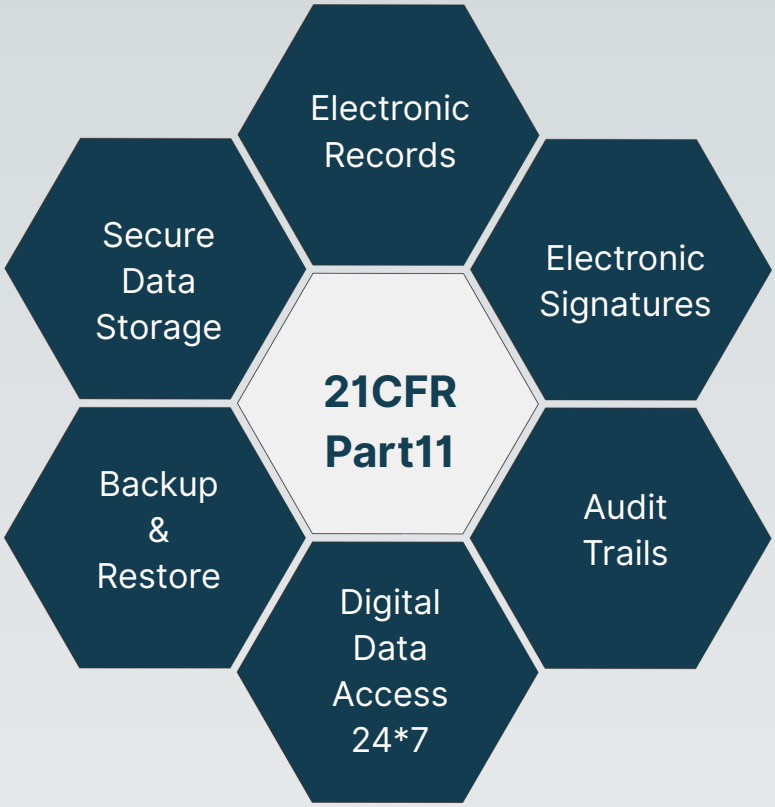
- Batch testing
- For new product set-up, test & development
- Production lines
- Non-destructive testing
- Bacteria-free ingress test

TECHNICAL SPECIFICATIONS

SPECIFICATIONS	MICRO LEAK DETECTION	CONTAINER CLOSURE INTEGRITY TESTING
Packaging Format	• Empty & pre-filled syringes • Liquid filled & lyophilized vials (glass or plastic) • Filled & sealed bottles, FFS bottles • BPC (Bulk Pharmaceutical Chemical) containers	• API (Active Pharmaceutical Ingredient) containers • BFS containers • Ophthalmic dropper tip bottles containing liquid materials • Glass or plastic ampoules containing liquid materials • Lidded (nonporous trays or cups) containing liquid materials
Testing Setup	Offline laboratory & production line applications	
Test Method	Vacuum/Pressure decay method	
Inspection Platform	Dual Transducer Technology	
Display Screen	7"/10" color touch screen - resistive/capacitive	
St&ard Procedure	ASTM F2338-09	
Accuracy	**Up to 0.5 micron**	
Measurement Unit & Limits	Pass/Fail in mBar & Pascal units	
Sample Feeding	Manual/Automatic	
Housing	ABS/SS	
Size	14.96" W × 10.23" D × 10.31" H	
Weight	14kg	
Electrical	100–240 VAC; 50/60 Hz	
Input Air Supply	External/in-built(optional)	

21CFR PART11 COMPLIANT LT-5000 CCIT

- To keep pace with the increasing use of electronic systems & technology in FDA-regulated industries, 21CFR Part11 was introduced, ensuring the same level of data integrity, authenticity, & reliability as paper-based systems
- Basically, 21CFR Part11 is a regulation established by the U.S. Food & Drug Administration (FDA) that outlines the requirements for the use of electronic records & electronic signatures in FDA-regulated industries, including pharmaceuticals.
- Adhering to these guidelines, the introduction of Information Technology (IT) in compliance was a milestone.
- It establishes requirements for the security, integrity, & availability of electronic records & the validation of electronic systems used for GxP (Good Laboratory Practices, Good Clinical Practices, Good Manufacturing Practices) activities.



Audit Trail:

- Tamperproof & Non-Editable Audit Trail Data Format.
- The time stamp of the change of the parameter value & the user making the change
- The audit trail records the following details-
- User Creation
- User Login/ Logout
- Wrong attempts at login
- User Block / Unblock by Administrator
- Old value & new value of the parameter change
- The time stamp of each event

Electronic signatures:

- Through 3/4 user level validation & authentication

System Data & Data Backup:

HMI offers basic connectivity for data exchange with Central SCADA / MES / ERP by following the means:

- Through OPC UA
- Through Data file transfer
- Through USB / SD Card Backup

Electronic Data Record & Data Storage:

- Review of the reports on the HMI Screen for Production, Alarms, & Audit Trail.
- Storage limit can be interlocked in terms of the number of batches produced or % of the memory consumed.

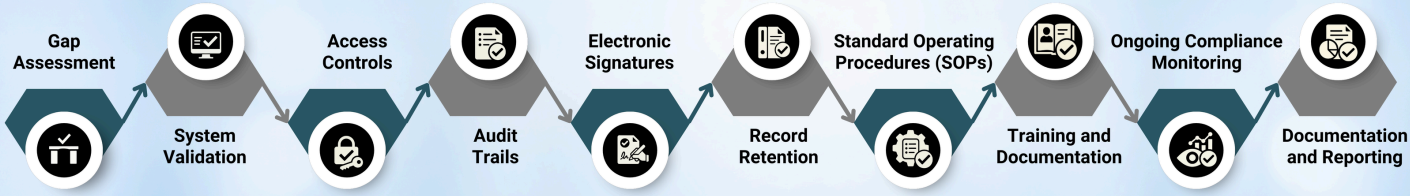
User Management Functionalities:

- Password-protected individual Unique user account.
- Password Complexity.
- Minimum 8 Character password length.
- Configurable Number of Wrong Attempts
- User Block/Unblock Facility
- Password Validity
- Multiple User Levels as per the User Rights

Report Generation & Printing:

- Batch data is stored in a secure database format, & the Batch Report can be generated using this data.
- The report printing has been offered in multiple ways
- Online printing of Alarms, Events, & Logged data through Serial Printer

STEP FOR IMPLEMENTATION OF 21CFR PART11



APPLICATIONS

Vials

Ampules

Pharma Bags

ACCESSORIES

- Vacuum Pump
- Micro calibrated leak
- Test Cavity
- Master(Solid dummy)
- Sealing & Connectors
- Barcode Printer
- Barcode Scanner
- External Start/Stop Pendant
- Micro drilling services
- Positive control (1µm, 5µm, 10µm, 20µm)

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