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

with *water*. Neutralise 50 ml of this solution to *litmus paper* with 5M *ammonia solution*, add 5 ml of *ammonia buffer pH 10.9* and 100 ml of *water* and titrate with 0.05M *disodium edetate VS* using *mordant black 11 solution* as indicator. Each ml of 0.05M *disodium edetate VS* is equivalent to 4.068 mg of ZnO.

Calculate the weight of the paste taken from the Weight of paste (g m^{-2}) and the Weight per unit area of fabric (g m^{-2}) determined above.

Zinc Paste and Ichthammol Bandage

Defintion Zinc Paste and Ichthammol 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 2.0% w/w of Ichthammol. 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 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 with *water*. Neutralise 50 ml of this solution to *litmus paper* with 5M *ammonia solution*, add 5 ml of *ammonia buffer pH 10.9* and 100 ml of *water* and titrate with 0.05M *disodium edetate VS* using *mordant black 11 solution* as indicator. Each ml of 0.05M *disodium edetate VS* is equivalent to 4.068 mg of ZnO.

Calculate the weight of the paste taken from the Weight of paste (g m^{-2}) and the Weight per unit of area of fabric (g m^{-2}) determined above.

Zinc Paste Bandage

Definition Zinc Paste Bandage consists of cotton fabric of plain weave evenly impregnated with a suitable paste containing not less than 6% w/w of Zinc Oxide. 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 After removal of the paste, 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 fabric, in g m^{-2}, making allowance for serrated edges if present.

Paste

Weight Not less than 150 g m^{-2} when determined by the method for *weight of adhesive mass*, Appendix XX D3, using Method I of Appendix XX D2, the determination being carried out using *water* as the first solvent. In bandages with a serrated edge, make allowance for the area of serration.

Content of zinc oxide Not less than 6.0% when determined by the following method. Boil 6 g of the bandage with 150 ml of *water* for 5 minutes, add 30 ml of 2M *nitric acid*, decant the liquid on to a Buchner funnel, wash the material and the filter with warm *water* until the washings are free from nitrates, return any loose threads or fibres retained on the filter to the bulk material, evaporate the combined filtrate and washings to 200 ml, cool and dilute to 250 ml with *water*. To 50 ml add 1 g of *ammonium chloride*, 1 g of *ammonium oxalate* and sufficient 5M *ammonia* to make the solution just alkaline to *litmus paper*, add a further 5 ml of 5M *ammonia*, heat to boiling, allow to stand for 1 hour, filter and wash the residue with hot *water*. Dilute the cooled, combined filtrate and washings to 150 ml with *water*, add 5 ml of *ammonia buffer pH 10.9* and titrate with 0.05M *disodium edetate VS* using *mordant black 11 solution* as indicator. Each ml of 0.05M *disodium edetate VS* is equivalent to 4.068 mg of ZnO.

Decant the titrated liquid through a sieve with a nominal mesh aperture of 106 μm, return any loose threads or fibres retained by the sieve to the bulk material, wash the residual fabric with several successive small quantities of *chloroform*, dry at 105° and weigh the residue. The difference between the weights represents the weight of paste taken. Calculate the percentage of ZnO in the paste.