Target product profile of container closure system

Compendial Background

Compendial Background

Ph.Eur.

- 3.1. Materials used for the manufacture of containers
  - 3.1.3. Polyolefines
  - 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations
  - 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations
  - 3.1.6. Polypropylene for containers and closures for parenteral preparations and opthalmic preparations

Compendial Background

Ph.Eur.

- 3.1. Materials used for the manufacture of containers
  - 3.1.7. Poly(ethylene-vinyl acetate) for containers and tubing for total parenteral nutrition preparations
  - 3.1.8. Silicone oil used as a lubricant
  - 3.1.13. Plastic additives
  - 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion
  - 3.1.15. Polyethylene terephthalate for containers for parenteral use

Compendial Background

Ph.Eur.

- 3.1. Materials used for the manufacture of containers
  - Structure of a material section
    - DEFINITION: description of basic polymer, e.g. homo- oder copolymer
    - PRODUCTION: listing of potential additives and specification of the acceptable types and nos. of additives and their limits
    - CHARACTERS: appearance of raw material, solubility in water and solvents
    - IDENTIFICATION: identity tests
    - TESTS: purity testing, e.g. extractables, sulphated ash
    - SUPPLEMENTARY TESTS: Tests for additives, e.g. phenolic or non-phenolic antioxidants, amides/stearates

Compendial Background

Ph.Eur.

- 3.2. Containers
  - 3.2.1. Glass containers for pharmaceutical use
  - 3.2.2. Plastic containers and closures for pharmaceutical use
    - 3.2.2.1. Plastic containers for aqueous solutions for infusion
  - 3.2.9. Rubber closures for aqueous parenteral preparations, for powders and for freeze-dried powders

Compendial Background

USP

<87> Biological reactivity tests - in-vitro

<88> Biological reactivity tests - in-vivo

<381> Elastomeric closures for injections

<660> Containers - Glass

<661> Plastic Packaging Systems and Their Materials of Construction

- <661.1> Plastic Materials of Construction
- <661.2> Plastic Packaging Systems for Pharmaceutical Use

<671> Containers – Performance Testing

Compendial Background

USP

<1207> Package Integrity Evaluation - Sterile Products

- <1207.1> Package Integrity Testing in the Product Life Cycle - Test Method Selection and Validation
- <1207.2> Package Integrity Leak Test Technologies
- <1207.3> Package Seal Quality Test Technologies

<1660> Evaluation of the inner surface durability of glass container

Compendial Background

USP

<1661> Evaluation of plastic packaging systems and their materials of construction with respect to their user safety impact

<1663> Assessment of extractables associated with pharmaceutical packaging/delivery systems

<1664> Assessement of drug product leachables associated with pharmaceutical packaging/delivery systems

<1664.1> Orally inhaled and nasal drug products

Target product profile of container closure system

Product related criteria

Product related criteria

Formulation

- Solid, semi-solid, liquid
- Lyophilisate for reconstitution
- Patient related dosing (e.g. body weight or surface)
- Concentration of active ingredient
- Pharmacological activity of active ingredient
- Content of volatile components (e.g. alcohols)
- Preservatives and/or other critical excipients

Product related criteria

Route of administration and application

- Oral, topical, parenteral (sc, im, iv – injection/infusion), others
- Use of application aids for product preparation (infusion sets, spikes, disposable syringes)
- Application with injectors (mechanical, automated)
  - Injection speed
  - Needle size
  - Resistance against mechanical stress (e.g. pressure resistance)

Product related criteria

User profile

- Application by professionals (nurses, physician) or by patients
  - Fool proof system vs. complex equipment
  - Known system vs. need for intense training
- Age and/or impairment of patients
  - Size of systems
  - Ease of use, easy to understand
  - Safety, hygiene

Product related criteria

Environmental considerations

- Influence of humidity
  - Barrier films
  - Alu-pouch for plastic infusion bags
- Influence of light
  - Light resistant (colored) glass
  - Light protection via secondary container
- Influence of gases (O_2, NO_x, CO_2)
- Other environmental influences on product quality
  - Temperature controlled storage and shipment
  - Dry-ice or liquid nitrogen storage and shipment

Product related criteria

Processability

- Aseptic processing
- Lyophilization
- Sterilization (e.g. for plastic packaging components)
- Processability on existing equipment
- Development of new process technology