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Association suisse des pharmaciens de l'administration et des hôpitaux
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**EAHP**

Bern, 16th January 2020

**Comment on the changes in the monograph 'eye drops' regarding sub-visible particles**

To whom it may concern:

The GSASA, Swiss Association of Public Health Administration and Hospital Pharmacists, would urgently like to encourage the EAHP, to make representations regarding the intentions of the EDQM to set specifications for sub-visible particles in the monograph "eye drops" in the European Pharmacopoeia.

Even if the deadline for comments to the draft in Pharmeuropa 31.4 has expired, we hope that the expert opinion of the EAHP may be of importance in this issue. The national authorities can provide their comments until the end of February 2020, so there might be a chance that the EDQM will also accept the representation of the EAHP.

From our point of view, there is no need to add a specification for particulate contamination for eye drops, even if they are only intended for use in surgical procedures, first-aid treatment and the treatment of the injured eye.

Not all hospital pharmacies are equipped with an apparatus to carry out the test on sub-visible particles. If this test were mandatory, eye drops would only be prepared as extemporaneous preparation in a hospital pharmacy, but not as stock preparation, because the required analytical test of the dosage form monograph could not be performed.

This is especially problematic, if these eye drops are to be used as a first-aid treatment, but cannot be manufactured on stock in advance.

Furthermore, to our knowledge an assessment is lacking, what risks are involved with any presence of particles in eye drops in the above-mentioned cases. In general, those risks may be assessed as being minor to absent as sometimes also suspension eye drops may be utilized.

We clearly support a risk-based approach for setting standards in the manufacturing of medicinal products. And if there is no risk for the patient, we don't see a need to add additional requirements.

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The situation in hospital pharmacies in Switzerland (and probably also in Europe) in most cases does not allow routine testing of prepared eye drops for sub-visible particles. We fear that these (in our opinion not necessary) specifications for particulate contamination in eye drops, will not lead to an advance in high quality health care of our patients, but on the other hand to a lack of therapy, as it will no longer be possible to do the preparation of clinically essential eye drops in the hospital pharmacy.

Yours sincerely

Dr. Stefanie Deuster
Former Head of the GSASA Department Manufacturing
On behalf of the GSASA

Annexe



Reference: PA/PH/Exp. 12/T (19) 19 ANP

*NOTE ON THE MONOGRAPH*

***Eye drops and Eye lotions**: a test for particulate contamination: sub-visible particles (2.9.53) has been added with corresponding acceptance criteria.*

***Definition**: added that preparations applied to the injured eyes are free from preservatives and supplied in single-dose containers.*

***Ophthalmic inserts**: the test to ensure suitable dissolution of the active substance has been moved from the Production section to the Test section.*

**XXXX:1163**

## EYE PREPARATIONS

### Ophthalmica

(…)

TESTS

**Particulate contamination: sub-visible particles** (*2.9.53*). Unless otherwise justified and authorised, eye drops that are solutions intended for use in surgical procedures, first-aid treatment and the treatment of the injured eye comply with the following limits using Method 1 or Method 2.

*Method 1 (light obscuration particle count test)*

The average number of particles present in the containers or units tested does not exceed 1000 per millilitre for particles equal to or greater than 10 µm in size and does not exceed 100 per millilitre for particles equal to or greater than 25 µm in size.

*Method 2 (microscopic particle count test)*

The average number of particles present in the containers or units tested does not exceed 3000 per container for particles equal to or greater than 10 µm in size and does not exceed 300 per container for particles equal to or greater than 25 µm in size.

In the case of emulsions, colloidal dispersions or liposomal preparations, higher limits may be appropriate.

Not all eye drops can be examined for sub-visible particles by these methods. When Method 1 is not applicable, e.g. in case of preparations having reduced clarity or increased viscosity, the test is carried out according to Method 2. Emulsions, colloids and liposomal preparations are examples. Similarly, preparations that produce air or gas bubbles when drawn into the sensor may also require microscopic particle count testing.