

Technical Information

Vials

In chromatography a broad variety of glass or plastic vials are used as sample containers for analysis usage. As they are mainly used within autosamplers or any other automatic instrument, strict obedience of all dimensions is crucial for a trouble-free run. Besides these physical properties the vials also have to fulfill requirements regarding inertness and cleanliness, as otherwise analysis results may be incorrect. La-Pha-Pack consider the physical and chemical demands in their production process by various implementations:

Almost all vials are made out of 1st hydrolytic class glass. First hydrolytic class glass is very hard and has a low expansion coefficient even at high temperature variations. It shows an excellent chemical resistance to acidic and neutral solutions, and even to alkaline solutions due to its relatively low Alkali content. Higher density of the glass surface offers a higher hydrolytic resistance. Clear Glass of 1st hydrolytic class is differentiated by 33 expansion (Type 1, Class A) and 51 expansion glass (Type 1, Class B),

whereas amber is generally worldwide only available as 51 expansion glass. The indicated lower expansion coefficient of 33 implies that this harder clear glass has to be processed at higher temperatures. These amount to approx. 1,200°C for 33 expansion glass in comparison to only approx. 1,000°C for glass of 51 expansion. In the USA typically clear glass in 33 expansion and amber glass in 51 expansion is used, whereas in Europe solely 51 expansion glass is processed. From a quality point of view both types of glass are equally suitable for usage in chromatography, as they both are glasses of 1st hydrolytic class.

All vials that carry a CleanPack label on the front side of the PP-Box have been packed in a certified cleanroom class 10,000 after having passed the annealing oven at approx. 600°C. These high hygienic conditions are pharmaceutical standard, however, new for chromatography vials. Thus the consumer can rely on clean, uncontaminated vials for a correct analysis.

Certified Vials and Closures

Certifications become more and more important in order to make processes more reproducible and avoid possible sources of errors right from the beginning. For La-Pha-Pack highest quality, consistency and quality control have always been very important and documents this now by two consecutive certification steps.



Specification Certified

This is a certification and guarantee, that our products meet the strict specification borders, which are compulsively necessary for a use of the autosampler. This is obtained by the following measures:

- During the manufacturing process opto-electronic devices at the machines check within fractions of a second, if the processed vials meet the physical specifications (dimensions, etc.). In case of mismatch the vial is automatically rejected.
- Besides this, 100 per cent automatic control, manual in-process controls as well as a final inspection according to DIN/ISO standards further ensure functionality and perfect fit in the instrument.
- Regular functional tests further ensure that the vial not only fits the instrument, but also all components that might be connected to it, such as Micro-Inserts, Seals, etc. A correct and reproducible analysis can only be carried out, if the whole unit of the vial (Micro-Insert) and closure correctly match with each other and achieve a tight seal.



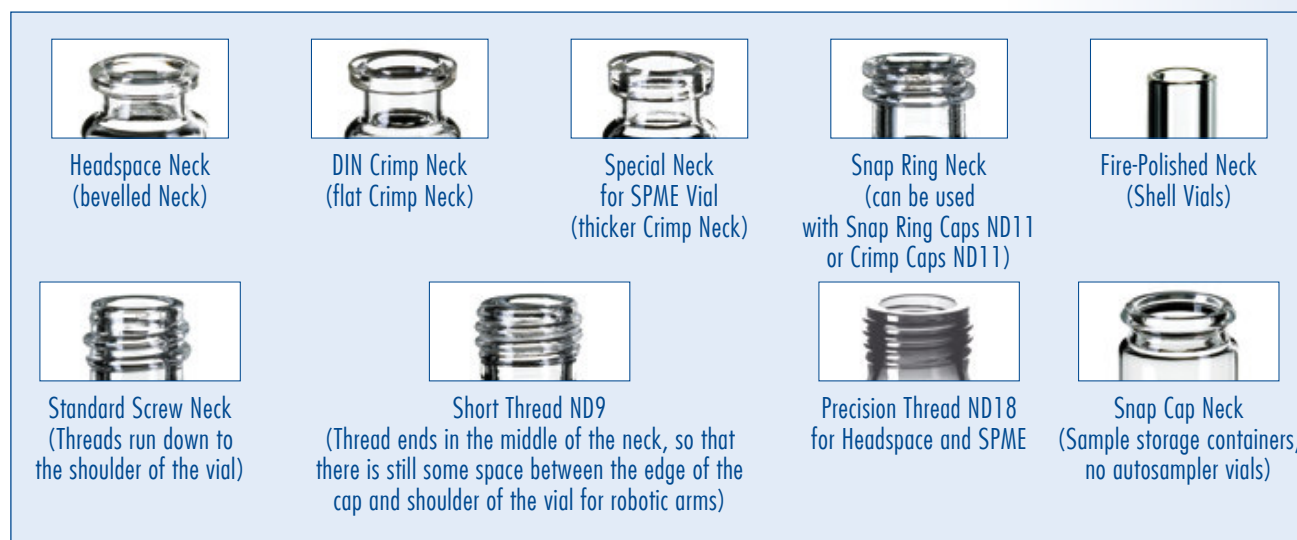
HPLC and GC Certified KITS

Based on the "Specification Certified" products each lot of the HPLC and GC certified KITS has been tested on 15 critical parameters. Here a HPLC/UV and GC/MS-test of the vial/closure combination on blank values and contaminations is done in a reality-near procedure.

- The batch-specific test certificate with the HPLC and GC-Chromatograms can be attached out upon request.
- The HPLC and GC certified KITS are delivered completely shrink-wrapped for reasons of originality, purity and transport safety. This means an additional safety for the end user.
- Available as 9mm Short Thread Vial in clear and amber with suitable closure combination.
- Upon request further HPLC GC Certified Vial KITS will be available.
- Optional LC/MS-test possible.

In order to visualize the most important characteristics that differentiate the different types of vials, we show below some drawings helping you to identify a vial:

A) Design of the Neck



B) Design of the Bottom



Besides standard glass vials La-Pha-Pack also supply some silanized glass products. Silanized glass products are used to reduce the adsorption of polar compounds onto the surface of the glass container (e.g. protein analysis). Some compounds like amino-acids, proteins or phenols tend to react with the glass, and the silanization process prevents this by deactivating the glass surface.

In some specific applications like atomic absorption, water and protein analysis, capillary electrophoresis, etc., even plastic vials have to be used. La-Pha-Pack also offer a broad range of Plastic Vials and Plastic Micro-Vials of different materials (PP, TPX).

In case the application requires pre-sealed vials (e.g. vials that are either already crimped or screwed), as for example in the tobacco industry, we can also supply you with any type of vial and closure already assembled. However, please note that the vials have to be taken out of the CleanPack packaging for the sealing process and thus cannot be called "cleanroom" packed anymore.

EPA Vials can be supplied with or without certificate of cleanliness depending on the consumer's requirements. Furthermore EPA vials can also be supplied pre-assembled with their seals.

Seals

Seals are the assembled combination of a cap and a septa. To carry out a correct analysis, it is important that besides the vial the seal is also inert and uncontaminated. La-Pha-Pack assemble and pack their seals fully automated according to internally defined room conditions. Thus it is guaranteed that they are not contaminated by human contact as it would be in case of manual assembly. Photocells check the side-orientation of the liner, so that it is ensured that the PTFE lamination is always directed towards the sample to build an inert barrier between sample and carrier material of the septa. A gauge control ensures that not more or less than one septa is installed. The final seals are automatically counted – and not weighed – by automates to guarantee quantity obedience. They are packed in tamper-proof evident zip-lock bags that allow easy identification of the content due to the transparent PE material. The

zip-lock enables resealing of the bag to avoid any contamination of the closures during consumption. The batch number of the manufactured seal is printed on each PE-bag for traceability.

UltraBond seals are closures where the cap and the septa form an inseparable unit without the use of any glue or adhesive which are not allowed in chromatography products. This firm connection is achieved by a patented process changing the molecular structure of the cap and the septa surface, so that they form a unit. This process ensures that the septa is not pushed into the vial during penetration, even if the needle is very thick and blunt. Examples for such UltraBond Seals are 24mm Screw Seals for EPA Vials or 9mm Short Thread Seals for Short Thread Vials.