

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*.

Water-retention capacity Types 1 and 3, not less than 15.0 g, Appendix XX T. Type 2, not less than 9.0 g, Appendix XX T.

Weight per unit area Types 1 and 3, not less than 150 g m⁻², Appendix XX D1, Method III. Type 2, not less than 132 g m⁻², Appendix XX D1, Method III.

Fluorescence When examined under ultraviolet light (365 nm) the dressing may display not more than a slight brownish violet fluorescence and a few yellow particles. Not more than a few isolated fibres show an intense blue fluorescence.

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

Labelling The label on the package states whether the dressing is Type 1, Type 2 or Type 3 Perforated Film Absorbent Dressing.

Permeable Plastic Wound Dressing

Definition Permeable Plastic Wound Dressing consists of an absorbent pad attached to a piece of permeable 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 perforated plastic film spread evenly with an adhesive mass. The perforations are regularly distributed. The tape is permeable to water vapour and air. 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 tape, 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 dimension of the dressing in that direction.

The corners of the dressing may be trimmed; any 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.

Perforations Diameter, not more than 1 mm; area, not more than 20% of the total area of the film.

Water-vapour permeability Not less than 500 g m⁻² per 24 hours, Appendix XX J1.

Weight of adhesive mass Not less than 25 g m⁻², Appendix XX D3, using Method III of Appendix XX D2.

Weight of film Not less than 60 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.

Polyurethane Foam Dressing

Definition Polyurethane Foam Dressing is an absorbent foam dressing of low adherence.

The dressing is supplied sterile in sheets of appropriate size.

Characteristics A light, pale yellow foam, heat treated to a smooth hydrophilic layer on one side with a hydrophobic foam on the reverse.

Identification The *infrared reflectance spectrum*, Appendix II A, is concordant with the *reference spectrum* of polyurethane (form A).

Absorbency Weigh a sample of dimensions 5 cm × 5 cm and immerse in *water* for 1 hour; a weight may be attached below the sample to ensure that it remains wholly immersed during this period. Remove the sample, allow to drain freely without compression at an angle of 45° for 5 minutes and reweigh. The increase in weight is not less than 7.5 times the initial weight.

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 filtered extract add 0.1 ml of *phenolphthalein solution*; to another 25 ml add 0.05 ml of *methyl orange solution*. Neither solution shows a pink colour.

Water-vapour permeability Not less than 1500 g m⁻² per 24 hours, Appendix XX J2.

Weight per unit area 315 to 395 g m⁻², Appendix XX D1, Method II.

Extractable tin Not more than 6 ppm of Sn when determined by the following method. To 5 g, previously cut into pieces not more than 50 mg in weight, add 50 ml of a 0.9% w/v solution of *sodium chloride* and shake for 4 hours. Filter and determine by *atomic absorption spectrophotometry*, Appendix II D, measuring at 224.6 nm and using a nitrous oxide—acetylene flame.

Water-soluble substances Not more than 1.0%, Appendix XX M.

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