ature 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.

## Elastic Adhesive Dressing

**Definition** Elastic Adhesive Dressing is available as a wound dressing and as a dressing strip. Each consists of an absorbent pad attached to a piece of Extension Strapping, which may be perforated or ventilated, so that a suitable adhesive margin is left. The pad and adhesive margin are covered with a suitable protector which, when removed, does not offset the adhesive and does not detach the pad from the adhesive backing. When ventilated Extension Strapping is used, the spread area of adhesive is not less than 50% of the total surface area.

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

### Wound dressing

**Assembly; Dimensions of adhesive margin** The pad is substantially the same shape as the dressing, attached as centrally as possible to the adhesive backing leaving an adhesive margin of not less than 5 mm or not less than 15% 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. Rectangular dressings may have an adhesive margin of not less than 1.5 mm on each of one pair of opposite sides provided that the adhesive margin on each of the other two sides is at least 25% of the overall dimensions of the dressing in that direction.

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

### Dressing strip

**Assembly; Dimensions of adhesive margin** The pad is attached to a square or rectangular piece of Extension Strapping. The pad and the strapping are of equal length, the pad being attached so that adhesive margins are left on the two sides parallel with the warp. The width of the margin is not less than 8 mm or not less than 20% of the overall dimension, whichever is the greater. The width of the margin on one side is not less than half the width of the margin on the other side.

### 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** Not less than 34 g $m^{-2}$, Appendix XX D1, Method II.

### Strapping

Complies with the requirements stated under Extension Strapping, except that it may be perforated or ventilated.

**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.

## Framycetin Gauze Dressing

Framycetin Tulle Gras

**Definition** Framycetin Gauze Dressing consists of fabric of leno weave with two picks in each shed in which the warp and weft threads consist of (a) cotton or (b) viscose or (c) combined cotton and viscose yarn. The fabric has been evenly impregnated with a suitable ointment containing 1% w/w of Framycetin Sulphate, in *microfine powder*, in a basis of White Soft Paraffin that contains 10% w/w of Wool Fat. For use in tropical countries, a suitable mixture of White Soft Paraffin with Wool Fat may be used.

The dressing is supplied sterile in single pieces.

### Fabric

**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.

**Weight per unit area** Not less than 39 g $m^{-2}$ when determined by the following method. Remove the dressing from the container and determine its area. Transfer it by means of forceps, leaving behind any impregnating material adhering to the container, to an apparatus for the *continuous extraction of drugs*, Appendix XI F, and extract the dressing with *ether* for 6 hours or until extraction is complete. 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

**Identification** Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel precoated plate (Merck silica gel 60 plates are suitable) and a mixture of 60 volumes of *methanol*, 40 volumes of 13.5M *ammonia* and 20 volumes of *chloroform* as the mobile phase. Apply separately to the plate 3 µl of each of the following solutions. For solution (1) cut 12 g of the impregnated gauze into strips, warm with 20 ml of *water*, allow to cool, decant the aqueous layer and filter. Solution (2) contains 0.4% w/v of *framycetin sulphate BPCRS*. Solution (3) is a mixture of equal volumes of solutions (1) and (2). After removal of the plate, allow it to dry in air, spray with a 1% w/v solution of *ninhydrin* in *butan-1-ol* and heat at 105° for 2 minutes. The principal red spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2) and the principal red spot in the chromatogram obtained with solution (3) appears as a single compact spot.

**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

In the chromatogram obtained with solution (1) the area of any peak corresponding to disulfiram is not greater than half the area of the peak in the chromatogram obtained with solution (2) (1%), the area of any other *secondary peak* is not greater than the area of the peak in the chromatogram obtained with solution (2) (2%) and the sum of the areas of any secondary peaks is not greater than 1.5 times the area of the peak in the chromatogram obtained with solution (2) (3%).

## Phenoxymethylpenicillin Capsules

*British Pharmacopoeia 1993, page 1054 and Addendum 1995, page 1679*

Delete the subsidiary title 'Penicillin V K Capsules'.

## Vancomycin Injection

*British Pharmacopoeia 1993, Addendum 1997, page 2090*

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION**

**Vancomycin B** Fourth paragraph. Lines 4 and 5. For 'the *symmetry factor* of the vancomycin peak is greater than 1.6' read 'the *symmetry factor* of the vancomycin peak is not greater than 1.6'.

# SURGICAL MATERIALS

## Framycetin Gauze Dressing

*British Pharmacopoeia 1993, page 1261 and Addendum 1997, page 2111*

**Ointment**
**Identification** Change the statement to:

**Identification** Complies with the test for Neomycin C.