SURGICAL DRESSINGS

The monographs in this section provide standards for a number of surgical dressings and for the fibres and fabrics used in their manufacture. The monographs are arranged in alphabetical order within categories in a sequence that reflects the similar standards applied to related types of product. The following types of product are represented in the Pharmacopoeia.

X-ray-detectable absorbents
Extensible bandages
Tubular bandages
Wound dressings and medicated bandages

Reference material The reference material *standard undyed bleached cotton lawn* required for the tests for Colour fastness (Appendix XX O) may be obtained from:

Society of Dyers and Colourists
P.O. Box 224, Perkin House
82 Grattan Road
Bradford BD1 2JB, England

Rubber Where the term 'rubber' is used in a monograph, it means natural rubber.

Viscose Where the term 'viscose' is used in a monograph, it means Viscose or Delustred Viscose, as described below.

Permitted antiseptics Where a monograph states that a permitted antiseptic may be used for a wound contact pad in a wound dressing, one of the following antiseptics may be used at the specified concentration.

Aminacrine hydrochloride (0.07 to 0.13%)
Chlorhexidine Hydrochloride (0.07 to 0.13%)
Chlorhexidine gluconate (0.11 to 0.20%)
Domiphen Bromide (0.05 to 0.25%)

These concentrations are expressed, unless otherwise indicated, in terms of the air-dried weight of wound contact pad material. The methods for determination of the concentrations are given in Appendix XX P.

Dyed dressings Dressings are undyed unless authority is given in the monograph for them to be dyed.

In general, the following guidelines should be followed wherever possible.

(a) Gauze products for use in the operating theatre should contain an X-ray-detectable component and should be either bleached or dyed green.

(b) Gauze products for use as immediate post-operative dressings should be bleached or dyed blue.

(c) Gauze products for use other than in the operating theatre should be bleached or dyed a colour other than green or blue.

Containers Surgical dressings are supplied in suitable packages that protect the contents from contamination with extraneous solids and do not allow the contents to be released unintentionally under normal conditions of handling, transport and storage. Products may be supplied in packages of the type described above but if so they are sealed with an easily-detachable device that prevents removal of the contents without the seal being broken (sealed packages).

Individual surgical dressings, or a number of surgical dressings, are presented in unit containers or packs. A suitable number of unit packs may be contained within a shelf container for ease of storage and to confer added protection. Further protection during transit may be provided by packaging unit containers into an outer container.

Storage Surgical dressings should be kept in a dry, well-ventilated place at temperatures not exceeding 25°. Adverse conditions, such as excessively humid, cold or hot locations, strong light sources and sources of electrical energy, can cause plastics, rubber and cellulose materials to become brittle, perished, stained or malodorous; such effects may be aggravated by lengthy exposure.

Labelling The label on the unit container states (1) the name given at the head of the monograph or an approved synonym; (2) the name or the trademark of the manufacturer or supplier; (3) where practicable, a batch reference consisting of figures or letters or a combination of figures and letters; (4) where practicable, the date of manufacture (month and year) unless this can easily be determined from the batch reference; (5) for a product with a determined shelf life, the date (month and year) after which the dressing should not be used; (6) where applicable, the name and concentration of a permitted antiseptic or active ingredient.

The label on the shelf container states (1) the name given at the head of the monograph or an approved synonym; (2) the name or the trademark of the manufacturer or supplier; (3) the address of the manufacturer or supplier; (4) a batch reference consisting of figures or letters or a combination of figures and letters; (5) the date of manufacture (month and year) unless this can easily be determined from the batch reference; (6) for a product with a determined shelf life, the date (month and year) after which the dressing should not be used; (7) where applicable, the name and concentration of a permitted antiseptic or active ingredient.

The label on the outer container states (1) the name given at the head of the monograph or an approved synonym; (2) the name or the trademark of the manufacturer or supplier; (3) a batch reference consisting of figures or letters or a combination of figures and letters; (4) the date of manufacture (month and year) unless this can easily be determined from the batch reference; (5) where necessary, the conditions under which the dressing should be stored; (6) for a product with a determined shelf life, the date (month and year) after which the dressing should not be used; (7) where applicable, the name and concentration of a permitted antiseptic or active ingredient.

VISCOSE

Definition Viscose is made from wood cellulose or cotton linters by solution in alkali and carbon disulphide, followed by precipitation of the cellulose in the form of a thread by forcing the solution of cellulose through fine holes in a metal plate into a coagulating fluid (viscose process).

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

Acidity or alkalinity To 25 ml of the filtered extract obtained in the test for Colour of 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.

Colour of extract 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. The filtered extract is *colourless*, Appendix IV B, Method I.

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.

Ether-soluble substances Not more than 0.30%, Appendix XX N.

Hydrogen sulphide To 10 ml of the filtered extract obtained in the test for Colour of extract 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 (10 ppm Pb)*, 10 ml of the filtered 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 0.70%, Appendix XX M.

Loss on drying When dried to constant weight at 100° to 105°, loses not more than 13.0% of its weight. Use 5 g.

Sulphated ash Not more than 0.45%, Appendix IX A. Use 5 g.

DELUSTRED VISCOSE

Definition Delustred viscose consists of viscose, as described above, that has been deprived of its sheen by dispersing finely divided titanium dioxide throughout the cellulose solution during manufacture.

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

Acidity or alkalinity; Colour of extract; Colouring matter; Ether-soluble substances; Hydrogen sulphide; Water-soluble substances; Loss on drying Complies with the requirements stated under Viscose.

Sulphated ash Not more than 1.7%, Appendix IX A. Use 5 g.

STERILE SURGICAL DRESSINGS

Sterile Surgical Dressings comply with the requirements stated under Surgical Dressings. In addition the standard in the monograph for a non-sterilised dressing applies to the corresponding sterile dressing except that sterilised undyed dressings may be slightly less white.

Sterilisation Methods of sterilisation that may be used for surgical dressings are described in Appendix XVIII.

The repeated sterilisation of a surgical dressing may cause irreversible deleterious changes in the materials used in its construction. For example, X-ray-detectable components may deteriorate after repeated autoclaving. Some materials withstand sterilisation on one occasion only. The suitability of a particular material for repeated sterilisation should be confirmed with the manufacturer before reprocessing.

Sterility Sterile surgical dressings comply with the *test for sterility*, Appendix XVI A, modified where necessary as stated in the individual monograph.

Containers Sterile surgical dressings are supplied in suitable sealed packages that maintain the sterility of the dressing until the package is opened and that are tamper-evident.

Packaging materials for unit packs vary and are selected according to the method of sterilisation to be used. Wrapping papers for unit packs that are to be steam sterilised should comply with the requirements of British Standard 6254:1982 (Specification for creped sterilization paper for medical use) or British Standard 6255:1982 (Specification for plain sterilization paper for medical use) or British Standard 6256:1982 (Specification for paper for steam sterilization paper bags for medical use).

Paper bags used to contain steam sterilised surgical dressings should comply with the requirements of British Standard 6257:1982 (Specification for paper bags for steam sterilization for medical use).

Packaging suitable for sterile dressings falls into two categories depending upon the situation in which the item is used.

(a) Packaging suitable for surgical dressings and packs containing surgical dressings, instruments and sundry items, applied and used in surgical and nursing procedures with aseptic precautions.

(b) Packaging suitable for surgical dressings that are not to be applied with aseptic precautions but that are required to reach the user in a sterile form.

It is desirable that items in category (a) should be double wrapped. For some of these items double wrapping may not be practicable. They should be sterilised in the sealed unit pack and preferably in a shelf container that has been designed to enable unit packs to be removed singly at the time of use. The wrappers for items in both categories should be applied and sealed before the unit packs are sterilised. A carton or a case is not considered to be a suitable outer wrapper for items in category (a).

For items in category (a) the unit container should permit *in situ* sterilisation of the contents without the need for further sealing of a pack. Items in category (b) may be sterilised in the primary wrappers and then packaged further after sterilisation, for example, into a carton.

Where the chemical or physical characteristics of the surgical dressings prevent *in situ* sterilisation, then the sterile components of such surgical dressings should be assembled and sealed under aseptic conditions. Before any method of packaging is adopted it should have been evaluated to establish its suitability for the intended purpose.

Storage Sterile surgical dressings should be stored in the shelf container; the unit container should be removed from the shelf container immediately before use. If a pack becomes damaged, wet or otherwise soiled it is regarded as being unsafe for use.

Labelling The label on the unit container states (1) the word 'sterile', which may form part of the name; (2) where necessary and practicable, directions for opening the container and aseptically removing the contents.

The label on the shelf container states (1) the word 'sterile', which may form part of the name; (2) where necessary and if not stated on the unit container, directions for opening the unit container and aseptically removing the contents.

The label on the outer container states the date of sterilisation (month and year) where this is different from the date of manufacture.