www.intertechdevelopment.com
Instrumentation
Air Test Systems
Helium Test Systems
Hydraulic Test Systems
Functional Test Systems
Integrated Assembly & Test

InterTech Development Company
7401 N. Linder Avenue, Skokie, IL 60077, USA
T: 1.847.679.3377
W: intertechdevelopment.com
E-mail: sales@intertechdevelopment.com

ISO 9001 Registered
ISO 17025 Accredited

Worldwide Support:

InterTech Europe
19 rue Clement Michut 69100 Villeurbanne
T: (33)437.434.116
W: intertecheurope.com
E-mail: intertechinfo@intertecheurope.com

InterTech Shanghai Technical Center
Part D, No.3 Building, No.81 MeiYue Road,
China (Shanghai) Pilot Free Trade Zone
T: (021) 5868 2102
E: sales@intertechdevelopment.com

InterTech Mexico
Carr. Saltillo - Monterrey 5762 Km.4
Plaza Comercial San Agustin Local 12
Saltillo, Coah. 25210
E-mail: sales@intertechdevelopment.com

DR175

Updating Functional Tests for Accurate Dosing of Higher Viscosity Drugs

The Challenge:

Functionally testing medical devices or performing sufficient audit testing to assure quality of drug delivery or blood collection devices are not new requirements. What is new, however, is the need to measure much smaller volumes – as small as one microliter. Medical device manufactures seek to use deterministic test methods to assure the reliability of new generation devices used both in clinical settings and in home self-care environments.

These inherent challenges are amplified by recent advances in therapeutic proteins and more targeted drug products that encumber drawing and weighing methods with handling higher viscosity liquids. With these newer drugs, conventional delivery is precluded due to the need for longer injection times to reduce patient discomfort. Instead, smart injectors, infusion pumps and/or digital pills are the drug delivery devices of choice for a wide range of these high viscosity protein-based therapeutics. These devices enable low volume dispensing over a longer period of time.

Historically, makers of collection tubes and drug delivery systems have relied on drawing and weighing methods to test the accuracy of their devices. Weighing must be done twice – before and after – introducing significant measurement uncertainties at both stages, as well as an increase in potential effects of ambient temperature variations affecting laminar flow and introducing distortions from vibrations.

Traditional drawing and weighing methods are not up to the challenge – whether one is testing in-line or with extensive audit testing – to ensure that the specified drug volumes are delivered accurately. A key objective today is to cultivate a risk-based approach in the product development phase that allows medical device manufacturers to leverage testing as a means to better analyze and ultimately eliminate risks of releasing defective products to clinical and homecare settings.

The InterTech Solution:

InterTech's test method correlates fluids with dry air testing, eliminating the need for cumbersome conventional flowmeters. InterTech MicroScale MED75 testers can detects leaks of 0.008 sccm with a test time of 10 seconds or less and GR&R of less than 20%.

This InterTech technique using the air pressure rise to measure liquid flow significantly improves accuracy and repeatability by eliminating the variable effects of bulk modulus (fluid compressibility) and temperature that distort results in conventional test methods.

Benefits:

- Superior accuracy – both by eliminating the variable effects of bulk modulus (fluid compressibility) and temperature that are the inherent source of distortions in conventional test methods and the measurement uncertainties required in two-step draw and weigh methods.
- Data is quantitative, objective and traceable.

An InterTech Design Report

www.intertechdevelopment.com
Instrumentation
Air Test Systems
Helium Test Systems
Hydraulic Test Systems
Functional Test Systems
Integrated Assembly & Test

InterTech Development Company
7401 N. Linder Avenue, Skokie, IL 60077, USA
T: 1.847.679.3377
W: intertechdevelopment.com
E-mail: sales@intertechdevelopment.com

ISO 9001 Registered
ISO 17025 Accredited

Worldwide Support:

InterTech Europe
19 rue Clement Michut 69100 Villeurbanne
T: (33)437.434.116
W: intertecheurope.com
E-mail: intertechinfo@intertecheurope.com

InterTech Shanghai Technical Center
Part D, No.3 Building, No.81 MeiYue Road,
China (Shanghai) Pilot Free Trade Zone
T: (021) 5868 2102
E: sales@intertechdevelopment.com

InterTech Mexico
Carr. Saltillo - Monterrey 5762 Km.4
Plaza Comercial San Agustin Local 12
Saltillo, Coah. 25210
E-mail: sales@intertechdevelopment.com

DR175

- Faster response times than conventional flow meters resulting in more accurate measurements.

Additional Features and Benefits:

– **Cost effective:** eliminates time consuming, inaccurate weighing techniques with associated measurement uncertainties.

– **21 CFR 11 compliant:** data security requirements are met.

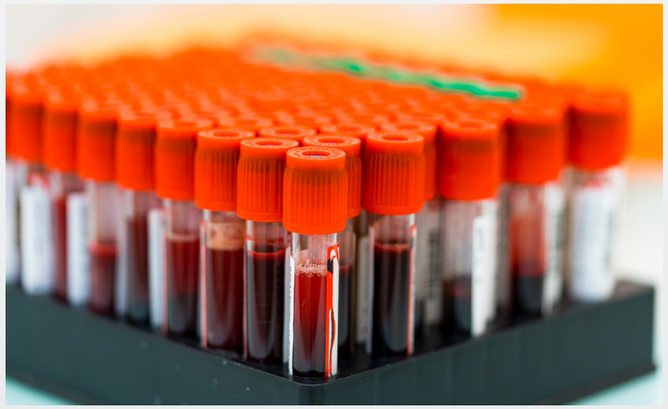
– **Eliminates changeover time:** by using universal tooling.

– **User friendly:** automated R&R mode facilitates scheduled machine qualification and audit traceability.

– **EtherNet IP compliant:** test system is integrated into customer's quality control system to ensure traceability and compliance with ISO requirements.

Case studies:

A family of blood collection tubes are audit tested to ensure vacuum level and consistent draw performance.



The InterTech MicroScale MED75 controls the test cycle and servo actuated needle insertion. Draw volumes in the range of 2 ml to 10 ml are measured using distilled water. A unique InterTech designed needle insertion mechanism ensures consistent draw operation, and the long-life needle assembly is designed for quick-change replacement after 6,000 cycles.

Autoinjectors are audit tested to ensure accurate dispensing over an adjustable period of time up to 96 hrs. When the device is triggered, measurements include:

– The total volume dispensed;

– Total time elapsed to end of dispense;

– Cumulative volume dispensed at programmed points in time;

– Dispense rate vs. time dispense rate at programmed points in time.