[1][24. Lipsalve IS:10284.
25. Powder Hair Dye IS: 10350.
26. Bindi (Liquid) IS: 10998.
27. Kum Kum Powder IS: 10999.
28. Henna Powder IS: 11142.]
[2][29. Bathing Bars IS: 13498: 1997
3[30. Sindoor IS: 14649: 1999
[4][31. Liquid Foundation makeup IS 14318
4[32. Cold Wax Hair remover IS 15152
[4][33. Face pack IS 15153
[4][34. Kajal IS 15154
[4][35. Oxidation Hair Dyes (Emulson Type) IS 15205
4[36. Cream Bleach IS 15608

1. Ins. by G.S.R. 553(E), dt. 20.7.1995.
2. Ins. by G.S.R. 592(E), dt.13.8.2008.
3. Ins. by G.S.R. 724(E), dt. 07.11.2013.
4. Ins. by G.S.R. 203(E), dt.18.03.2015.

## [5][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 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 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 G.M.P.

5. Subs. by G.S.R. 560(E), dt. 07.3.2003.

PART I
**GOOD MANUFACTURING PRACTICES**

1.1 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.

**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 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 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 material, in process medicine or medicines which require drying before packing. This space will be protected from flies/ insects/dust etc., by proper flooring, wire-mash 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) *Packaging 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/labelling as well as the 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, labelling and packing etc. to ensure ease in movement of workers and orderliness in operations 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 licensee 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 1940). 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 Unani 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. Certain 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 efficacy 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.

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. 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 till the expiry date of product 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 and proprietary Ayurveda, Siddha, and Unani medicines shall provide their own specification and control references 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: –

[1][(i) (a) Expert in Ayurveda or Sidha or Unani medicine who possesses a degree qualification recognized under Schedule II of Indian Medicine Central Council Act 1970;

(b) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda), awarded by a recognized University; and

(c) Botanist (Pharmacognosist), who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University.]

(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 recognised laboratory for Ayurveda, 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 recognised laboratory.

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

## 1.2. Requirement for Sterile Product:

(A) *Manufacturing Areas*: – For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed areas specifically designed 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.

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1. Subs. by G.S.R. 463(E) dated 08-07-2005.

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 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.

(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 clarity shall be checked and recorded.

## PART II

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

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing areas like powdering, furnace, packing of liquids and Avaleha, Paks, could also be shared for these items.

| Sl.No. | Category of Medicine | Minimum manufacturing space required | Machinery/equipment recommended |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| | | 1200 Square feet covered area with separate cabins or 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, karel. End runner/Ball-Mill Sieves/Shifter. |
| 2. | Churna / Nasya/ Manjan/Lepa/ Kwath Churn | 200 sq feet | Grinder/disintegrator/Pulveriser/ Powder mixer/sieves/shifter. |
| 3. | Pills/Vati /Gutika Matirai 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 case of sugar-coated tablets,mechanised chattoo (for mixing guggulu) where required. |
| 4. | Kupi pakava/Ksara/ Parpati/LavanaBhasm a Satva/Sindura Karpu/ Uppu / Param | 150 sq. feet | Bhatti, Karahi/Stainless steel Vessels/Patila Flask, Multani Matti/Plaster of Paris, Copper Rod, Earthern container, Gaj Put Bhatti, Mufflefurnace(Electrically operated) End/EdgeRunner, Exhaust Fan, Wooden/S.S.Spatula. |
| 5. | Kajal | 100 sq. feet | Earthern lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, S.S.Patila, Filling/ packing and manufacturing room should be provided with exhaust fan and ultra violet lamps. |
| 6. | Capsules | 100 sq. feet | Air Conditioner, De-humidifier, hygrometer, thermometer, Capsule filling machine and chemical balance. |
| 7. | Ointment/Marham Pasai | 100sq. feet | Tube filling machine, Crimping Machine/Ointment Mixer, End Runner/ Mill (Where required) S.S. Storage Container S.S.Patila. |

| Sl.No. | Category of Medicine | Minimum manufacturing space required | Machinery/equipment recommended |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 8. | Pak/Avaleh/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. |
| 11. | Sura | 100 sq. ft | Same as mentioned above plus Distillation plant and Transfer pump. |
| 12. | Ark Tinir | 100 sq. ft | Maceration tank, Distillation plant, Liquid filling tank with tap / Gravity filter/Filter press, Visual inspection box. |
| 13. | Tail/Ghrit Ney | 100 sq. ft | Bhatti, Kadahi/S.S. Patila S.S.Storage Containers, Filtration equipment, filling tank with tap/Liquid filling machine. |
| 14. | Aschyotan / Netra Malham Panir/Karn Bindu/Nasa-bindu | 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. |
| 15. | Each manufacturing unit will have a separate area for Bhatti, furnace boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc. The furnace section could have tin roof. | 200 sq. ft | |

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

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing areas like powdering, furnace, packing of liquids could also be shared for these items.

| 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 Ayurveda / Siddha medicines are also manufactured in same premises an additional area of 400 square feet will be required. | |
| 1. | Itrifal Tirya/majoon/ Laooq/Jawarish Khamiras | 100 sq. feet | Grinder/ Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Bhatti and other accessories, plant mixer for Khamiras. |
| 2. | Arq. | 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 sugar coating, polishing pan in case of sugar-coated tablets, mechanized chattoo, (for mixing guggul) where required. |

| | | | |
|---|---|---|---|
| 4. | Sufoof (Powder) | 200 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 | Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if required). |
| 8. | Qurs (Tab.) | 100 sq. feet | Grinder/Pulveriser, Sieves, Powder mixer (where needed), Granulator, Drier, Tablet Compressing Machine, Die punches Trays, O.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 50-100kgs. Capacity, Gendna, Bhatti. |
| 11. | Capsule | 100 sq. feet | Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, De-humidifier, Balance with weights, storage containers, glass. |
| 12. | Sharbat and Joshanda | 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, hot air oven electrically heated with thermostatic control, kettle. |
| 13. | Qutoor-e- Chashm and Marham(Eye drops, eye ointment) | 100 sq. feet | Hot air oven electrically heated with thermostatic control, kettle |
| 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, insects, 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, Glassware 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. | | |

## [1][D. SUPPLEMENTARY GUIDELINES FOR MANUFACTURING OF RASAUSHADHIES OR RASAMARUNTHUKAL AND KUSHTAJAT (HERBO-MINERAL-METALLIC COMPOUNDS) OF AYURVEDA, SIDDHA AND UNANI MEDICINES

These guidelines are intended to complement those provided above and should be read in conjunction with the parent guidelines. The supplementary guidelines are to provide general and minimum technical requirements for quality assurance and control in manufacturing Rasaushadhis or Rasamarunthukal and Kushtajat (Herbo-mineral-metallic formulations). These supplementary guidelines deal with Bhasmas, Sindura, Pishti, Kajjali, Khalviya Ras, Kupipakwa, Rasayan, Parpati, Potali Rasa, Satwa (of Metals and Minerals origin) Druti Parpam, Karpu, and Kushta etc. used in Ayurvedic, Siddha and Unani Systems of medicine.

The supplementary GMP guidelines for Rasaushadhi or Rasamarunthukal and Kushtajat are needed to establish the authenticity of raw drug, minerals and metals, in-process validation and quality control parameters to ensure that these formulations are processed and prepared in accordance with classical texts and for which safety measures are complied. Only those manufacturing units which have Good Manufacturing Practices for ASU drugs and supplementary certificate for Rasaushadhi or Rasamarunthukal and Kushtajat formulations shall be allowed to manufacture th e same. Supplementary Good Manufactur ing Pr actices Certificate for Rasaushadhies shall be issued by the State Licensing Authority only after thorough inspection by an expert team including Rasashastra experts nominated by the Department of AYUSH.

**2. Manufacturing Process Areas :-**

For the manufacture of Bhasma and Kupipakawa and Rasaushadhi preparations made from metals and minerals the following specific areas shall be provided, which should be completely segregated from the production area used for preparation of plants and animal by product based formulation to avoid cross contamination. The following exclusive areas the required for Rasaushadhies or Rasamarunthukal and Kushtajat:-

**2.2** (a) Bhatti or Heating Device Section for Bhasma and Rasaushadhies :- 100 sq. feet for heating, burning, putta and any heat related work with proper ventilation, exhaust and chimney. This could be tin shed also.

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1. Ins. By G.S.R. 157(E), dated 04-03-2009

(b) Grinding, Drying and Processing Section for Bhasma and Rasaushadhies:- 100 Sq. feet (Manual or Mechanical, oven etc.). Drying [1][Shall be] done in a space which is covered by glass or other transparent material to allow entry of sunrays on the material to keep for the purpose. If drying is being done in oven the temperature of the same may be selected specific temperature.

(c) Rashaushadi Related Store :-100 Sq. feet.

The size and dimensions of each Bhatti Section would be so designed to suit the batch size or quantity of materials to be processed, keeping in mind the processing is done as per the conditions of Drug and Cosmetics Act mentioned under Schedule I official books.

In addition to the fuels prescribed in the schedule books namely coal, fire wood, cow dung cakes etc., use of other heating devices e.g. electrical heating, oil or gas fired furnaces and others Shall be] employed so as to provide the required temperature as per the nature of material and object of heating. Depending on the formulation being manufactured, manufacturers may adopt aerobic or anaerobic process. Properly baked and clean earthen pots of other crucibles and glass containers of appropriate design shall be used.

The manufacturing area should be designed with special attention to process the products that generate toxic fumes like SO2, arsenic and mercury vapor, etc. When heating and boiling of the materials is necessary, suitable ventilation and air exhaust flow mechanism should be provided to prevent accumulation of unintended fumes and vapors. Such areas may be provided with properly designed chimneys or ducts fitted with exhaust system and suitable scrubbing system to remove fumes and smoke, so that safety of personnel and environment is taken care of.

Since processing of Rasaushadhis may introduce heavy metal contamination and cross contamination etc., therefore, cleaning of equipment is particularly important after every process by using appropriate cleaning agent which should not react with material of equipment and must be free from unwanted properties e.g. corrosiveness.

**2.3** Records shall be maintained specially for temperatures attained during the entire process of Bhasmikaran, while employing different kinds of classical puta, furnaces using oil, gas or electricity. Appropriate temperature measuring instrument should be employed such as pyrometer and, pyrograph for manual reading or recording by heat sensors, connected to computer as the case may be.

In order to handle large quantities, appropriate technology like use of hand operated extruders for making chakrikas or pellets may be adopeted. However, such equipments made of aluminium or its alloys should not be used.

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1. Subs. by G.S.R.Subs. by G.S.R.338(E), dated 15-04-2010.

Access to manufacturing areas shall be restricted to minimum number of authorized personnel only.

**3. Quality Control :-**

**A. Inprocess Quality Control :-**

The registers as indicated below should exclusively be maintained for ready reference :-

**(a) Shodhan Register with following details :-**

1. Sl No.
2. Batch No. and Size
3. Date, time and duration
4. Name of the Raw-material with Quality reference and quantity
5. Quantity of Shodhana Dravya
6. Book Reference followed
7. Methodology

**(b) Bhavana and Putta Register with following details :-**

1. Sl No.
2. Batch No.
3. Date, time
4. Name of the material and quantity of starting materials
5. Quantity of Nirvapya Dravya
6. Quantity of Bhavana Dravya
7. Date and time of Starting and completion of Bhavana or Mardana and duration
8. Type and Number of Puttas
9. Time and Date of completion of Puttas
10. Color and texture of the product or standards
11. Inprocess tests followed (Bhasma Pariksha and any other tests)
12. In case heating at a particular temperature is required, record of attainment of that temperature.

**(c) Grinding Record Register**:- (Finished Product / Intermediate procedure)

1. Sl. No.
2. Batch No.
3. Date and time
4. Name of the material and quantity
5. Name of the equipment (SS/granite)
6. Duration of grinding
7. Repeat the grinding if required (Number of repetition)

**(d) Packing details**:-

1. Name of Rasaushadhi
2. Type of Dosage Form (eg. Powder, pill, tablet etc)
3. Weight of Rasaushadhi in each unit

**B. Product Quality Control:-**

The specifications for finished Rasaushadhi are primarily intended to define the quality rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the quality. Consistent quality for Rasaushadhi can only be assured if the starting material-metals and minerals are used of pharmacopoeial standards. In some cases more detailed information may be needed on aspects of their process. The manufacturer will ensure in-house standards for the uniform quality of product.

Quality testing will be carried out as per official Pharmaceutica or Schedule books for texts namely, color, taste, varitaratwa, Rekhapurnatwa, Laghutva, Nirdhumatwa, Dntagre Kachakacha, Niruttha, Apunarbhava and Nischandratwa.

The Particle size of the product should be tested by adopting microscope fitted with micrometer or particle size analyzer or any appropriate other techniques. Required physio-chemical characterization of the product should be undertaken by appropriate analytical equipment. The Standard Manufacturing Process of the product should be evolved/follow up. The disintegration time of pills-vati and tablets should also be recorded.

**4. Product recalls**:- Literature inserted inside the product package should indicate the name, address of the manufacturing unit [1][and] telephone number for reporting of any adverse drug reaction by physicians or patients. On receipt of such Adverse Drug Reaction report, it will be the responsibility of the manufacturer to ensure the recall of the product from the market.

Standard Operating Procedures (SOP) should be included for storage of recalled Rasaushadhies in a secure segregated area, complying with the requirements specified for storage till their final disposal.

**5. Medical examination of the Employees**:- Employees engaged in manufacturing should be medially examined periodically at least once a year for any adverse effect of the drug during manufacturing process for which necessary investigations [1][Shall be] carried out for ensuring that there is no effect of material on the vital organs of the employees. Annual examination reports of the employees shall be made available to statutory inspectors during Good Manufacturing Practices inspections.

**6. Self-Inspection**:- The release of Rasaushadhis should be under the control of a person who has been trained in the specific features of the processing and quality assurance of Rasaushadhis. Personnel dealing with the production and quality assurance of Rasaushadhis manufacturing section should have an adequate training in the specific subject of Rasaushadhis manufacturing. He will be at least a degree holder in Ayurvedic, Siddha / Unani medicines or B.Pharma degree holder in Ayurvedic / Siddha / Unani medicines.

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1. Subs. by G.S.R. 338(E) dated 15-04-2010.

**7. Dosage form of Rasaushadhis**:- The Rasaushadhis may be made into an acceptable dosage forms such as churna, vati, guti, tablet or capsules etc. after adding suitable permissible fillers or binding agents as permissible under the Ayurvedic Pharmacopoeia of India or Indian pharmacopoeia as updated from time to time. In such cases the label must indicate the quantity of Ayurveda, Siddha and Unani medicines in one Tablet or Pill or Capsule in addition to the filler. The crystalline product may be grinded before packing in the individual dispensing size. All the Rasaushadhis or Rasamaruthukal or Kushtajat shall be packed in a dosage form which is ready for use for the consumer. Grinding and weighing of individual dose of potentially poisonous products will not be permissible in patient consumer pack. This arrangement may reduce the Adverse Drug Reaction of Rasaushadhi which takes place due to dose variation. However, for hospital bulk pack, it will not be applicable and label will clearly indicate the "Hospital pack."

**8. Area Specifications/ requirement for an applicant companies only to have GMP of Rasaushadhis or Rasamarunthukal and Kushtajat (Herbomineral/metallic compounds) of Ayurveda, Siddha and Unani medicines:-**

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1. Subs. by G.S.R. 338(E) dated 15-04-2010

| Sr. No. | Category of Medicine / Manufacturing area | Minimum Manufacturing space required (1500 sq. ft.) | Machinery equipme recommended |
|---|---|---|---|
| 1. | Pisti / grinding area for Bhasma, Pishti, Kushtajat | 100 sq. ft. | Kharal/mechanized/motorized Kharal, End runner / Ball-Mill Sieves / Sifter. |
| 2. | Powdering area for raw drugs of plant origin giving in Rasaushadhis (Herbo-metalic formulations) | 200 sq. ft. | Grinder / Distintegrator /Pulverisor / Powder mixer / Sieves / Sifter |
| 3. | Pills / Vati/ Gutika Matrica and tablets / Habb making area | 100 sq. ft. | Ball Mills, 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 case of sugar coated tablets, mechanized chatoo, (for mixing of guggulu) where required. |
| 4. | Kupi pakva / Ksara / Parpati / Lavana Bhasma Satva / Sindura Kapu / Uppa / Param / Qushta / Jawhar | 150 sq. ft. | Bhatti, Karahi / stainless steel vessels /patila flask, Multani Matti / Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Muffle furnace (electrically operated) End / Edge Runner, Exhaust Fan, Wooden, S.S. Spatula. |
| 5. | Receiving and storing raw material | 200 sq. ft. | |
| 6. | Quality Control Section | 150 sq. ft. | |
| 7. | Quarantine / observation | 50 sq. ft. | |
| 8. | Finished goods store | 150 sq. ft. | |
| 9. | Rejected goods store | 50 sq. ft. | |
| 10. | Bhatti-putta area | 200 sq. ft. | |
| 11. | Area for water and washing etc. | 50 sq. ft. | |
| 12. | Office | 100 sq. ft. | |
| | **TOTAL** | **1500 sq. ft** | |

**Note** : The above requirements of machinery, equipments, space 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 them in the circumstances in a particular case, [1][he may do so after recording reasons in writing]].

1. Added by G.S.R.463(E), dated 08-07-2005

[1][Schedule TA

(See rule 157 A)

**FORM FOR RECORD OF UTILIZATION OF RAW MATERIAL BY AYURVEDA OR SIDDHA OR UNANI LICENSED MANUFACTURING UNITS DURING THE FINANCIAL YEAR**

Identification Particulars:

Manufacturing License No .....

Issued by.....

Name: .....

Address: .....

State: ..... Pin Code: .....

Telephone:..... Fax: .....

Email: .....

1. Quantity of Medicinal Plants/Extracts/Essential Oils/Metals/Animal By-Products Minerals Used During 1st April, to 31st March of the preceeding year (For Productions at the identified facility)

**(a) Herbs Used**

| Common Name as in AFI/API* | Plant's Botanical Name | Quantity Used/per annum (in Kgs.) | Sources of Supply | | | | | Part Used | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Traders/ Manufacturers | Forest Collectors | Cultivators | Imported | Total | Whole plans | Root | Leaf | Others |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
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| | | | | | | | | | | | |

*Ayurvedic Formulary of India/Ayurvedic Pharmacopoeia of India

**(b) Extracts Used**

| Name of Extracts | | Quantity Used/per annum (in Kgs.) | Sources of Supply | | | |
|---|---|---|---|---|---|---|
| Common Name as in AFI/API* | Botanical Name | | In-House | Export Suppliers | Imported | Total |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

* Ayurvedic Formulary of India/Ayurvedic Pharmacopoeia of India

**(c) Metals/Minerals Used**

| Name of Mineral | | Quantity Used/per annum (in Kgs.) | Sources of Supply | | | |
|---|---|---|---|---|---|---|
| Common Name | Chemical Name | | Manufacturers Traders (Domestic) | | Importers | Total |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

1. Ins. By G.S.R. 512 (E), dated 09-07-2008

## (d) Animal By-Products Used

| Name of By-Product | | Quantity Used/per annum (in Kgs.) | Sources of Supply | | | |
|---|---|---|---|---|---|---|
| Common Name | Biological/Chemical Name (if any) | | Manufacturers Traders (Domestic) | | Importers | Total |
| | | | | | | |
| | | | | | | |

2. Shortage of raw material(s)/inputs during the preceeding year.

Y N

If yes, please indicate name(s) of such raw material(s) by level of importance starting from most important to least important, reason for shortage [availability, quality or any other (please specify)]

| Name of Raw Materials | | Appro. Qty of shortage (in Kgs.) | Reason |
|---|---|---|---|
| Name of the drug and part used as mentioned in official formulary / Pharmacopoeial/ Schedue I books | Biological/ Chemical Name (if any) | | |
| | | | |
| | | | |

[1][SCHEDULE U

(*See* rules 74, 74A, 74B, 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.

1. Subs. by G.S.R. 735(E) dated 24-06-1988