SCHEDULE T

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC SIDDHA AND UNANI MEDICINES

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The Good Manufacturing Practices are prescribed to ensure that

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 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.

PART I

Good Manufacturing Practices

1. Factory Premises

- The manufacturing plant should have adequate space for:

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.

2. General Requirements

A. Location and surroundings

B. Buildings

The building used for factory shall be such as to permit production of drugs under hygenic conditions and should be free from cobwebs and insects/rodents.

The premises used for manufacturing, processing, packaging and labelling 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 or omission of manufacturing or control step.

III. Designed, constructed and maintained to prevent entry of insects and rodents.

IV. 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 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.

C. Water Supply

D. Disposal of Waste

E. Container's cleaning

F. Stores

(F-A) Raw Materials

All raw materials procured for manufacturing shall be stored in the raw materials store.

While designing such containers, cabins 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 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 ‘UNDERTEST’ or ‘APPROVED’ or ‘REJECTED’. The labels shall further indicate and identify the particular supply in the form of batch No. or lot No. and the date of receipt of the consignment.

(F-B) Packaging Materials

(F-C) Finished Goods Stores

The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores with in an area marked “Quarentine”. After the quality control laboratory and the expects have checked the correctness of finished goods with reference to its packing/labelling as well as finished product quality as prescribed then it will be moved to “Approved Finished Goods Stock” area.

G. Working space

H. Health Clothing Sanitation and Hygiene of Workers.

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.

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, labelling and packing etc.

K. Batch Manufacturing Records

The license shall maintain batch manufacturing records 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 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 Drugs and Cosmetics Act.1940 .

L. Distribution Records

M. Record of Market Complaints

Manufactures 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.

Reports 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.

N. Quality Control

Preferably for such quality control, there should be a separate expert. The quality control section shall have the following facilities:

1. There should be 150sq. 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 established shelf life and storage requirements for the drugs.
7. Manufactures who are manufacturing patent, proprietary Ayurveda, Sidda and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.

9. The standards for identity, purity and strength as given in respective pharmacopeias 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 minimise such contamination.

11. Quality control section will have a minimum of

a) One person with Degree qualification in Ayurveda/Siddha/unani(A.S.U) as per Schedule II of indian Medicine Central Council Act, 1970 (84 of 1970) of a recognized university or Board.

b) Provided that Bachelor of Pharmacy, Pharmacognosy and Chemistry may be associated with the quality control section.

Requirement for sterile product

A. Manufacturing Areas

For the manufacturing of Ayurvedic, Siddha and Unani drug that can be sterilised in their final containers,the design of the areas shall preclude the possibility of the products intended for sterilisation being mixed with or taken to be products already sterilised. Incase of terminally sterilised products, the design of the areas shall preclude the possibility of mix up between nonsterile and sterile products.

Requirement for sterile product

B. Precaution against the contamination and mix

a. Carrying out manufacturing operation in a separate block of adequately isolated building or operating in an isolated enclosure within the building.

b. Using appropriate pressure differential in 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 opthalmic 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.

PART-II

A. List of machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of ayurvedic, siddha system medicines

Sr.No	Category of Medicine	Minimum manufacturing space required 1200 Square feet covered area with separate cabins partitions for each activity. If Unani medicine are manufactured in same premises an additional Area of 400 sq. feet will be required.	Machinery/equipment recommended
1.	Churna / Nasya / Manjan/ Lepa Kwath Chum	200 Sq. feet	Grinder/Disintegrator/Pulverisar/Powder mixer/Sieves/shifter
2.	Pills/Vatti/Gutika Matirai	100 Sq. feet	Ball Mill, Mass mixer/power mixer, pill/vati cuttin machine, stainless steel trays/Containers for Storage. Driers/ Machanised chatee (for mixing quggul) where required.

3	Tablets	100 Sq. feet	Ball Mill, Mass Mixer/Powder mixer, Granulator drier, Tablet compressing Machine and sugarcoating, foliching pay in case of sugar coated tablets, mechanised chatte (for mixing of guggulu) where required.
4	Kajal	100 Sq. feet	Karthen lamps for Collection of Kajal, Tipple Roller Mill, End Runner, Sieves, S.S Patila, Filling/packing manufacturing room should be provided with exhaust fan and ultra violet lamps.
5	Capsules	100 Sq. feet	Air-Conditioner, De humidifier, hygrometer, Thermometer, Capsule filling Machine and chemical balance.

6	Ointment/Marham Pasai	100 Sq. feet	Tube filling machine, Crimping Medicine/Ointment Mixer, End Runner/Mill (Where required), S.S Patila.
7	Asava/Aristha	100 Sq. feet	200 Sq. feet
8	Each manufacturing unit will have a separate area for Bhatti, furnaces, boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insects, 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

Sr.No	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
		1200 Square feet covered area with separate cabins partitions for each activity. If Ayurveda/Siddha medicines are manufactured in same premises an additional Area of 400 sq. feet will be required.	
1	Habb (Pills) and Tablets	100 sq. ft	Ball Mill, Mass Mixer Powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, staineless steel trays/container for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanised chatoo, (for mixing of guggul) where required.

2	Sufoof (Powder)	200 sq. ft.	Grinder/Pulveriser, Seiver, Trays, Scoups, Powder mixer, (where required).
3	Raughan (Oils) (Crushing and Boiling)	100 sq. ft.	Oil Expeller, S.S. Patilas Oil filter bottle filling machine, bottle drier, Bhatti.
4	Marham, Zimad (Ointment)	100 sq. ft.	Kharal, Bhatti, End runner, Grinder, Pulversiser, Tripple Roller Mill.
5	Qurs (Tab)	100 sq. ft.	Grinder/Pulveriser, Sieves,power mixer (where needed),Granulator, Drier, Tablet compressing machine, Die punches Trays, O.T. Apparatus, Balance with weights, Scoops, Sugar coating pan, Polishing pan, Heater.

6	Capsule	100 sq. ft.	Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, De-humidifier balance with weights, storage containers, glass.
7	Qutoor-e-Chashm and Marham (Eye drops, eye ointment)	100 sq. ft.	Hot air oven electrically heated with Thermostatic control, kettle.
8	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, insects,dust etc.		

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

(Alternatively unit can get the testing done from the Government approved laboratory).

A	CHEMISTRY SECTION	(B)	PHARMACOGNOSY SECTION
1.	Alcohol Determination Apparatus (complete set).	1.	Microscope Binocular.
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.
9. Moisture Meter
10. Muffle Furnace
11. Electronic Balance
12. Magnetic Stirrer.
13. Hot Air Oven
14. Refrigerator.
15. Glass/Steel Distillation Apparatus

8. Chemicals, Glass-ware etc.

THANK YOU