

PDA Training Container Closure Systems

Definitions





Content

- Compendial definition
- Functional definition
- Components vs CCS
- Description of options
- Materials

Containers (Ph.Eur. - section 3.2.): a container....

- contains or is intended to contain a product,
- is in direct contact with a product,
- is so designed, that the content may be removed in a manner appropriate to the intended use of the preparation,
- provides varying degree of protection depending on the nature of the product and the hazards of the environment,
- Minimises the loss of constituents,
- does not interact physically or chemically in a way that alters product quality beyond the limits tolerated by official requirements.

Primary or immediate container

- In direct contact with product
- Provides the major protection for the drug product against environmental stress

Secondary container

- Provides information (printed packaging materials)
- Might provide additional protection against light and/or water vapor

Tertiary container

- „logistical“ packaging components (cartons, palettes, shrink wraps etc.)

Packaging Components

- Rubber closures, bottles, vials, ampoules etc.

Container Closure System (CCS)

- Combination of packaging components: e.g. rubber closure-vial-closure cap or syringe barrel-plunger-tip-cap
- Combination of primary and secondary packaging materials: e.g. infusion bag + pouch to block water vapor

CCS for parenterals

- Ampoules
- Injection vials + closures
- Infusion bottles + closures
- Infusion bags
- Prefilled syringes
- Form-fill-seal/ Blow-fill-seal containers
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Glass

- Glass types I, II und III
- Colorless and amber glass

Polymers

- Plastics
 - PVC, PE, PP, PET, PVA, COC
 - Coatings: sealants, silicone oil, teflon
- Elastomers
 - Butyl-, bromobutyl- und chlorobutyl rubber, silicone rubber
 - Special rubber types for special applications (e.g. nitrile rubber for oily solutions)



Thank you very much for your attention!!