Relative density 1.055 to 1.105, Appendix V G.

Viscosity 2.0 to 6.0 Pa s, Appendix V H, Method IV.

Tin(II) 2-ethylhexanoate

Characteristics A straw-coloured liquid.

Identification A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of tin(II) 2-ethylhexanoate.
B. Dissolve 0.1 g in 20 ml of *1,2-dichloroethane* and extract with 20 ml of 0.1M *hydrochloric acid*. To 5 ml of the extract add 5M *sodium hydroxide* dropwise until a white precipitate is produced. The precipitate dissolves on further addition of 5M *sodium hydroxide*.

Content of tin(II) 25.0 to 30.0% when determined by the following method. Boil 200 ml of *water* with 100 ml of *hydrochloric acid* for 10 minutes and pass a current of carbon dioxide continuously through the mixture until the assay is complete. Add 0.5 g of the substance being examined and boil for 5 minutes. Cool to room temperature, add 0.5 g of *potassium iodide* and titrate with 0.0167M *potassium iodate VS* using *starch mucilage* as indicator. Each ml of 0.0167M *potassium iodate VS* is equivalent to 5.935 mg of Sn.

Dressing

The dressing, prepared as directed on the label immediately before examination, complies with the following requirements.

Characteristics Soft and slightly absorbent solid.

Acidity or alkalinity To 15 g, previously cut into pieces not greater than 50 mg in weight, add 150 ml of *water*, macerate for 2 hours in a closed vessel, decant the liquid, carefully squeezing out the residual liquid with a glass rod, mix and filter. To 25 ml add 0.15 ml of *phenolphthalein solution*; to another 25 ml add 0.05 ml of *methyl orange solution*. Neither solution shows a pink colour.

Apparent density Not more than 190 kg m^{-3} when determined by Method 2 of British Standard 4443: Part 1:1979 (Methods of test for flexible cellular materials).

Water-vapour permeability Not less than 600 g m^{-2} per 24 hours, Appendix XX J2. Prepare the material for testing in the following manner using two glass plates (100 mm × 200 mm × 3 mm) and a glass rod 7.0 mm in diameter, bent to form a U-shape, with side arms 200 mm in length and 75 mm in base width. Lay the rod horizontally on one of the glass plates. To 20 g of the silicone elastomer base in a suitable container add 1.2 g of the tin(II) 2-ethylhexanoate and mix thoroughly for 15 seconds. Immediately pour this mixture on to the glass plate within the area of the central cavity close to the closed end of the U-shaped rod and place the other glass plate on top of the U-shaped rod spacer. Clamp the plates into position, stand the assembly on its edge with the open end of the U-shaped rod uppermost and allow the foam to expand and cure for 5 minutes. Carefully remove the glass plates and the U-tube spacer. Allow the resultant foam sheet to stand for 24 hours and then cut circular test discs 54 to 56 mm in diameter.

Extractable tin Not more than 6 ppm of Sn when determined by the following method. To 5 g, previously cut into pieces not more than 50 mg in weight, add 50 ml of a 0.9% w/v solution of *sodium chloride* and shake for 4 hours. Filter and determine by *atomic absorption spectrophotometry*, Appendix II D, measuring at 235.5 nm and using a nitrous oxide—acetylene flame.

Cadmium, copper, lead and zinc Not more than 5 ppm of each metal when determined by the method described in the test for Extractable tin, but using an air—acetylene flame and measuring at 228.8 nm for Cd, at 324.7 nm for Cu, at 217.0 nm for Pb and at 213.9 nm for Zn.

Water-soluble substances Not more than 1.5%, Appendix XX M, with the following modification. Cut the dressing into pieces not more than 50 mg in weight.

Storage The components of the dressing should be kept in well-closed containers and stored at a temperature not exceeding 25°.

Labelling The label on the package states (1) the directions for preparing the dressing; (2) the conditions under which the components should be stored.

Sodium Fusidate Gauze Dressing

Definition Sodium Fusidate Gauze Dressing consists of cotton fabric of leno weave with two picks in each shed which has been impregnated with Sodium Fusidate Ointment.

The dressing is supplied sterile in single pieces.

Fabric

Fibre identification The separated fabric, obtained in the test for Weight per unit area, complies with the tests for *cotton*, Appendix XX A.

Threads per 10 cm Warp, not less than 74; weft, not less than 80, Appendix XX C1, Method I, when determined on the impregnated fabric.

Weight per unit area Not less than 39 g m^{-2} when determined by the following method. Determine the area of 1.5 g of the dressing. Separate the dressing from the facing material using forceps, leaving behind any ointment adhering to the facing material, transfer it to an apparatus for the *continuous extraction of drugs*, Appendix XI F, and extract with 150 ml of *ether* for 6 hours. Reserve the ether solution for the test for Ether-soluble substances. Remove the extracted fabric from the apparatus and dry it to constant weight at 105°. Calculate the weight per unit area of the fabric in g m^{-2}.

Ointment

Content of sodium fusidate, $C_{31}H_{47}NaO_6$ 90.0 to 110.0% of the prescribed or stated amount.

Identification A. Cut 100 cm^2 of the dressing and facing material into pieces of suitable size (about 4 cm^2) and extract with 15 ml of n-*hexane*. Shake the hexane solution with 3 ml of *water* and allow to separate. Remove the aqueous layer, mix it with 5 ml of 0.2M *orthophosphoric acid* and extract with two 5-ml quantities of *chloroform*. Dry the combined chloroform extracts with *anhydrous sodium sulphate*, evaporate to dryness and dissolve the residue in 0.6 ml of *chloroform IR*. The *infrared absorption spectrum* of the resulting solution, Appendix II A, is concordant with the *reference spectrum* of fusidic acid.
B. In the Assay the principal peak in the chromatogram obtained with solution (2) has the same retention time as the peak due to fusidic acid in the chromatogram obtained with solution (1).

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Ether-soluble substances Not less than 70 g m^{-2} when determined by the following method. Evaporate the ether solution reserved in the test for Weight per unit area of the fabric and dry the residue to constant weight at 105°. Divide the weight of the residue by the area taken for the test.

Related substances Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 80 volumes of *chloroform*, 10 volumes of *cyclohexane*, 10 volumes of *glacial acetic acid* and 2.5 volumes of *methanol* as the mobile phase. Apply separately to the plate 5 µl of each of the following solutions. For solution (1) take not less than 200 cm^2 of the dressing, remove the ointment from the gauze and facing material, mix and extract a quantity containing 50 mg of Sodium Fusidate with 25 ml of n-*hexane*. Shake the hexane solution with 5 ml of *ethanol (70%)*, allow the layers to separate and use the ethanol layer. Solution (2) contains 0.040% w/v of *diethanolamine fusidate BPCRS* in *ethanol (96%)*. Solution (3) contains 0.040% w/v of *3-ketofusidic acid BPCRS* in *ethanol (96%)*. After removal of the plate, dry it at 110° for 10 minutes, spray with a 10% w/v solution of *sulphuric acid* in *ethanol (96%)*, dry at 110° for 10 minutes and examine under *ultraviolet light (365 nm)*. Any red *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the principal spot in the chromatogram obtained with solution (2). Any yellow spot in the chromatogram obtained with solution (1) is not more intense than the principal spot in the chromatogram obtained with solution (3).

Assay Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution (1) contains 0.07% w/v of *diethanolamine fusidate BPCRS* in the mobile phase. For solution (2) take 500 cm^2 of the dressing and facing material and cut into pieces of suitable size (about 25 cm^2). Weigh and transfer the pieces to a separating funnel and add 50 ml of n-*hexane* and 125 ml of the mobile phase. Shake vigorously for 15 minutes, allow the layers to separate and reserve the lower layer. Allow the solvent to drain from the extracted pieces of fabric and facing material, wash them with two 20-ml quantities of *acetone* and then with two 20-ml quantities of *petroleum spirit (boiling range, 40° to 60°)* and dry to constant weight at 105°. Calculate the weight of ointment from the initial weight of the dressing and facing material. Filter the reserved lower layer through glass fibre paper (Whatman GF/C is suitable) and dilute 10 ml of the clear filtrate to 20 ml with the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (20 cm × 4.6 mm) packed with *stationary phase C* (5 µm) (LiChrosorb RP-18 is suitable), (b) a mixture of 60 volumes of *acetonitrile*, 30 volumes of a 1% v/v solution of *glacial acetic acid* and 10 volumes of *methanol* as the mobile phase with a flow rate of 1.5 ml per minute and (c) a detection wavelength of 235 nm.

The *column efficiency*, determined using the peak due to fusidic acid in the chromatogram obtained with solution (1), should be not less than 14,000 theoretical plates per metre.

Calculate the percentage content of $C_{31}H_{47}NaO_6$ in the ointment using the declared equivalent content of $C_{31}H_{47}NaO_6$ in *diethanolamine fusidate BPCRS* and using the weight of ointment taken for the test.

Sterility Complies with the *test for sterility*, Appendix XVI A, with the following modifications. Use Method II: Direct Inoculation. Using aseptic precautions open a sufficient number of individual packages to provide an appropriate number of 'portions' as defined in Table III, treating each portion separately as follows. Transfer the portion to a container containing 200 ml of sterile isopropyl myristate that has been shown not to have antimicrobial properties under the conditions of the test, mix thoroughly and heat to a temperature not exceeding 40°. Maintain the contents of the container at this temperature for 15 minutes with intermittent agitation to aid dispersion. Transfer 5 ml of the resulting isopropyl myristate suspension to a container containing 200 ml of sterile quarter strength Ringer solution to which has been added 1% w/v of *polysorbate 80*; mix thoroughly. Transfer 1 ml of this dilution to each of the culture media used so that it is diluted approximately 10-fold. Incubate the inoculated media and observe the cultures as described in Appendix XVI A.

Zinc Paste and Coal Tar Bandage

Definition Zinc Paste and Coal Tar Bandage consists of cotton fabric of plain weave, evenly impregnated with a suitable paste containing not less than 6% w/w of Zinc Oxide and containing 3.0% w/w of Coal Tar. The fabric is bleached to a good white, is reasonably free from weaving defects and contains not more than traces of leaf residue, seed coat and other impurities. It is in one continuous length. The edges are cut evenly, parallel to the warp threads, or may be serrated and are reasonably free from long loose threads. The warp and weft yarns have counts not finer than 15 tex and 25 tex respectively.

Fabric

Fibre identification The dried material obtained in the test for Weight per unit area complies with the tests for *cotton*, Appendix XX A.

Threads per 10 cm Warp, 109 to 131, Appendix XX C1, Method II; weft, 73 to 90, Appendix XX C1, Method I.

Weight per unit area Not less than 39 g m^{-2} when determined by the following method. Measure the area of a sample weighing about 10 g. Boil the sample in *water* until the soluble ingredients in the mass have completely dissolved and the insoluble ingredients have become loosened, add sufficient 2M *hydrochloric acid* to remove any adhering zinc oxide, decant the liquid through a tared sieve with a nominal mesh aperture of 106 µm, transfer the residual fabric to the sieve, wash thoroughly with *water* and dry to constant weight at 105°. Calculate the weight of the fabric, in g m^{-2}, making allowance for serrated edges if present.

Paste

Weight Not less than 150 g m^{-2}, calculated from the weight and area of the sample and the weight of fabric obtained in the test for Weight per unit area.

Content of zinc oxide, ZnO Not less than 6.0% when determined by the following method. Ignite 6 g of the bandage until all the carbon is removed, cool the residue, dissolve in 30 ml of 2M *nitric acid* and dilute to 250 ml

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