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Harmonising standards for pharmaceutical glass

Margaret Flower* reviews recent revisions on pharmacopoeia standards for glass containers.

Recent revisions on pharmacopoeia standards for glass containers have led to simplification and cost saving for customers across the pharmaceutical supply-chain, according to independent research and development, consultancy and testing facility, Glass Technology Services (GTS).

Commenting on the latest standards for hydrolytic resistance testing of pharmaceutical bottles, vials, ampoules, cartridges and syringes, GTS Technologist Margaret Flower, said:

"Although plastic has seen increased use for primary and secondary packaging of many pharmaceutical preparations, glass remains essentially the container material of choice for parenteral and other sensitive products.

"Hydrolytic stability testing of those containers is clearly critical to maintaining that position and ensuring confident use of glass across the pharmaceutical, laboratory and medical sectors.

"The United States (USP) and European (Ph. Eur.) Pharmacopoeias remain the most widely used in the global market and recent revisions to the USP have brought harmonisation between the two - bringing welcome simplification and, in many cases, cost savings for customers that regularly test to both USP and Ph. Eur. standards."

Key changes include:

- Replacement of the USP powdered glass test by the Ph. Eur. glass grains test;
- Deletion of the USP water attack at 121 degrees C test;
- Incorporation of the Ph. Eur. surface glass test into the USP; and
- Inclusion of a new chapter, 1660, to the USP for delamination propensity pre-screening - a new service that GTS has been offering in advance of its publication.

Margaret stated: "This partial harmonisation will be well received, both by glass manufacturers and by pharmaceutical and medical companies, who are increasingly using our services to achieve product certification.

"One set of tests for hydrolytic stability makes the process much simpler and more cost-effective and for an industry which is heavily regulated and where development and innovation is constant, that has to be very welcome news."

GTS provides a UKAS accredited testing service for pharmaceutical and medical companies as well as glass manufacturers and processors and participates in collaborative studies on glass containers for pharmaceutical and medical use.

In addition to US and European Pharmacopoeia, GTS also tests for British, Russian and Japanese Pharmacopoeia standards.

Full details of the pharmacopoeia testing programme and other analysis services provided by GTS are available on the company's newly launched website at www.glass-ts.com. ■

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