General chapter 3.2.1
Glass containers for pharmaceutical use

Speakers:

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Dr. Emanuel Guadagnino
The presentations take account of the evaluation of the questions received on the general chapter 3.2.1 Glass containers for pharmaceutical use during the last 1.5 years.
Points to be addressed

**Part 1** presented by Dr. Ellen Pel:

- Introduction to the Ph. Eur.
- History of the general chapter 3.2.1.
- How to participate in the revision

**Part 2** presented by Dr. Guadagnino:

- Ongoing revision of chapter 3.2.1: hydrolytic resistance
- Delamination risk: Ph. Eur. approach
The purpose of the European Pharmacopoeia is to promote public health by the provision of recognised common standards for the quality of medicines and their components. Such standards are to be appropriate as a basis for the safe use of medicines by patients.
Lays down common, compulsory quality standards for all medicinal products in Europe.

Mandatory on the same date in 37 states (CoE) and the EU (European Union Directives 2001/82/EC, 2001/83/EC, and 2003/63/EC, as amended, on medicines for human and veterinary use).

The Ph. Eur. is legally binding. The legislation also includes a mechanism to provide the pharmacopoeia authority with information on the quality of products on the market;

The European Pharmacopoeia needs to keep pace

with the regulatory needs of licensing, control and inspection authorities in the public health area,

with technological and scientific advances, and with industrial constraints.
Ph. Eur. – General organisation

Introduction
General notices
General chapters
General monographs
Individual monographs
1. General notices

- apply to all monographs and other texts of the Ph. Eur.
- instructions to understand texts, conventional expressions
- essential reading before starting to use general chapters and monographs
Flexibility in the Ph. Eur.
- Alternative methods

- **Ph. Eur. tests are reference methods**, essential in cases of dispute.
- Compliance is required, but **alternative methods** may be used as long as they lead to the **same pass/fail result**.
- It is the responsibility of the user to demonstrate their suitability. **Approval of the competent authority** is necessary in many cases.
“An article is not of Pharmacopoeia quality unless it complies with all the requirements stated in the monograph. This does not imply that performance of all the tests in a monograph is necessarily a prerequisite for a manufacturer in assessing compliance with the Pharmacopoeia before release of a product. The manufacturer may obtain assurance that a product is of Pharmacopoeia quality from data derived, for example, from validation of the process and from validation studies of the manufacturing process and from in-process control”.

General Notices (3rd Edition to Supplement 8.1)
1.3. GENERAL CHAPTERS

Containers. ... The test methods and limits for materials depend on the formulation and are therefore applicable only for materials whose formulation is covered by the preamble of the specification. The use of materials of different formulations, and the test methods and limits applied to them, are subject to agreement by the competent authority....
Ph. Eur. – General organisation

Introduction

General notices

General chapters

General monographs

Individual monographs

2 - Methods of analysis

3 - Materials for containers and containers

4 - Reagents

5 - General texts
Ph. Eur. – General organisation

Introduction
General notices
General chapters
General monographs
Individual monographs

2 - Methods of analysis
3 - Materials for containers and containers
4 - Reagents
5 - General texts

5.12 – European Pharmacopoeia reference standards
Ph. Eur. – General organisation

Introduction
General notices
General chapters
General monographs
Individual monographs

23 general monographs + Dosage forms monographs in Ph. Eur. 8.7
- Pharmaceutical preparations
- Substances for pharmaceutical use
- Vaccines for human use
- Essential oils
- Parenteral preparations
...
DEFINITION

Parenteral preparations are sterile preparations intended for administration by injection, infusion or implantation into the human or animal body. ....

Parenteral preparations are supplied in glass containers (3.2.1) or in other containers such as plastic containers (3.2.2, 3.2.2.1 and 3.2.9) and prefilled syringes. ....
Ph. Eur. – General organisation

Introduction
General notices
General chapters
General monographs

More than 2500 monographs
- Chemicals
- Herbals
- Antibiotics
- Biologicals
- Vaccines
- Fats
- Radiopharmaceuticals
- ….
History of the general chapter on glass containers for pharmaceutical use

1972: First publication (Ph. Eur. 1st edition)

2004: Deletion of type IV glass from the scope. Hydrolytic resistance: Distinction of vials/ bottles and ampoules in the hydrolytic resistance test. Introduction of flame spectrometric method in the annex (Ph. Eur. 5.0)

2010: Alignment of limits for hydrolytic resistance test for glass grains with ISO 720 (Ph. Eur. 6.8)

2015: Clarification of hydrolytic resistance test (ongoing)

Participating in the work of the European Pharmacopoeia

Knowledge Database

Knowledge database: new version released
A new version of the Knowledge Database has been released: please read the instructions given under “How to read this table” immediately underneath the information displayed for the monograph. The new feature provides detailed information on work on-going either for a new monograph under elaboration or for a published monograph under revision with a view to being more transparent to our users. This will also allow Ph.Eur users to contribute to the work of the European Pharmacopoeia more easily.

› "How to read this table"

Search Database online

Search Knowledge

https://www.edqm.eu/Knowledge-Database-707.html
### Participating in the work of the European Pharmacopoeia

<table>
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<tr>
<td>Monograph Number</td>
<td>30201</td>
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<tr>
<td>English Name</td>
<td>Glass containers for pharmaceutical use (3.2.1.)</td>
</tr>
<tr>
<td>French Name</td>
<td>Récipients de verre pour usage pharmaceutique (3.2.1.)</td>
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<td>8.4</td>
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<td>8.4</td>
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#### Description
- Hydrolytic resistance: clarify description of sample preparation process

#### Chromatogram
- Not available

#### Additional information
- Not available

#### History
- [View history](#)

#### Interchangeable (ICH Q4B)
- NO

#### International Harmonisation chapter 5.8
- NO

#### Reference standards

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>To be used in test(s)</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>Test B. Hydrolytic resistance of glass grains</td>
<td>Steel mortar and pestle, Humboldt Manufacturing Co., 7300 West Agate, Norridge, Chicago, IL 60656, USA</td>
<td></td>
</tr>
</tbody>
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SUPPLEMENT 8.4
It has been decided to further emphasise the need for control of specific components that may be toxic for chronic use and for vulnerable patient groups. The statements in the definition section of Parenteral preparations (0520), in chapter 3.2.1. Glass containers for pharmaceutical use and in chapter 3.2.2. Plastic containers and closures for pharmaceutical use have therefore been supplemented.

SUPPLEMENT 8.3
Production: section introduced to address the risk related to potential delamination of glass containers, by raising awareness of the glass manufacturers and users of the glass containers in the pharmaceutical industry to the factors contributing to the phenomenon.
Harmonisation with ISO 4802-1 and 4802-2: adjustments made to avoid ambiguities with ISO, including an additional volume specification for containers of 2-3 mL in Table 3.2.1.-3 and Table 3.2.1.-7.
Hydrolytic resistance of glass grains: alternative grinding device introduced to include state-of-the-art equipment that increases reproducibility of sample preparation.

SUPPLEMENT 6.8
Test B. Hydrolytic resistance of glass grains: the limits have been corrected to fit with the ISO 720 (1985) standard. The equivalence of alkali expressed as mass of Na2O per gram of glass has been deleted because this information is redundant.

PUBLICATION 5.0: for more than 50 years it has been known that alkaline or neutral preparations for parenteral use may affect the inner surface of glass containers. A small amount of alkali may be leached and can cause a change in the composition of the preparation. The intensity of the attack in comparable conditions depends on the nature of the product, and the composition of the glass type used for...
Participating in the work of the European Pharmacopoeia

http://pharmeuropa.edqm.eu/home/
End of part 1

Thank you!
General chapter 3.2.1
Glass containers for pharmaceutical use

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