Streptomycini ad injectionem
Streptomycin for injection

(July 2013)

DRAFT FOR COMMENT

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SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/13.529
Streptomycini sulfatis pulvis ad injectionem - Streptomycin sulfate powder for injections

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[Note from the Secretariat. It is proposed to harmonize the colorimetric identification test of the monograph on Streptomycin for injection in The International Pharmacopoeia with that of the British Pharmacopoeia and to delete the requirement for the colour of the solution. Concurrently, editorial changes are suggested.]

For simplicity, only the sections of the monograph, which contain changes, are given in the document below.

Changes from the current monograph are indicated in the text by insert or delete.]
**Streptomycini sulfatis pulvis ad injectionem**

**Streptomycin sulfate powder for injections**

 [...] 

**Definition.** Streptomycin sulfate powder for injections is a sterile powder of streptomycin sulfate. Streptomycin sulfate powder for injections may contain suitable buffers, preservatives, and stabilizers. The powder is sterilized by a suitable method (see 5.8 Methods of sterilization).

**Identity tests**

 [...] 

**B.** Dissolve a quantity of the powder for injections equivalent to 0.1 mg of Streptomycin sulfate in 4 ml of water, add 1 ml of sodium hydroxide (~80 g/l) TS and heat on a water-bath for 5 minutes. Cool and add 1.5 ml of hydrochloric acid (~70 g/l) TS and 1 drop of ferric chloride (25 g/l) TS; an intense violet colour is produced.

**B.** Dissolve a quantity of the powder for injections equivalent to 8 mg of Streptomycin sulfate in 4 ml of water, add 1 ml of sodium hydroxide (~40 g/l) TS and heat on a water-bath for 4 minutes. Cool and add 1 ml of hydrochloric acid (~70 g/l) TS and 0.1 ml of ferric chloride (63 g/l) TS; a violet colour is produced.

 [...] 

**Clarity and colour of solution.** A solution of the powder for injections equivalent to 2.5 g of Streptomycin sulfate in 10 ml of carbon-dioxide-free water R is clear and colourless. (Keep this solution for the "pH value").
Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 0.25 IU of endotoxin RS per mg of streptomycin.

Sterility. Complies with 3.2 Test for sterility.

To be added to the section on Reagents, test solutions and volumetric solutions chapter:

Ferric chloride (63 g/l) TS.
A solution of ferric chloride R containing about 63 g of FeCl₃ per litre.