Alcuronium chloride (Alcuronii chloridum)

C_{44}H_{50}Cl_{2}N_{4}O_{2}

Relative molecular mass. 737.8

Chemical name. N,N'-Diallylnortoxiferinium dichloride; CAS Reg. No. 15180-03-7.

Other name. Alcuronium dichloride.

Description. A white to yellow-white, crystalline powder.

Solubility. Soluble in water and ethanol (~750 g/l) TS.

Category. Muscle relaxant.

Storage. Alcuronium chloride should be kept in a tightly closed container.

Labelling. The designation Alcuronium chloride for parenteral use indicates that the substance complies with the additional requirements and may be used for parenteral administration. Expiry date.

Additional information. CAUTION: Alcuronium chloride is highly toxic. It must be handled with care, avoiding contact with the skin and inhalation of airborne particles. It is hygroscopic.

Requirements

Alcuronium chloride contains not less than 98.0% and not more than 101.0% of C_{44}H_{50}Cl_{2}N_{4}O_{2}, calculated with reference to the anhydrous substance.

Note: All tests must be carried out immediately after opening the container, and as rapidly as possible.

Identity tests

• Either tests A and D or tests B, C, and D may be applied.

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from alcuronium chloride RS or with the reference spectrum of alcuronium chloride.

B. The absorption spectrum of a 14 μg/mL solution in phosphate buffer, pH 7.0 (0.067 mol/l) TS, when observed between 230nm and 350nm, exhibits a maximum at about 293 nm and a minimum at about 237 nm; the absorbance of a 1-cm layer at the maximum wavelength is about 0.9.

C. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

D. A 20mg/mL solution yields reaction A described under 2.1 General identification tests as characteristic of chlorides.

Specific optical rotation. Use a 10mg/mL solution, measured within 10 minutes of preparation, and calculate with reference to the anhydrous substance: [α]_{D}^{20°C} = -430° to -451°.

Heavy metals. Use 2.5 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 3; determine the heavy metals content according to Method B; not more than 20 μg/g.

Clarity and colour of solution. A solution of 0.10 g in 10 mL of carbondioxide- free water R is clear and not more intensely
coloured than standard colour solution Yw2 when compared as described under 1.11 Colour of liquids.

**Sulfated ash.** Not more than 1.0 mg/g.

**Water.** Determine as described under 2.8 Determination of water by the Karl Fischer method, Method A, using about 0.5 g of the substance; the water content is not more than 0.050g/g.

**pH value.** pH of a 10 mg/mL solution in carbon-dioxide-free water R, 6.0-8.5.

**Related substances.** Carry out the test protected from daylight until the start of detection as described under 1.14.1 Thin-layer chromatography, using silica gel R6 as the coating substance (a precoated plate from a commercial source is suitable) and a mixture of 1 volume of methanol R and 1 volume of ammonium nitrate TS as the mobile phase. Apply separately to the plate 5 μl of each of 4 solutions in methanol R containing (A) 40mg of Alcuronium chloride per mL, (B) 40 mg of alcuronium chloride RS per mL, (C) 0.20mg of alcuronium chloride RS per mL, and (D) 0.10 mg of alcuronium chloride RS per mL. Prior to development allow the plate to dry in a current of cold air and place in a chromatographic chamber. After removing the plate from the chromatographic chamber, allow it again to dry in a current of cold air, and examine the chromatogram in ultraviolet light (254 nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution C (0.5%), and no more than 3 of these spots are greater than the spot obtained with solution D (0.25%).

**Assay.** To about 0.3 g, accurately weighed, add 70 mL of acetic anhydride R and place the mixture in an ultrasonic bath for 15 seconds. Titrate the turbid solution with perchloric acid (0.1 mol/l) VS as described under 2.6 Non-aqueous titration, Method A.

Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 36.89 mg of $\text{C}_4\text{H}_{50}\text{Cl}_2\text{N}_4\text{O}_2$.

**Additional requirements for Alcuronium chloride for parenteral use**

Complies with the monograph for "Parenteral preparations".

**Bacterial endotoxins.** Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 17.5 IU of endotoxin RS per mg.