[3]SCHEDULE T

[*See* Rule 157]

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES.

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II to ensure: -

i) raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination;

ii) the manufacturing process is as has been prescribed to maintain the standards;

iii) adequate quality control measures are adopted;

iv) the manufactured drug which is released for sale is of acceptable quality;

v) to achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. However, under IMCC Act 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of Good Manufacturing Practices (GMP).

PART I

GOOD MANUFACTURING PRACTICES

Factory Premises:

The manufacturing plant should have adequate space for: -

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[1]Ins. by G.O.I. Notification No. GSR 673(E) dt 27.10.1993.

[2]Ins. by G.O.I. Notification No. GSR 553(E) dt 20.7.1995.

[3] Sub. By G.O.I. Notification No. GSR 198(E) dt 07.3.2003.

(i) receiving and storing raw material;

(ii) manufacturing process areas;

(iii) Quality control section;

(iv) finished goods store;

(v) office;

(vi) rejected goods/drugs store.

1.1.*General Requirements*:

1.1(A) *Location and surroundings.* - The factory building for manufacture of Ayurveda, Siddha and Unani medicines shall be so situated and shall have such construction as to avoid contamination from open sewerage, drain, public lavatory for any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust and smoke.

1.1(B) *Buildings.* - The buildings used for factory shall be such as to permit production of drugs under hygienic conditions and should be free from cobwebs and

insects/rodents. It should have adequate provision of light and ventilation. The floor and the walls should not be damp or moist. The premises used for manufacturing, processing, packaging and labeling will be in conformity with the provisions of the Factory Act. It shall be located so as to be:

(I) Compatible with other manufacturing operations that may be carried out in the same or adjacent premises.

(II) Adequately provided with working space to allow orderly and logical placement of equipment and materials to avoid the risk of mix up between different drugs or components thereof and control the possibility of cross contamination by other drugs or substances and avoid the risk of omission of any manufacturing or control step.

(III) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean. The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

(IV) Provided with proper drainage system in the processing area. The sanitary fittings and electrical fixtures in the manufacturing area shall be proper and safe.

(V) Furnace/Bhatti section could be covered with tin roof and proper ventilation, but sufficient care should be taken to prevent flies and dust.

(VI) There should be fire safety measures and proper exits should be there.

(VII) Drying Space: - There should be separate space for drying of raw materials, in process medicine or medicines require drying before packing. This space will be protected from flies/ insects/ dust etc., by proper flooring, wire mesh window, glass panels or other material.

1.1(C) *Water Supply*. - The water used in manufacture shall be pure and of potable quality. Adequate provision of water for washing the premises shall be made.

1.1(D) *Disposable of Waste*. - From the manufacturing section and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off. .

1.1(E) *Container's Cleaning*. - In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

1.1(F) *Stores*. - Storage should have proper ventilation and shall be free from dampness. It should provide independent adequate space for storage of different types of material, such as raw material, packaging material and finished products.

1.1. (F)(A) *Raw Materials*. - All raw materials procured for manufacturing will be stored in the raw materials store. The manufacture based on the experience and the characteristics of the particular raw material used in Ayurveda, Siddha and Unani system shall decide the use of appropriate containers which would protect the quality of raw materials as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation, etc. If certain raw materials require such controlled environmental conditions, the raw materials stores may be sub-divided with proper enclosures to provide such conditions by suitable cabinization. While designing such containers, cupboard or areas in the raw materials store, care may be taken to handle the following different categories of raw materials:-

1. Raw material of metallic origin.
2. Raw material of mineral origin
3. Raw material from animal source
4. Fresh Herbs
5. Dry Herbs or Plant parts
6. Excipients etc
7. Volatile oils/perfumes and flavours
8. Plant concentrates/ extracts and exudates/resins.

Each container used for raw material storage shall be properly identified with the label which indicates name of the raw material, source of supply and will also clearly state the status of raw material such as 'UNDER TEST' or 'APPROVED' or 'REJECTED'. The labels shall further indicate the identity of the particular supply in the form of Batch No. or Lot No. and the date of receipt of the consignment.

All the raw materials shall be sampled and got tested either by the in-house Ayurvedic, Siddha and Unani experts (Quality control technical person) or by the laboratories approved by the Government and shall be used only on approval after verifying. The rejected raw material should be removed from other raw material store and should be kept in separate room. Procedure of 'First in first out' should be adopted for raw materials wherever necessary. Records of the receipt, testing and approval or rejection and use of raw material shall be maintained.

1.1. (F)(B) *Packing Materials*. - All packaging materials such as bottles, jars, capsules etc. shall be stored properly. All containers and closure shall be adequately cleaned and dried before packing the products.

1.1. (F)(C) Finished *Goods Stores*. - The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores within an area marked "Quarantine". After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labeling as well as finished product quality as prescribed, then it will be moved to "Approved Finished Goods Stock" area. Only approved finished goods shall be dispatched as per marketing requirements. Distribution records shall be maintained as required.

If any Ayurvedic, Siddha and Unani drug needs special storage conditions, finished goods store shall provide necessary environmental requirements.

1.1(G) *Working space*. - The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of the operations for which these employed so as to facilitate easy and safe working and to minimize or to eliminate any risk of mix-up between different drugs, raw materials and to prevent the possibility of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

1.1(H) *Health Clothing, Sanitation and Hygiene of Workers*.- All workers employed in the Factory shall be free from contagious diseases. The clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean. The uniform shall also include cloth or synthetic covering for hands, feet and head wherever required. Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided. Separate provision shall be made for lavatories to be used by men and women, and such lavatories shall be located at places separated from the processing rooms. Workers will also be provided facilities for changing their clothes and to keep their personal belongings.

1.1. (I) *Medical Services*: The manufacturer shall also provide:-

(*a*) Adequate facilities for first aid;

(*b)* Medical examination of workers at the time of employment and periodical check up thereafter by a physician once a year, with particular attention being devoted to freedom from infections. Records thereof shall be maintained.

1.1(J) *Machinery and Equipments*. - For carrying out manufacturing depending on the size of operation and the nature of product manufactured, suitable equipment either manually operated or operated semi-automatically (Electrical or steam based) or fully automatic machinery shall be made available. These may include machines for use in the process of manufacture such as crushing, grinding powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labeling and packing etc. to ensure case in movement of workers and orderliness in operation a suitably adequate space will be ensured between two machines or rows of machines. These equipments have to be properly installed and maintained with proper cleaning. List of equipments and machinery recommended is indicated in Part II A.

Proper Standard Operational Procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

1.1(K) Batch *Manufacturing Records.* - The licencee shall maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs manufactured irrespective of the type of product manufactured (classical preparation or patent and proprietary medicines). Manufacturing records are required to provide an account of the

list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetics Act, 1940 (23 of 19400. These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product. These records shall be duly signed by Production and Quality Control Personnel respectively. Details of transfer of manufactured drug to the finished products store including dates and quantity of drugs transferred along with record of testing of the finished product, if any, and packaging, records shall be maintained. Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

It should be essential to maintain the record of date, manpower, machine and equipments used and to keep in process record of various shodhana, Bhavana, burning and fire and specific grindings in terms of internal use.

1.1(L) *Distribution Records.* - Records of sale and distribution of each batch of Ayurveda, Siddha and Unai Drugs shall be maintained in order to facilitate prompt and complete recall of the batch, if necessary.The duration of record keeping should be the date of expiry of the batch. Ceertain category of Ayurvedic, siddha and Unani medicines like Bhasma, Rasa, Kupi-pakva, Parpati, Sindura, Karpu/uppu/puram, kushta, Asava-arishta etc. do not have expiry date in contrast their efficiency increases with the passage of time. Hence, records need be maintained upto five years of the exhausting of stock.

1.1(M) Record *of Market Complaints*. - Manufacturers shall maintain a register to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises.

Records of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

1.1(N) *Quality Control.* - Every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory. The test shall be as per the Auurveda, Siddha and Unani pharmacopoeial standard. Where the tests are not available, the test should be performed according to the manufacturers specification or other information available. The quality control section shall verify all the raw materials, monitor in process, quality checks and control the

quality of finished product being released to finished goods store/warehouse. Preferably for such Quality control there will be a separate expert. The quality control section shall have the following facilities: -

1) There should be 150 sq. feet area for quality control section.
2) For identification of raw drugs, reference books and reference samples should be maintained.
3) Manufacturing record should be maintained for the various processes.
4) To verify the finished products, controlled samples of finished products of each batch will be kept for 3 years.
5) To supervise and monitor adequacy of conditions under which raw materials, semi-finished products and finished products are stored.
6) Keep record in establishing shelf life and storage requirements for the drugs.
7) Manufacturers who are manufacturing patent proprietary Ayurveda Siddha, and Unani medicines shall provide their own specification and control reference in respect of such formulated drugs.
8) The record of specific method and procedure of preparation, that is, "Bhavana", "Mardana" and "Puta" and the record of every process carried out by the manufacturer shall be maintained.
9) The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurveda, Siddha and Unani systems of medicines published by Government of India shall be complied with.
10) All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.

11) Quality control section will have a minimum of:

(i) One person with Ayurveda /Siddha/ Unani qualification recognized under Schedule II of Indian Medicine Central Council Act, 1970 (84 of 1970). Two other persons one each with Bachelor qualification in Botony/ Chemistry/ Pharmacy could be on part time or contractual basis.

(ii) The manufacturing unit shall have a quality control section as explained under Section 35(ii). Alternatively, these quality control provisions will be met by getting testing etc., from a recognized laboratory for Ayuveda, Siddha and Unani drugs; under Rule 160-A of the Drugs and Cosmetics Act. The manufacturing company will maintain all the record of various tests got done from outside recognized laboratory.

(iii) List of equipments recommended is indicated in Part II C.

1.2. *Requirement for Sterile Product***:**

1.2(A) *Manufacturing Areas*: For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed areas specifically designated for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The

filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurvedic, Siddha and Unani drug manufacturing areas shall be carried out during operations. Results of such count shall be checked against established in-house standards and record maintained.

Access to manufacturing areas shall be restricted to minimum number of authorized personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed.

For the manufacturing of Ayurvedic, Siddha and Unani drug that can be sterilized in their final containers, the design of the areas shall be preclude the possibility of the products intended for sterilization being mixed with or taken to be products already sterilized. In case of terminally sterilized products, the design of the areas shall preclude the possibility of mix up between non-sterile products.

1.2(B) *Precautions against contamination and mix*:

(a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building,
(b) Using appropriate pressure differential in the process area.
(c) Providing a suitable exhaust system.
(d) Designing laminar flow sterile air system for sterile products.
(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.
(f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.
(g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature, relative humidity, volume filled, leakage and clarify shall be checked and recorded.

PART II

A. LIST OF MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PREMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF AYURVEDIC, SIDDHA SYSTEM OF MEDICINES.

Sl.No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended

(1)	(2)	(3)	(4)
		1200 Square feet covered area with separate cabins partitions for each activity. If Unani medicines are manufactured in same premises an additional area of 400 sq. feet will be required.	
1.	Anjana/Pisti	100 sq. feet.	Karel/mechanized/motorized, kharel. End runner/Ball-Mill Sieves/Shifter
2.	Churna / Nasya Manjan/Lepa Kwath Churn	200 Sq feet	Grinder / disintegrator / Pulverisar / Powder mixer / Sieves / Shifter.
3.	Pills / Vatti / Gutika Matrica and tablets	100 sq. feet	Ball Mill, Mass mixer powder mixer, granulator, drier, tablet compressing machine, pill/vati cutting machine, stainless steel trays/container for storage and sugar coating, polishing pan in the case of sugar coated tablets,mechanised chattoo (for mixing guggulu) where required.
1	2	3	4
4.	Kupi pakava / Ksara / Parpati / Lavana Bhasma Satva / Sindura Karpu / Uppu / Param	150 Sq. feet	Bhatti,Karahi/StainlessSteelVessels/ Patila Flask, Multani Matti/Plaster of Paris, copper Rod, Earthern container, GajPutBhatti,Mufflefurnace(Electri-callyoperated)End/EdgeRunner,ExhaustFan,Wooden/S.S.Spatula.
5.	Kajal	100 Sq. feet	Earthern lamps for Collection of Kajal, Triple Roller Mill, End Roller, Sieves, S.S.Patila, filling / packing and manufacturing room should be provided with exhaust fan & ultra violet lamps.
6.	Capsules	100 Sq. feet	Air Conditioner, De humidifier, hygrometer, thermometer, Capsule filling machine and chemical balance.

7.	Ointment /Marham / Pasai	100 Sq. feet	Tube filling machine, Crimping machine/Ointment mixer, End Runner/ Mill (Where required) S.S. Storage Container S.S.Patila.
8.	Pak /Avalesh / Khand / Modak /Lakayam	100 Sq. feet	Bhatti section fitted with exhaust fan and should be fly proof, iron kadahi / S.S.Patila and S.S. Storage container.
9.	Panak / Syrup / Pravahi Kwath Manapaku	150 Sq, feet	Tincture press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, filter press / Gravity filter liquid filling machine, P.P. Capping Machine.
10.	Asava / Arishta	200 Sq. ft	Same as mentioned above. Fermentation tanks containers and distillation plant where necessary, Filter Press.
12.	Sura	100 Sq. ft	Same as mentioned above plus distillation plant and transfer pump.
13.	Ark/ Tinir	100 Sq. ft	Maceration tank, Distillation plant, Liquid filling tank with tap / Gravity filter/Filter press, Visual inspection box.
14.	Tail/Ghrit Ney	100 Sq. ft	Bhatti, Kadahi/S.S. Patila S.S.Storage Containers, Filtration equipment, filling tank with tap/Liquid filling machine.
15.	Aschyotan / Netra Malham Panir	100 Sq. ft	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangements collation mill, or ointment mill, tube filling equipment, mixing and storage tanks of stainless steel or of other suitable material sintered glass funnel, seitz filter or filter candle, liquid filling equipment, autoclave.
16.	Each manufacturing unit will have a separate area for Bhatti, furnace,	200 Sq. ft	

boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc. the furnace section could have tin roof.

B. LIST OF MACHINERY, EQUIPMENT AND MINIMUM MANUFACTURING PREMISES REQUIRED FOR THE MANUFACTURE OF VARIOUS CATEGORIES OF UNANI SYSTEM OF MEDICINES.

Sl.No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended

(1)	(2)	(3)	(4)
1.		1200 square feet covered area with separate cabins, partitions for each activity. If Ayurveda / Siddha, Medicines are also manufactured in same premises an addition area of 400 square feet will be required.	
1.	Itrifal Tiryao / majoon / Laooq / Jawarish Khamiras	100 Sq. feet	Grinder/ Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Bhatti and other accessories, Planter mixer for Khamiras.
2.	Araq.	100 Sq. feet	Distillation Plant (garembic) S.S. storage tank, boiling vessel, gravity filter, bottle filling machine, bottle washing machine, bottle drier.
3.	Habb (Pills) and tablets.	100 Sq. feet	Ball Mill, Mass Mixer/Powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, stainless steal trays/ container for storage and in the case of sugar coated tablets, mechanized chattoo, (for mixing guggulu) where required.
4.	Sufoof (Powder)	100 Sq. feet	Grinder / Pulveriser, Sieves, Trays, Scoops, Powder mixer (where required).
5.	Raughan (oils) (Crushing and boiling)	100 Sq. feet	Oil expeller, S.S. Patilas oil filter bottle, filling machine, bottle drier, bhatti.
6.	Shiyaf, Surma, Kajal	100 Sq. feet	End runner,mixing S.S. Vessel.
7.	Marham, Zimad (Ointment)	100 Sq. feet	Karal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if needed).

(1)	(2)	(3)	(4)
8.	Qurs (Tab)	100 Sq. feet	Grinder / Pulveriser, Sieves, Powder mixer (where needed), Granulator, Drier, Tablet Compressing Machine, Die punches Trays, D.T. apparatus, Balance with weights, Scoops, Sugar Coating Pan, polishing pan, Heater.
9.	Kushta	100 Sq. feet	Bhatti, Kharal, Sil Batta, Earthen pots.
10.	Murabba	100 Sq. feet.	Aluminium Vessels 50-100 kgs. Capacity, Gendna, Bhatti.
11.	Capsule	100 Sq. feet	Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, Dehumidifier Balance with weights, storage containers, glass.
12.	Sharbat & Jushanda	100 Sq. feet	Tinctum Press, exhaust fan fitted, Bhatti section, Bottle washing machine, Filter Press, Gravity filter, Liquid filling tank with tap/liquid filling machine, PP capping machine, air over electrically heated with thermostatic control, kettle.
13.	Qutoor Chasm and Marham (Eye drops eye ointment)	100 Sq. feet	Hot air oven electrically heated with thermostatic control, kettle.

(1)	(2)	(3)	(4)
14.	Each manufacturing unit will have a separate area for Bhatti, furnaces, boilers, putta, etc. this will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc.	200 Sq. feet	

C. LIST OF EQUIPMENT RECOMMENDED FOR IN HOUSE QUALITY CONTROL SECTION

(alternatively unit can get testing done from the government approved laboratory.)

(A)	CHEMISTRY SECTION	(B)	PHARMACOGNOSY SECTION
1	Alcohol determination Apparatus (complete set)	1.	Microscope Binoculor.
2.	Volatile Oil Determination Apparatus.	2.	Dissecting Microscope.
3.	Boiling Point Determination Apparatus	3.	Microtome.
4.	Melting Point Determination Apparatus	4.	Physical Balance.
5.	Refractometer	5.	Aluminium Slide Trays.
6.	Polarimeter	6.	Stage Micrometer.
7.	Viscometer.	7.	Camera Lucida (Prism and Mirror Type.)
8.	Tablet Disintegration Apparatus.	8.	Chemicals, Glass-ware etc.
9.	Moisture Meter.		
10.	Muffle Furnace.		
11.	Electronic Balance.		
12.	Magnetic Stirrer.		
13.	Hot Air Oven.		
14.	Refrigerator.		
15.	Glass/Steel Distillation apparatus.		
16.	LPG Gas Cylinders with Burners.		
17	Water Bath(Temperature controlled.)		
18	Heating Mantles/ Hot Plates.		
19.	TLC Apparatus with all accessories (Manual)		
20	Paper Chromatography apparatus with accessories.		
21.	Sieve size 10 to120 with Sieve shaker.		
22	Centrifuge Machine.		
23.	Dehumidifier.		
24	PH Meter.		
25.	Limit Test Apparatus.		

Note: - The above requirements of machinery, equipments, space, qualifications are made subject to the modification at the discretion of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter then in the circumstances in a particular case.