

Tech Note

Quality Aspects for Ampules

Abstracts

This tech note informs about tolerances and shapes of Zeochem primary packaging material. For simplifying solvent handling in ¹H-NMR spectroscopy Zeochem AG offers its portfolio of solvents in small and easy to handle amber ampules.

The glass ampules are filled and subsequently sealed hermetically. A 100% leak test is applied to the sealed ampules.

Additionally, some recommendations are listed to avoid any contamination when using pipettes and sample tubes.

Ampule shapes: The sealing process

Empty ampules are filled with a precision piston stroke pump. The product loaded ampules are overlaid with nitrogen to prevent any kind of moisture uptake and exchange with hydrogen from ambient air.

Before sealing, the content is cooled down keeping the nitrogen overlay until the ampule neck is fused to a dome shaped end. The ampule is now completely gastight.

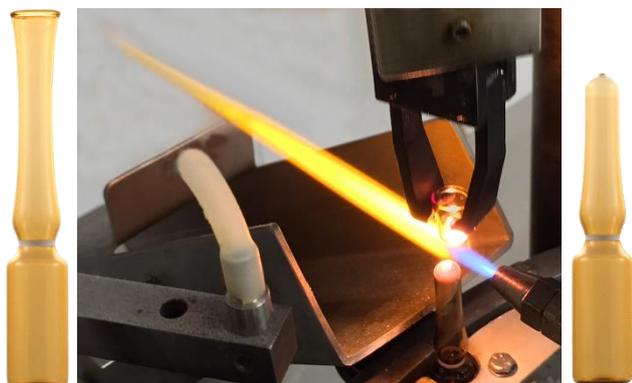


Fig. 1 Ampule shape before and after sealing



Sealed ampule dome shapes

Due to the different nature of products, the shape of the formed dome at the sealing zone may slightly vary. All shapes illustrated below are approved by Zeochem's Quality Unit and not subject to quality complaints.



Fig. 2 sealed and tight ampule dome shapes

Discoloration at the top of sealing

For sealing the ampule neck heat needs to be applied. The product will be protected by nitrogen overlaying during this process. In some case discoloration at the top of the sealing may evolve due to the nature of the product. E.g. iodomethane-d₃ causes a slight purple coloration, the product itself has a pale purple coloration also. This is not a reason for a quality complaint as it is an unavoidable attribute of certain products in the sealing process.

No carbon residues at the sealed ampules neck

Zeochem AG assures high quality product ampules that don't have any carbon residues inside the sealed ampule neck even in the presence of discolored sealing top.

100% leak test for Ampules

No compromises to safety and quality

After sealing all ampules undergo a leak test where they are stored at low pressure (200mbar) for 2 hours at ambient temperature (25°C). Only tight ampules are finally packed into the protective boxes.

Visual and quality inspection

The final quality inspection against the individual product specification is performed with the product

by opening a representative number of sealed ampules. Hence, the test results issued on the certificate of analysis reflects the real product quality of a composite sample after the sealing.

Each sealed ampule is inspected visually before packing into the cardboard protection box. Multiple inspection steps during manufacturing ensure high quality products our customer can rely on.

Ampule identification

Compromise to readability and identification

The cylindrical surface of ampules allows labelling with the content and grade of product (volume or weight, solvent, deuterium enrichment), without obscuring of the inner liquid behind a label.



Fig. 3 Product name and grade is printed on the ampule directly

The envelope boxes include the full information of the content including the item, amount, item No, Batch No and GHS safety marks.



Fig. 4 Ampules are protected in small cardboard container

Applied Regulatory

Amount, volume and weight

Zeochem AG uses well maintained dosing equipment. The correct filling quantity is verified by periodic weighing on a precision balance.

The precision of the balance is checked and approved periodically by external authorities. Additional functionality tests are regularly performed.

Compensation of error propagation during the filling process

All components of the filling process exhibit a small tolerance. The sum of tolerances and a safety margin is added to the declared filling volume of ampules conforming the Swiss directive. Hence, variations in the filled volumes may occur but are not reasons to quality complaints.

Swiss directive 941.281

Zeochem AG is committed to the Swiss directive 941.281 (Deklarationsverordnung). The filling process is controlled by determination of two parameters (volume and weight) and are controlled at Zeochem AG to comply with the Swiss directive 941.281. No individual container may fall below the declared content on the ampule and package label. To fulfill this regulatory requirement, Zeochem AG applies a safety margin by slightly overfilling the ampules.

Self verification of filling volume

Overlay pictures

Put your ampules in front of the appropriate drawing and check fill level in the vertical position (pay attention no liquid is caught in the ampule neck first!). The fill level must be above the mark lines indicated in the picture. Overfilling fluctuation is not a reason for a quality complaint.



Fig. 5 minimum filling level at different volumes

Recommendations for a safe application

Avoid contamination with lab glassware

We recommended using clean and dry lab glassware only. ¹H-NMR solvents dissolve any kind of material they are exposed to. We recommend avoiding plastic labware to prevent extractables, leachables or plasticizers dissolving and being detected later in the ¹H-NMR record.

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