Leak Test Validation

MET's medical device and pharmaceutical leak testers are supported by validation services.

The process involves Installation Qualification (IQ) and Operational Qualification (OQ). The particular requirements will depend upon the client's User Requirements Specification (URS).

The main part of the validation can be implemented in one of two ways.

Validation Method 1

This method uses laser drilled holes in aluminium discs. A hole is pierced in the product or more usually pack. This hole is then covered with the aluminium disc, which is fixed in place by a reinforcement ring. The disc has a 12.5 micron hole through it and it is this that is used as the pass / fail detection limit for the product.

Validation Method 2

This method uses a calibrated leak. This method is most often used in chamber tests or the calibrated leak can be added to leak test pneumatic circuit. In either case a good product with no leak is included in the system. The leak rate for the calibrated leak is usually indicated in the customer's URS. The pass / fail level is the set without and with the calibrated leak in the circuit.

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