

**Labelling** The label on the package states (1) the nominal lay-flat width; (2) where more than one type of tubular bandage with the same nominal lay-flat width is available, a reference to the appropriate type; (3) the colour of the final bandage if the bandage has been dyed.

	Nominal lay-flat width cm	Courses per 10 cm	Total number of wales	Ratio of elasticated threads
	3.7	67 to 83	120	1:2
	4.5	68 to 76	200	1:4
	5.0	61 to 67	300	1:3
Type A	6.25	56 to 64	360	1:2
Type B	6.25	64 to 72	284	1:4
Type A	6.75	64 to 72	360	1:4
Type B	6.75	64 to 72	360	1:3
Type A	7.5	68 to 76	348	1:4
Type B	7.5	68 to 76	360	1:4
Type A	8.75	68 to 76	400	1:4
Type B	8.75	68 to 76	440	1:4
Type A	10.0	76 to 84	440	1:4
Type B	10.0	75 to 83	400	1:4
Type A	12.0	76 to 84	552	1:4
Type B	12.0	75 to 83	440	1:4
Type A	17.5	76 to 84	1008	1:4
Type B	17.5	76 to 84	800	1:4
Type C	17.5	75 to 87	636	1:4
	20.0	56 to 64	1150	1:4
Type A	21.5	56 to 64	1248	1:3
Type B	21.5	71 to 87	888	1:4
	30.0	88 to 96	1368	1:4
Type A	32.5	88 to 96	1696	1:4
Type B	32.5	88 to 96	1872	1:4
Type C	32.5	71 to 87	1196	1:4

## WOUND DRESSINGS AND MEDICATED BANDAGES

### Chlorhexidine Gauze Dressing

Chlorhexidine Tulle Gras

**Definition** Chlorhexidine 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 a dispersion of Chlorhexidine Acetate.

The dressing is supplied sterile in single pieces.

#### Fabric

**Fibre identification** The extracted fabric, obtained in the test for Ether-soluble substances, 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<sup>-2</sup> when determined by the following method. Remove the dressing from the container and determine its area. Transfer it by means of forceps to an apparatus for the *continuous extraction of drugs*, Appendix XI F, leaving behind any ointment adhering to the facing material, 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<sup>-2</sup>.

#### Ointment

**Content of chlorhexidine acetate**, C<sub>22</sub>H<sub>30</sub>Cl<sub>2</sub>N<sub>10</sub>, 2C<sub>2</sub>H<sub>4</sub>O<sub>2</sub> 0.4 to 0.6% w/w.

**Identification** Shake a quantity of the dressing containing 10 mg of Chlorhexidine Acetate with 10 ml of *chloroform*. Add 10 ml of *water* and 2 ml of a 20% w/v solution of *cetrimide* followed by 1 ml of a 1% w/v solution of *bromine* in 10M *sodium hydroxide* and shake. A deep red colour is produced in the aqueous layer.

**Ether-soluble substances** Not less than 100 g m<sup>-2</sup> 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.

**Assay** Carefully remove and weigh 100 cm<sup>2</sup> of dressing. Shake with 25 ml of *chloroform* for 2 minutes, add 100 ml of 0.4M *hydrochloric acid* and shake continuously for 45 minutes. Discard the chloroform layer and filter the acid layer.

Wash the extracted fabric with hot *water* to remove all traces of the ointment and dry the fabric to constant weight at 105°. Determine the weight of the ointment from the initial weight of the dressing.

To 20 ml of the filtrate add 50 ml of *water* and 5 ml of a 20% w/v solution of *cetrimide* and shake. Add 8.5 ml of 1M *sodium hydroxide*, 1 ml of *propan-2-ol* and 2 ml of *sodium hypobromite solution*, dilute to 100 ml with *water* and shake. Allow to stand at 20° for 25 minutes. Measure the *absorbance* of the resulting solution at the maximum at 480 nm, Appendix II B. Calculate the content of C<sub>22</sub>H<sub>30</sub>Cl<sub>2</sub>N<sub>10</sub>, 2C<sub>2</sub>H<sub>4</sub>O<sub>2</sub> in the ointment from the *absorbance* obtained by repeating the procedure using 20 ml of a solution prepared by diluting 5 ml of a 0.12% w/v solution of *chlorhexidine acetate* in *water* to 100 ml with 0.4M *hydrochloric acid* beginning at the words 'add 50 ml of *water* ...'. Use 0.4M *hydrochloric acid* in the reference cell.

**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 temper-

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 anti-septic, 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<sup>-2</sup>, 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<sup>-2</sup> 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<sup>-2</sup>.

### Ointment

**Identification** Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel pre-coated plate (Merek 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.