phenomena plus the challenge of cleaning test chambers contaminated from liquid leakage are disadvantages that should be considered prior to leak test method selection.

### Weight Loss or Gain

Product-package weight change as a function of time and temperature is a practical integrity method that can be readily incorporated as part of product stability studies. This technique is especially useful for semipermeable packages containing volatile products or products prone to moisture sorption.

## CONCLUSION

In recent years, regulatory bodies have encouraged the pharmaceutical industry to explore novel package integrity test methods that do not rely on traditional dye or microbial ingress tests. This movement has driven improvements in leak testing technologies and sparked exciting new developments. Today, rapid, sensitive, and nondestructive leak test methods exist for testing most pharmaceutical parenteral product-package systems. Vacuum decay is primarily useful for detecting leaks in packages having gas headspace, but unique applications exist for testing liquid-filled container–closures as well. Electrical conductivity or HVLD tests have demonstrated great potential for testing a large portion of liquid-filled packages. FMS is ideal for integrity testing clear or translucent containers sealed under low pressure or with an inert gas headspace. Other techniques exist that are important tools for laboratory use in package development and forensics testing, including helium mass spectrometry, dye or liquid tracer ingress, bubble tests, and weight change, checks for seal quality assurance, for example, RSF, are vital as well. These and other methods likely on the horizon provide a leak test method arsenal that can help ensure better quality products, with fewer recalls linked to container–closure integrity failures.

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