(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.

(1) *of the containers*

(i) The statement 'Use the solution within one month after opening the container'.

(ii) Name and concentration of the preservative, if used.

(iii) The words 'NOT FOR INJECTION'.

(2) of container or carton or package leaflet

(i) Special instructions regarding storage, wherever applicable.

(ii) A cautionary legend reading as

"*WARNING* *(i) if irritation persists or increases, discontinue the use and consult the phycian.*

(ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions".

Part B: Ophthalmic Ointments

Ophthalmic Ointments shall-

(a) be sterile when dispensed or when sold in the unopened container of the manufacturer;

(b) be free from foreign matter;

(c) in addition to complying with the provisions for labelling laid down in the rules the following particulars shall be shown on the container or carton or package leaflet-

(i) Special instructions regarding storage wherever applicable;

(ii) A cautionary legend reading

"Warning :- If irritation persists or increases discontinue the use and consult Physicians"].