

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

Adhesiveness 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 $\pm 1.5 \text{ mm}$ from the declared width. Tape of declared width more than 5 cm does not vary by more than $\pm 2.5 \text{ mm}$ 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.

Weight per unit area *Fabric* Not less than 39 g m^{-2} when determined by the following method. Remove the dressing from the container and determine its area. If the pack contains a continuous strip, take three samples, each of approximately 100 cm^2 , from the second, middle and penultimate layers of the strip and determine the total area. Transfer by means of forceps to an apparatus for the *continuous extraction of drugs*, Appendix XI F, leaving behind any paraffins adhering to the container, 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} .

Ether-soluble substances *Impregnated fabric* Light loading, 90 to 130 g m^{-2} . Normal loading, not less than 200 g m^{-2} ; when presented in single-piece packs, not less than 175 g m^{-2} . Determine 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.

If the pack contains two dressings, determine the average weight of ether-soluble substances in the two dressings. If the pack contains more than two dressings, select dressings from the top, centre and bottom of the container and determine the average weight of ether-soluble substances in the three dressings. If the pack contains a continuous strip, take three samples, each of approximately 100 cm^2 , from the second, middle and penultimate layers of the strip and determine the average weight of ether-soluble substances in the three samples.

Sterility Complies with the *test for sterility*, Appendix XVI A, with the following modifications. Use Method II: Direct inoculation.

For individually packaged dressings Using aseptic precautions, open a sufficient number of individual packages to provide an appropriate number of portions.

For packages containing more than one dressing Using aseptic precautions, open the sealed package and remove an appropriate number of portions from different places in the package.

For packages containing a continuous strip Using aseptic precautions, open the sealed package and take five samples, each of approximately 100 cm^2 , from any one package, two each from the second and penultimate layers and one from the middle of the strip.

For each medium use a 'portion' as defined in Table III (from each of the three different places in the package where appropriate), treating each portion separately as follows. Transfer the portion to a container containing 50 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 10 ml of the resulting isopropyl myristate suspension directly into the culture medium so that it is diluted approximately 10-fold. Incubate the inoculated media and observe the cultures as described in Appendix XVI A.

Labelling The label on the container states whether the loading of the dressing is Light or Normal.

Perforated Film Absorbent Dressing

Definition Perforated Film Absorbent Dressing is a dressing of low adherence consisting of three layers.

For Type 1 the wound-facing layer consists of a film of poly(ethylene terephthalate) perforated in a regular pattern. The absorbent middle layer is a non-woven material consisting of bleached cotton fibres or viscose fibres or a mixture of bleached cotton and viscose fibres together with polyacrylonitrile fibres. The backing layer is an apertured non-woven cellulose material.

For Type 2 the wound-facing layer is similar to that in Type 1, the absorbent middle layer consists of bleached cotton fibres and the backing layer is identical with the wound-facing layer.

For Type 3 the outer layer comprises a sleeve consisting of a film of poly(ethyl methyl acrylate) perforated in a regular pattern. This sleeve forms the wound-facing layer on the side without the join and the backing layer on the side with the join. The absorbent middle layer consists of bleached cotton fibres or viscose fibres or a mixture of both sandwiched between two layers of an apertured non-woven cellulose material.

The dressing is free from toxic adhesives and binders and from fluorescent whitening agents and does not shed an appreciable quantity of fibres.

The dressing is supplied sterile in single pieces.

Wound-facing layer

Identification Types 1 and 2 comply with the tests for *polyester*, Appendix XX A. For Type 3 the *infrared absorption spectrum*, Appendix II A, without using solvent dilution, is concordant with the *reference spectrum* of poly(ethyl methyl acrylate).

Perforations Type 1, elliptical holes, of nominal size $0.5 \text{ mm} \times 0.2 \text{ mm}$, regularly spaced so that the number is 150 to 175 cm^{-2} . Type 2, circular holes, of nominal diameter 0.7 mm , regularly spaced so that the number is 55 to 75 cm^{-2} . Type 3, rounded holes of nominal size 0.9 mm , regularly spaced so that the number is 12 to 24 cm^{-2} .

Absorbent layer

Identification Remove the film and backing layer. Type 1 complies with the tests for *polyacrylonitrile* and for *cotton* or for *viscose* or for both *cotton* and *viscose*, Appendix XX A. Type 2 complies with the tests for *cotton*, Appendix XX A. Type 3 complies with the tests for *cotton* or for *viscose* or for both *cotton* and *viscose*, Appendix XX A.

Content of polyacrylonitrile Type 1, not less than 12.5% when determined by Method 8 of British Standard 4407:1975 (Methods of test: Quantitative analysis of fibre mixtures).

Backing layer

Identification Type 1 complies with tests A and B described below. Type 2 complies with the tests for *polyester*, Appendix XX A. For Type 3, the *infrared absorption spectrum*, Appendix II A, without using solvent dilution, is concordant with the *reference spectrum* of poly(ethyl methyl acrylate).

A. Treat with *iodinated zinc chloride solution*. The fibres become violet.

B. The fibres are soluble in a 66% v/v solution of *sulphuric acid*.