Bonfiglioli™ Engineering

PK-A

Inline Ampoules and Cartridges CCI Tester

Non-Invasive, Non-Destructive, 100 % In-Line Integrity Inspection System at high production speed.

HIGHLIGHTS

- **Autotest in real time**
- **Easy to validate**
- **CFR 21 part 11 compliance and 4.0 full integration**
- **Quick format changeover**
- **High installation flexibility**
- **Automatic Drying System, no testing chamber contamination (Vacuum Decay Only)**
- **Easy cleaning**

TECHNICAL FEATURES

Container Application: Ampoules, Cartridges

Products: Liquid

Container Dimensions: Standard ampoule from 1 to 50 ml

Speed: Up to 600 cpm

Technology: CCIT

Inspection Features: Non-Invasive, Non-Destructive CCIT based on Vacuum & Pressure Decay Method

Inspection Capabilities: Microleaks detection; Tip Inspection integrity

ADDITIONAL PLUS

- **Full batch control testing:** fast, reliable and repeatable
- Testing of **all nominal production line speed**
- **MES** (Manufacturing Execution System connection) allows remote machine data exchange & download
- **Statistical Process Control** reduces deviations for a better yield control
- **Real time display** of testing cycle diagrams, statistical raw data
- Easy, quick and safe **remote access**
- **AHE** (Automatic Head Exclusion)

TECHNOLOGY

Container Closure Integrity Testing is a non-destructive measurement technology based on the following testing methods:

- **Vacuum Decay Method**
- **Pressure Decay Method**

Measurement system comprises applying a pressure differential into an airtight testing group enclosing the container.

The test objective is to detect container leakages by measuring the reached pressure level as well as the pressure change over test time.

QUALITY ASSURANCE

Equipment test method refers to:

- Approved industry standard "**ASTM F2338-09**": "Standard Test Method for Non-Destructive Detection of Leaks in Packages"
- United States Pharmacopoeia – **USP General Chapter «1207»** "Packaging Integrity Evaluation"
- EU Guidelines to **GMP** Medicinal Products for Human and Veterinary Use – **Annex 1** "Manufacture of Sterile Medicinal Products"
- **PDA Technical Report No. 27** "Pharmaceutical Package Integrity"
- **FDA 21 CFR part 11** as well as **EMA Annex 11**