Packing, Labelling and Storage

Bandage Cloth for Plaster of Paris shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. In packages of cut and rolled bandages, each bandage shall also individually be warpped in suitable paper. The package shall be labelled as "Cloth for Plaster of Paris Bandage". The net content is stated on the label in terms of number of rolls and length and width. Bandage Cloth for Plaster of Paris must be stored in packed condition protected from dust.

[1][SCHEDULE F (III)

(*See r*ule 124-D)

STANDARDS FOR UMBILICAL TAPES

(A) Standards for Sterilised Umbilical Polyster Tape.

Description. - A uniform strand of Polyester yarn prepared by braiding and may be finished with a suitable silicone finishing material, white to yellowish-white in colour. Tape shall be sterilized by Gamma Radiation or other suitable method approved by the Licensing Authority.

Other requirements. - The Umbilical Polyester Tape shall conform to the claims made on the label in respect of length and width.

Tensile strength. - The Umbilical Polyester Tape shall have Tensile strength of not less than 4 kg. on straight pull.

Packing and labelling. - The Umbilical Polyester Tape shall be packed in sealed Polythene bags or sealed plastic containers which ensure that when packed, the tape is sterile. The packing shall protect the tape from contamination and damage. Every packing offered for sale shall bear a clear and permanent marking with the following particulars: -

(i) The proper name of the drug i.e. Umbilical Polyester Tape 'Sterile'
(ii) Manufacturer's name and address.
(iii) Batch number.
(iv) Licence number under which the tape is manufactured.
(v) Date of manufacture and date of expiry.
(vi) Length and width of the Tape.

Storage condition. - It should be stored in a cool place protected from light.

(B) Standards for Sterilised Umbilical Cotton Tape–

Description. - A uniform strand of cotton yarn prepared by braiding and may be finished with a suitable silicone finishing material, white to yellowish-white in colour. The tape shall be sterilized by Gamma Radiation or by any other suitable method approved by the Licesing Authority.

Other Requirement. - The Umbilical Cotton Tape shall conform to the claims made on the label in respect of length and width.

Tensile strength. - The Umbilical Cotton Tape shall have a Tensile strength of not less than 4 kg. on straight pull.

Packing and labelling. - The Umbilical Cotton Tape shall be packed in sealed Polythene bags or sealed plastic containers which ensure that when packed the tape is sterile. The packing shall protect the tape from contamination and damage. Every packing offered for sale shall bear a clear and permanent marking with the following particulars:-

(i) The proper name of drug i.e. Umbilical Cotton Tape "Sterile".

(ii) Manufacturer's name and address.

1. Ins. by G.S.R. No.1115(E), dt.. 30-9-1986.

(iii) Batch number.

(iv) Licence number under which the tape is manufactured.

(v) Date of manufacture and the date of expiry.

(vi) Length and width of the Tape.

Storage condition.- It should be stored in a cool place protected from light.]

[1][SCHEDULE FF

(See rule 126-A)

Standards for ophthalmic preparations.

Part-A. Ophthalmic Solutions and suspensions.

Ophthalmic Solutions and Suspensions shall-

(a) be sterile when dispensed or when sold in the unopened container of the manufacturer, except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopoeia;

(b) contain one or more of the following suitable substances to prevent the growth of micro-organisms:-

(i) Benzalkonium Chloride, 0.01 per cent (This should not be used in solutions of nitrates or salicylates).

(ii) Phenyl mercuric nitrate, 0.001 per cent.

(iii) Chlorbutanol 0.5 per cent.

(iv) Phenyl ethyl alcohol 0.5 per cent.

Provided that solutions used in surgery shall not have any preservative and be packed in single dose container.

Provided further that the Licensing Authority may in his discretion authorise the use of any other preservative or vary the concentration prescribed on being satisfied that its use affords equal guarantee for preventing the growth of micro-organisms:-

(c) be free from foreign matter;

(d) be contained in bottles made of either neutral glass or soda glass specially treated to reduce the amount of alkali released when in contact of aqueous liquids, or in suitable plastic containers which would not in any way be incompatible with the solutions;

The droppers to be supplied with the containers of ophthalmic solutions and suspensions shall be made of neutral glass or of suitable plastic material and when supplied separately shall be packed in sterile cellophane, or other suitable packings;

(e) In addition to complying with the provisions of labelling laid down in the rules the following particulars shall also be shown on the label:-

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1. Added by Notification No. F-1-13/69-D , dt.. 3-1-1970.