Ether-soluble substances Not less than 110 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.

Neamine Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel H* as the coating substance and a freshly prepared 3.85% w/v solution of *ammonium acetate* as the mobile phase. Apply separately to the plate 2 µl of each of the following solutions. For solution (1) remove the ointment from the gauze and surrounding material, disperse 1.0 g in 20 ml of *chloroform*, add 5 ml of *water*, mix, allow to separate and use the aqueous layer. Solution (2) contains 0.004% w/v of *neamine EPCRS*. After removal of the plate, dry it in a current of warm air, heat at 110° for 10 minutes and spray the hot plate with a solution prepared immediately before use by diluting *sodium hypochlorite solution* with *water* to contain 0.5% of available chlorine. Dry in a current of cold air until a sprayed area of the plate below the line of application gives at most a very faint blue colour with one drop of a 0.5% w/v solution of *potassium iodide* in *starch mucilage*; avoid prolonged exposure to the cold air. Spray the plate with a 0.5% w/v solution of *potassium iodide* in *starch mucilage*. Any spot corresponding to neamine in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2).

Neomycin C Carry out the method for *liquid chromatography*, Appendix III D, injecting 10 µl of each of the following solutions. For solution (1) add 1.5 ml of a freshly prepared 2% w/v solution of *1-fluoro-2,4-dinitrobenzene* in *methanol* to 0.5 ml of a 0.10% w/v solution of *framycetin sulphate BPCRS* in 0.02M *sodium tetraborate*, heat in a water bath at 60° for 1 hour and cool. Dilute the solution to 25 ml with the mobile phase, allow to stand and use the clear lower layer. For solution (2) remove the ointment from the gauze and surrounding material, disperse 0.5 g in 20 ml of *chloroform*, add 5 ml of 0.02M *sodium tetraborate*, mix and allow to separate. Proceed as for solution (1) but using 0.5 ml of the separated aqueous layer in place of 0.5 ml of the framycetin sulphate solution.

The chromatographic procedure may be carried out using (a) a stainless steel column (20 cm × 4.6 mm) packed with *stationary phase A* (5 µm) (Nucleosil 100-5 is suitable), (b) as the mobile phase with a flow rate of 1.6 ml per minute a solution prepared by mixing 97 ml of *tetrahydrofuran*, 1 ml of *water* and 0.5 ml of *glacial acetic acid* with sufficient of a 2.0% v/v solution of *absolute ethanol* in *ethanol-free chloroform* to produce 250 ml and (c) a detection wavelength of 350 nm. If necessary the tetrahydrofuran and water content of the mobile phase may be adjusted so that the chromatogram obtained with solution (1) shows resolution similar to that in the specimen chromatogram supplied with *framycetin sulphate BPCRS*. The mobile phase should be passed through the column for several hours before the solutions are injected. Continue the chromatography for 1.4 times the retention time of the peak due to neomycin B.

In the chromatogram obtained with solution (2) the area of any peak corresponding to neomycin C is not more than 3.0% of the sum of the areas of the peaks corresponding to neomycin B and neomycin C.

The *column efficiency*, determined using the peak due to neomycin B in the chromatogram obtained with solution (1), should be at least 13,000 theoretical plates per metre.

Assay Remove the ointment from the gauze and surrounding material and thoroughly mix the ointment thus obtained. Extract 1 g of the mixed ointment with 20 ml of *chloroform* and sufficient sterile *phosphate buffer pH 8.0* to give a solution containing 0.01% w/v of Framycetin Sulphate. Carry out the *biological assay of antibiotics*, Appendix XIV A, using the Standard Preparation of neomycin B. The precision of the assay is such that the fiducial limits of error are not less than 95% and not more than 105% of the estimated potency.

Calculate the content of framycetin sulphate in each g of the mixed ointment, taking each 676 Units found to be equivalent to 1 mg of Framycetin Sulphate. The upper fiducial limit of error is not less than 90.0% and the lower fiducial limit of error is not more than 120.0% of the prescribed or stated amount.

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.

Impermeable Plastic Wound Dressing

Waterproof Plastic Wound Dressing

Definition Impermeable Plastic Wound Dressing consists of an absorbent pad attached to a piece of impermeable plastic adhesive tape so that a suitable adhesive margin is left. The pad and adhesive margin are covered with a suitable protector which, when removed, does not detach the pad from the tape.

The pad may be impregnated with a suitable antiseptic, as specified in the general requirements for Surgical Dressings. It may be dyed with a suitable yellow dye.

The tape consists of an extensible waterproof plastic film spread evenly with an adhesive mass which does not offset when the tape is unrolled. The tape is supplied wound on spools or cores.

The film may be coloured with a suitable pigment.

Assembly; Dimensions of adhesive margin The pad is substantially the same shape as the dressing, attached as centrally as possible to the adhesive tape leaving a margin of not less than 3 mm or not less than 10% of the overall dimensions, whichever is the greater. The width of the

margin on any one side is not less than half the width of the margin on the opposite side.

The corners of the dressing may be trimmed; such trimming is disregarded when defining the shape and dimensions of the dressing.

Tape

Adhesivesness Complies with the tests, Appendix XX H.

Extensibility Complies with the test, Appendix XX G.

Waterproofness Complies with the test, Appendix XX K.

Water-vapour permeability Not more than 75 g m^{-2} per 24 hours, Appendix XX J1.

Joins Lengths of less than 3 m have no joins; lengths of 3 m or more contain not more than one join.

Width Tape of declared width not more than 5 cm does not vary by more than ±1.5 mm from the declared width. Tape of declared width more than 5 cm does not vary by more than ±2.5 mm from the declared width.

Weight of adhesive mass Not less than 30 g m^{-2}, Appendix XX D3, using Method III of Appendix XX D2.

Weight of film Not less than 65 g m^{-2}, Appendix XX D2, Method III.

Absorbent pad

Content of antiseptic If present, complies with the appropriate requirement, Appendix XX P.

Dimensions Not less than 33% of the overall dimensions of the dressing.

Weight per unit area Not less than 34 g m^{-2}, Appendix XX D1, Method II.

Labelling The label on the unit container, the label on the shelf container and the label on the outer transit container state, where applicable, that the pad has been dyed.

Knitted Viscose Primary Dressing

Definition Knitted Viscose Primary Dressing consists of a warp knitted fabric manufactured from a viscose multifilament yarn, with a nominal count of 22 tex. It has an essentially smooth surface and is free from filamentation. The viscose multifilament yarn may be treated with a proven innocuous finishing agent as an aid to manufacture.

Type 1 dressings are supplied uncoated and Type 2 dressings are supplied coated with a cured silicone elastomer.

The dressings are supplied sterile in single pieces.

Fibre identification Complies with the tests for *viscose*, Appendix XX A.

Coating identification For Type 2 the *infrared absorption spectrum*, Appendix II A, recorded by multiple reflection, is concordant with the *reference spectrum* of cured silicone elastomer.

Acidity or alkalinity To 15 g 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 of the aqueous extract 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.

Colouring matter Slowly extract 10 g in a percolator about 30 mm in diameter with *ethanol (96%)* until 50 ml of extract is obtained, pour the liquid into a colourless glass cylinder and examine a 20-cm layer against a white background. A very faint yellow tinge may be observed, but no bluish or greenish tinge is apparent.

Courses per 10 cm Not less than 76.

Wales per 10 cm Not less than 80.

Weight per unit area Type 1, not less than 150 g m^{-2}, Appendix XX D1, Method II. Type 2, not less than 200 g m^{-2}, Appendix XX D1, Method II.

Ether-soluble substances Type 1, not more than 3.5%, Appendix XX N. Type 2, 20 to 40% when determined by the method described in Appendix XX N with the following modifications. Heat the ether extract on a water bath for 15 minutes, dry the residue at 60° for 1 hour and weigh.

Hydrogen sulphide Type 1 complies with the following test. To 20 ml of the aqueous extract obtained in the test for Acidity or alkalinity add 1.9 ml of *water*, 0.15 ml of 2M *acetic acid* and 1 ml of *lead acetate solution*, mix and allow to stand for 2 minutes. The colour of the solution is not more intense than that of a solution prepared by mixing 1.7 ml of *lead standard solution (20 ppm Pb)*, 20 ml of the aqueous extract, 0.15 ml of 2M *acetic acid* and 1.2 ml of *thioacetamide reagent* and allowing to stand for 2 minutes.

Water-soluble substances Not more than 2.5%, Appendix XX M, with the following modification. Dry the residue at 100° to 105° for 2 hours.

Loss on drying When dried to constant weight at 100° to 105°, loses not more than 13% of its weight. Use 5 g.

Sulphated ash Type 1, not more than 0.45%, Appendix IX A. Type 2, not more than 20%, Appendix IX A. Use 5 g.

Sterility Complies with the *test for sterility*, Appendix XVI A.

Paraffin Gauze Dressing

Tulle Gras

Definition Paraffin Gauze Dressing consists of fabric of leno weave with two picks in each shed in which the warp and weft threads are of cotton, or viscose, or of combined cotton and viscose yarn, which has been impregnated with White Soft Paraffin or with Yellow Soft Paraffin. For use in tropical countries a suitable mixture of soft paraffin and Hard Paraffin may be used. The dressing is available as a light or normal loading.

The dressings are supplied sterile in single pieces or up to ten pieces may be supplied in a suitable container. The dressing is also available as a continuous strip.

Fibre identification The extracted fabric, obtained in the test for Weight per unit area, complies with the tests for *cotton* or for *viscose* or for both *cotton* and *viscose*, 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.