Hyiodine®

Medical device for coverage, cleaning and wound hydration with an antiseptic agent

Quality and content of the final product are evaluated. Randomly selected samples of the final product are taken from each batch. The specification parameters are determined using validated analytical methods.

Test methods

Appearence

This test method describes the visual assessment of the appearance of HYIODINE. Following parameters are evaluated: presence of foreign particles, colour, opalescence, viscosity, homogeneity etc. HYIODINE is tested in its original packaging (colourless transparent glass) when examined by day scattered light. This method provides a rapid pass/fail test. It is a qualitative assessment only. The test passes if the sample is in compliance with a specification (amber coloured high viscous liquid).

pH

Potentiometric measurement of pH is based on the determination of difference between potentials on two suitable electrodes immersed into tested solution. First electrode is sensitive to oxonium cations (usually glass electrode) and second one is reference (i.e. saturated calomel electrode). Nowadays, both electrodes are usually combined within one system.

Hyiodine is measured in its original glass bottle. First, electrode is washed with water and dried with cellulose pad. Then, electrode is immersed into non-diluted Hyiodine tempered to 25±1 °C. After stabilization pH value is recorded to the nearest 0.001 pH unit. Two repetitive measurements are performed for each sample. Final value is calculated as an arithmetic mean of two repetitions.

Kinematic Viscosity

Principle of the method is based on measurement of flow time of Hyiodine in Ubelohde capillary viscometer under defined conditions. From each batch two units are taken and from each unit two samples are prepared. Each sample is tested in three repetitions.

First, viscometer is rinsed with 10 ml of measured sample (working solution of Hyiodine). Viscometer is filled with working solution of Hyiodine in required amount and is then tempered for at least 15 minutes to required temperature (25±0.03 °C). Then, time needed for decrease of liquid level between two set marks is measured with stopwatch with readability of 0.01 s.

Deviation between two consecutive measurements must be ≤ 1%. Kinematic viscosity is then calculated.

Arithmetic mean is calculated from two measurements of one unit. Final value of kinematic viscosity is calculated as an arithmetic mean of two units.

Identification I_2

Identification test is based on ability of iodine or rather tri-iodide anion to penetrate into amylose helix (starch component) while creating characteristic blue colour. After heating colour disappears because of helix straightening, after cooling colour reappears.

Hyiodine solution is mixed with the solution of starch. The solution is shortly stirred and then is heated (not boiled) at heating plate until blue colour disappears. After that beaker with solution is cooled to room temperature and blue colour reappears.

Both tested samples of Hyiodine must pass the test.

Content I_2

The principle of the determination of iodine content is based on spectrophotometric measurement of absorbance of Hyiodine solution at wavelength of 352 nm.

First, absorbance of solutions of the calibration curve at a wavelenght of 352 nm is measured and testing of the individual samples then follows. KI solution (0.2 mol/l) is used as a blank. Each point is measured in two repetitions.

Iodine concentration (mg/ml) in diluted Hyiodine solution is read from the calibration curve and the amount of iodine (mg/ml) in native Hyiodine is recalculated.

Two diluted solutions are prepared from each tested Hyiodine sample. Each prepared solution is measured in two repetitions. Final result for tested Hyiodine sample is calculated as an average value.

Identification KI

A. Potassium

The presence of potassium in Hyiodine samples is determined using ICP-OES (inductively coupled plasma - atomic emission spectroscopy) method. After ionization and excitation of sample in plasma, emitted electromagnetic radiation is detected and evaluated. For detection of potassium emission, the line at wavelength of 766.491 nm is used, because it is most intensive from all potassium emission lines.

First, verification of ICP-OES system with blank (2% nitric acid) and standard potassium solution 5mg/l is performed. Then samples are measured.

The test passes if a readable signal at 766.491nm is detected.

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B. Iodide

During evaporation of Hyiodine iodine is released. After re-dissolution of the sample and addition of ferric chloride and chloroform following reaction proceeds:

$2FeCl_3 + 2KI \rightarrow 2FeCl_2 + 2KCl + I_2$

Released iodine causes colouring of chloroform layer to purple or purple-red.

Two Hyiodine samples are tested as follows: 5 ml of Hyiodine is pipetted into a porcelain bowl and the sample is evaporated to dry in a water bath. After cooling 5 ml of water is added to the colourless residue. 0.5 ml of working solution of ferric chloride (105 g/l) and 5 ml of chloroform are added and the whole amount is transferred into a test tube and stirred. Chloroform layer is coloured violet or violet-red.

Both tested samples of Hyiodine must pass the test.

Content KI

The method is based on reaction of Ag^+ cations with I^- anions, in which insoluble precipitate of AgI is formed. This reaction proceeds under acidic conditions and $AgNO_3$ is used as a standard solution. Equivalence point is set in potentiometric titration using silver and saturated calomel electrodes.

Two working solutions are prepared from each tested Hyiodine sample. Each prepared working solution is measured in two repetitions. For each measurement amount of KI content is calculated.

Final result for tested Hyiodine sample is counted as an average value.

Sterility

The principle of the test is based on direct cultivation of Hyiodine samples with liquid trypton-soy (TSB) and thioglycolate (TGB) broths.

Under aseptic conditions, sample of Hyiodine is transferred to the bottles with TGB and TSB broth (number of samples and the volume tested is given by Ph.Eur., chap. 2.6.1 Sterility). Broths inoculated with Hyiodine are cultivated at 20-25 °C (TSB) and 30-35 °C (TGB) for 14 days. Ongoing visual control is performed every 3-4 days and final evaluation is performed on 14th day of incubation. Presence of microbial contamination is evaluated based on the presence of turbidity, coating, sediment, flocculation, mold mycelium or any other difference from negative control. In case of any positive finding, verification and identification of microorganisms at solid broth is performed.

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Content

The determination is based on weighing of filled, closed and labelled packaging unit of Hyiodine and its comparison with average weight of empty packaging unit (glass bottle + rubber stopper + clinching cap + label). The difference between these two values corresponds with the amount of Hyiodine in the packaging unit.

Final average value is rounded to 1 decimal place.

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