

Smart Automated Inspection Laboratory

SAIL is an automated inspection laboratory for different container types, sizes, and contents bringing together CCIT, AVI and HGA all in one machine suitable for in-process, clinical trials and laboratory use.



HIGHLIGHTS



- All in one Industry 4.0 based laboratory
- Ergonomic workstation
- Scientific and objective inspection
- 100 % traceability
- Time & cost saving

TECHNICAL FEATURES



Container Application: BFS, Vials, Ampoules, PFS, Cartridges

Products: Lyo, Liquid, Powder

Container Dimensions: Ø [10 - 69] mm

Speed: 50 - 500 cph (depending on configuration)

Technology: CCIT - AVI - HGA

Inspection Features: A COBOT optimizes the collaborative non-destructive inspection processes

Inspection Capabilities: Integrity testing; foreign matters, cosmetic and cap defects; Oxygen/Moisture/Carbon Dioxide level, Absolute Pressure value

ADDITIONAL PLUS



- Single operator
- Single validation & qualification procedure
- Multiple inspections, containers, formats
- Easy & fast evaluation thanks to **real time HD display**
- **Automatic Container Handling**
- New user-friendly **touchscreen HMI, Android-like, 22"** size adjustable panel
- Tool-less, **no format change** by means of automatic adjustments and regulations

TECHNOLOGY



SAIL modular structure provides adequate flexibility upon all **3 of testing technologies:**

- **AVI (Automatic Visual Inspection)/ SAVI** a collection of images is acquired using high resolution matrix cameras under designed illumination conditions.
- **CCIT (Container Closure Integrity Testing)** non-destructive integrity testing in packages by Vacuum Decay Method.
- **HGA (Headspace Gas Analysis)** inspection process is based on the Tunable Diode Laser Absorption Spectroscopy (TDLAS) method which accurately quantifies gaseous concentration levels.

QUALITY ASSURANCE



- Software designed to comply with **FDA 21 CFR Part 11** and **EU Annex 11**
- Visual Testing method conforms to current pharmaceutical regulations, such as USP – **United States Pharmacopeia – General Chapter <790>** and European Pharmacopeia **§ 2.9.20**
- Vacuum decay Method based on the approved industry standard **ASTM F2338-09**, recognised by the FDA
- HGA Testing method in conformity with provisions of **USP General Chapter <1207>**
- The Machines Qualification and Validation complies with requirements stated in **EU Annex 15**
- Machine manufacturing process and materials are compliant with applicable **GMP** requirements