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Public Consultation for Ph. Eur. dosage form monograph on Parenteral preparations (0520) and new informative chapter on testing for visible particles (5.17.2)

The European Pharmacopoeia (Ph. Eur.) Commission is consulting its stakeholders on two major texts for the testing of parenteral drug products.

The pivotal dosage form monograph *Parenteral preparations (0520)* prescribes the mandatory requirements and tests for preparations intended for injection, infusion or implantation.

The monograph has been modernised to meet current testing requirements e.g. for (sub-)visible particles, bacterial endotoxins, uniformity and release, particularly as applied to liquid parenteral preparations.

The revision contains the following main changes:

- The definition of solutions for injection or infusion has been clarified, as has the requirement that solutions have to be guaranteed practically free from particles during production and quality control.
- In addition to testing for sub-visible particles according to *2.9.19.*, testing for visible particles (*2.9.20*) is a requirement for liquid preparations for injection and infusion and this information has been added to the test section.
- A test for bacterial endotoxins or pyrogens is generally required for all parenteral products and this has therefore been moved to the general test section with updated wording. It should be noted that chapter *2.6.9* states that the monocyte-activation test should replace the test for pyrogens wherever possible.
- The definition of injections has been updated to focus on the route of administration in order not to exclude any products.
- A release test for gels for injections and implants has been added, as well as uniformity requirements for implants.
- A subsection on intravitreal preparations has been added to clarify their status as parenteral preparations.

The monograph also refers to the newly elaborated informative non-mandatory chapter *5.17.2. Recommendations on testing of particulate contamination: visible particles*. The requirements for the test method are laid down in chapter *2.9.20*, which is also under revision, and a revised text is planned for publication in 2019 (a draft was published in Pharmeuropa 30.2).

The new text highlights the many sources of particulate contamination and states that every effort should be made to avoid their presence. Consideration is given to the different inspection stages during production and quality control, including stability testing. The possibility of additional AQL testing (with reference to ISO standard 2859-1) following a 100% inspection of the batch is mentioned; this is already performed by manufacturers.

Testing for visible particles in parenteral products is probabilistic in nature and the occurrence of particles is random. The chapter therefore provides advice on how users can accomplish the difficult task of verifying that their product is practically free from particles.

The two texts have been published for public consultation in Pharmeuropa 30.4 (October issue).
Users and parties concerned can submit their comments until 31 December 2018: http://pharmeuropa.edqm.eu/home/

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**
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Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic , Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg , Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia , Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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