[1][SCHEDULE U

(*See* rules 74, 74A, 74-B, 78 and 78A)

I. Particulars to be shown in Manufacturing Records

A. SUBSTANCES, OTHER THAN PARENTERAL PREPARATIONS IN GENERAL.

1. Serial number
2. Name of the product
3. Reference of Master Formula Records.
4. Lot/Batch Size.
5. Lot/Batch Number.
6. Date of commencement of manufacture and date of completion of manufacture and assigned date of expiry.
7. Name of all ingredients, specifications quantities required for the lot/Batch size and quantities actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture.
8. Control Numbers of raw materials used in the formulation.
9. Date, time and duration of mixing.
10. Details of environmental controls like room temperature, relative humidity.
11. Date of granulation, wherever applicable.
12. Theoretical weight and actual weight of granules/powder blend.
13. Records of in-processes controls (Periodically whenever necessary):
    (a) Uniformity of mixing.
    (b) Moisture content of granules/powder in case of Tablet/Capsules.
    (c) pH of solution in case of liquid.
    (d) Weight variation.
    (e) Disintegration time.
    (f) Hardness
    (g) Friability test
    (h) Leak test in case of strip packing.
    (i) Filled volume of liquids.
    (j) Quantity of tablets/capsules in the final container.
    (k) Content of ointment in the filled containers.
14. Date of compression in case of Tablets/date of filling in case of capsules.
15. Date of sealing/coating /polishing in case of capsules/tablets wherever applicable.
16. Reference to analytical Report number stating the result of test and analysis.
17. Separate records of the disposal of the rejected batches and of batches withdrawn from the market.

18. The theoretical yield and actual productions yield and packing particulars indicating the size and quantity of finished packings.

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1. Subs. by . G.S.R. 735(E) , dt. 24.6.1988.

19. Specimen of label/strip, carton with batch coding information like Batch Number, date of manufacture, date of expiry, retail price as applicable stamped thereon and inserts used in the finished packings.

20. Signature with date of competent technical staff responsible for the manufacture.

21. Counter-signature of the head of the testing units or other approved person-in-charge of testing for having verified the batch records and for having released and batch for sale and distribution, the quantity released and date of release.

22. Date of release of finished packings and quantity released for sale and distribution.

23. Quantity transferred to warehouse.

24. For Hypodermic tablets and ophthalmic preparations, which are required to be manufactured under aseptic conditions, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.

B. PARENTERAL PREPARATIONS

1. Serial number.
2. Name of the product.
3. Reference of the master formula record.
4. Batch /Lot size.
5. Batch No. and/or Lot No.
6. Date of commencement of manufacture and date of completion.

7. Names of all ingredients, specifications and quantity required for the Lot/Batch size and quantity actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be countersigned by the technical staff under whose personal supervision the stock are issued and by another competent technical staff under whose supervision the ingredients are used for manufacture.

8. Control numbers of raw materials used in the formulation.

9. Date, time and duration of mixing.

10. Details of environmental controls like temperature, humidity, microbial count in the sterile working areas.

11. pH of the solution, wherever applicable.

12. Date and method of filtration.

13. Sterility test, reference on bulk batch wherever applicable.

14. Record of check on volume filled.

15. Date of filling.

16. Records of tests employed: -

(a) To ensure that sealed ampoules are leak proof

(b) To check the presence of foreign particles.

(c) Pyrogen test, wherever applicable.

(d) Toxicity test, wherever applicable.

17. Records of checking of instruments and apparatus of sterilization (indicators).

18. Records of cleaning and sterilization of containers and closures, if necessary.

19. Records of sterilization in case of parenteral preparations which are heat sterilized including particulars of time, temperature and pressure employed. Such records should be marked to relate to the batch sterilized.

20. Number and size of containers filled and quantity rejected.

21. The theoretical yield and actual yield and the percentage yield thereof.

22. Reference to Analytical report numbers stating whether of standard quality or otherwise.

23. Specimen of labels, cartons, etc. with Batch coding information like batch number, date of manufacture, date of expiry, as applicable, stamped thereon, and inserts used in the finished packings.

24. Signature with date of the component technical staff responsible for manufacture.

25. Particulars regarding the precautions taken during the manufacture to ensure that aseptic conditions are maintained.

26. Countersignature of head of the testing unit or person in charge of testing for having verified the documents and for having released the product for sale and distribution, the quantity released and date of release.

27. Records for having transferred to warehouse giving packings and quantities.

28. Separate records of the disposal of the rejected batches and of all batches withdrawn from the market.

29. Records of reprocessing if any and particulars of reprocessing.

II. Records of Raw Materials

Records in respect of each raw material shall be maintained indicating the date of receipt, invoice number, name and address of the manufacturer/supplier, batch number, quantity received, pack size, date of manufacture, date of expiry, if any, date of analysis and release/rejection by quality control, analytical report number with special remarks, if any, quantity issued, date of issue and the particulars of the name and batch numbers of products for the manufacture of which issued and the proper disposal of the stocks.

III. Particulars to be recorded in the Analytical Records

A. TABLETS AND CAPSULES.

1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample.
4. Batch/Lot number.
5. Protocols of tests applied.

(a) Description.

(b) Identification.

(c) Uniformity of weight.

(d) Uniformity of diameter (if applicable).

(e) Disintegration test (time in minutes).

(f) Any other tests.

(g) Results of Assay.

Note: Records regarding various tests applied (including readings and calculations) should be maintained and necessary reference to these records should be entered in Col. 5 above whenever necessary.

6. Signature of the Analyst.
7. Opinion and signature of the approved Analyst.

B. PARENTERAL PREPARATIONS.

1. Analytical report number.
2. Name of the sample.
3. Batch number.
4. Date of receipt of samples.
5. Number of containers filled.
6. Number of containers received.
7. Protocols of tests applied.
    (a) Clarity.
    (b) pH wherever applicable.
    (c) Identification.
    (d) Volume in container.
    (e) Sterility – (i) Bulk sample wherever applicable (ii) container sample.
    (f) Pyrogen test, wherever applicable.
    (g) Toxicity test, wherever applicable.
    (h) Any other tests.
    (i) Results of Assay.

Note*:* Records regarding various tests applied (including readings and calculations) should be maintained and necessary reference to these records should be entered in Col. 7 above, wherever necessary.

8. Signature of the Analyst.
9. Opinion and signature of the approved Analyst.

PYROGEN TEST:

1. Test Report Number.
2. Name of the sample.
3. Batch Number.
4. Number of rabbits used.
5. Weight of each rabbit.
6. Normal temperature of each rabbit.

7. Mean initial temperature of each rabbit.
8. Dose and volume of solution injected into each rabbit and time of injection.
9. Temperature of each rabbit noted at suitable intervals.
10. Maximum temperature.
11. Response.
12. Summed response.
13. Signature of the Analyst.
14. Opinion and signature of the approved Analyst.

TOXICITY TEST

1. Test Report Number.
2. Name of the sample.
3. Batch Number.
4. Number of mice used and weight of each mouse.
5. Strength and volume of the drugs injected.
6. Date of injection.
7. Results and remarks.
8. Signature of Analyst.
9. Opinion and signature of the approved Analyst.

C. FOR OTHER DRUGS

1. Analytical report number.
2. Name of the sample.
3. Batch/Lot number.
4. Date of receipt of sample.
5. Protocol of tests applied.
   (a) Description.
   (b) Identification.
   (c) Any other tests.
   (d) Results of Assay.

Note*:*Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in Column 5 above, wherever necessary.

6. Signature of Analyst.

7. Opinion and signature of the approved Analyst.

D. RAW MATERIALS

1. Serial number.
2. Name of the materials.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan number and date.
6. Protocols of tests applied.

Note: Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in Column 6 above, wherever necessary.

E. CONTAINER, PACKING MATERIALS ETC.

1. Serial number.
2. Name of the item.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan number and date
6. Results of tests applied.

Note: Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered in Column 6 above, wherever necessary

7. Remarks.
8. signature of the examiner.

Notes: (1) The foregoing provisions represent the minimum requirements to be complied with by the licensee. The Licensing Authority may, however, direct the nature of records to be maintained by the licensee for such products as are not covered by the categories described above.

2. The Licensing Authority may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down above are complied with.

3. The Licensing Authority may at its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.]