UNIT -5

A. General Introduction to Herbal Industry

B. Schedule T- Good Manufacturing Practice of Indian Systems of Medicine

A.

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

- Recently there has been a shift in universal trend from synthetic to herbal medicine, which we can say **'Return to Nature'.**
- Medicinal plants have been known for **millennia & highly** esteemed all over the world as a rich source of **medicinal agents.**
- One reason for popularity of natural products is that belief that all are safe, non –toxic, less side effect, easily affordable prices.
- In international market now a days, herbal drug industry is very fast growing sector.
- India has not done well in this international trade of herbal products in market.

Current and Future Trends in Herbal Medicine

- Herbal medicine is an important component towards alternative medicine.
- It is become more popular in today's world because of natural remedies.
- Herbal medicine-based Traditional Medical system of treatment is a rapidly growing healthcare system of economic importance and is now widely used in many countries of the world.
- In Africa, up to 80 per cent of the population uses this herbal traditional medicine system to help meet their healthcare needs.
- In Asia and Latin America, people continue to use the system as a result of historical circumstances and cultural beliefs. In China, TM accounts for around 40 per cent of all health cares delivered.

Scope of Herbal Drug Industry

- In india, raw drugs obtained from around 2,400 plant species.
- Fastest growing market & may attain to **14,500 crore by 2012 & exports to 9000 crore with a CAGR (compound annual growth rate) of 20 % & 25%** respectively, according to **Associated Chambers of Commerce & Industry of India(Assocham)**
- The '**Herbal Industry Biz' has reveled that currently, the Indian herbal market size is estimated at 7000 crore &** over **3600 crore of herbal raw materials & medicine are exported by india.**
- Reason for unexpected growth of herbal farm by gov. for improving quality of drugs and promotion of exports.

- As per **Associated chamber of Commerce & Industry (ASSOCHAM), the herbal drug & its application become** very popular across the world.
- **In India, about 25,000 licensed pharmacy are working.**
- Presently **1000 single drugs & about 3000 compound formulations are registered.**
- In india, about **8000 medicinal plants are used.**
- Non of them have a standerd marker & animal for their bioactivity.
- From abt **8000 manufaturares , 25 mfgs large scale** mfgs.
- The **annual turnover is around US $ 300 million in** Ayurvedic & Unani medicine was about **US $ 27.7 million.**

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Various plant based industries in India are involved in work on medicinal and aromatic plants. Some of these are:

1. Shree Dhootapapeshwar Ltd

The oldest Ayurveda Firm in India, Shree Dhootapapeshwar Ltd was founded in 1872 in Mumbai. Legend has, the firm was opened by a local Ayurveda practitioner dwelling in Girgaon area of Mumbai.

2. Dabur India Ltd

Dabur a small herbal medicines company was founded by Visionary Dr.SK Burman in Kolkata in 1884. Since the last 123 years, Dabur has grown from strength to strength. Dabur is also one of the oldest and trusted Ayurveda companies in India. Dabur is well known for its nutritional supplement 'Chayanprash.'

3. Arya Vaidya Sala, Kottakkal

The pioneer of India's commercial Ayurveda industry. Arya Vaidya Sala is located in Kottakkal, Kerala. Arya Vaidya Sala was founded by Vaidyaratnam PS Varier in 1902. It began as a village clinic. The popularity of Varier's treatment spread far and wide. Patients from various parts of Kerala and neighbouring areas began pouring into this nondescript village for medical treatment. With a history of over 115 years, Arya Vaidya Sala now operates around 30 branches in India and abroad. Its products are sold by about 2,000 pharmacies worldwide. The multi-million dollar company has about 1,000 healthcare and beauty products.

5. Baidyanath

The company Shree Baidyanath Ayurved Bhavan Ltd of Kolkata was founded in 1917. Baidyanath pioneered several types of research in Ayurveda. Baidyanath is a very popular Ayurveda company in India. The company offer specialized preparations to treat various ailments as well as powders and extracts of herbs.

6. Himalaya Wellness

M Manal, the founder of Himalaya, wanted to scientifically test the herb's properties. With no money and only a pocketful of dreams, he pawned his mother's jewellery to buy a hand-operated tabletting machine. His vision was to 'bring the traditional Indian science of Ayurveda to society in a contemporary form'. Himalaya took Indian Ayurveda worldwide. Some 30 million units of Himalayan's products are consumed worldwide every year.

7. Charak Pharma

Founded in 1946, Charak Pharma is the brainchild of brothers DN Shroff and Dr.SN Shroff. The company was launched with a vision to position Ayurveda based medicines and herbal products in Indian and foreign markets. Charak has a wide range of proprietary medicines, beauty products and nutritional supplements.

8. Zandu Ayurveda

Zandu Balm is perhaps the most renowned product of this company named after Zandu Bhatt, the personal physician of erstwhile ruler of Jamnagar. Zandu Ayurveda is a multi-million dollar Indian company. Its products range from Ayurveda based medicines to cure complex ailments from poor memory to uterine cyst.

9. Vicco Laboratories

In 1952, KV Pendharkar, an Ayurveda expert founded Vicco Laboratories. In an era where fluoride-based toothpaste made by multinationals were ruling the market, Vicco launched Vajradanti, a herbal toothpaste. The brand was an instant hit. Shortly, Vicco came up with its new product Vicco Turmeric skin cream, the herbal cosmetic. Vicco Vajradanti and Vicco Turmeric are in great demand in India and abroad.

10. Patanjali Ayurved

Five years ago, consumers would have baulked at the idea of an Indian company becoming global super-brand. Nobody could imagine a 'Made In Bharat' tag. Patanjali Ayurved changed this rapidly. Founded by dynamic Yoga guru Baba Ramdev, today Patanjali is a household name in India and abroad. Patanjali has taken Ayurveda to a whole new dimension. Modern consumer products such as instant noodles, jams and jellies, biscuits and cosmetics are made in conformity to traditions of Ayurveda.

11. Nagarjuna Herbal Concentrates

NHCL manufactures proprietary Ayurveda based medicines and over the counter (OTC) Ayurveda and herbal products. The product portfolio consists of more than 570 products providing head to heel healthcare and wellness solutions. Nagarjuna R&D has developed specialities medicines for the cure and better management of the core group of diseases.

12. SriSri Ayurveda

The newest entrant in Ayurveda based medicines and beauty treatment is Sri Sri Ayurveda. The company was founded by Art of Living Foundation of spiritual leader, Sri Sri Ravishankar. SriSri Ayurveda products are highly demanded worldwide. So, these are the topmost Ayurvedic companies in India.

Plant Based Institutions in India

- Indian Agricultural Research Institute (IARI), New Delhi
- National Dairy Research Institute, Karnal, Haryana
- National Bureau of Plant Genetic Resources (NBPGR), New Delhi
- Forest Research Institute (FRI), Dehradun, Uttarakhand
- Institute of Forest Genetics and Tree Breeding, Coimbatore, Tamil Nadu
- Tropical Forest Research Institute, Jabalpur, Madhya Pradesh
- Central Soil Salinity Research Institute, Karnal, Haryana
- Indian Veterinary Research Institute (VRI), Bareilly, Uttar Pradesh
- Central Institute of Post Harvest Engineering & Technology, Ludhiana, Punjab
- Central Marine Fisheries Research Institute, Kochi, Kerala
- Central Institute of Fisheries Technology, Kochi, Kerala
- Central Institute of Freshwater Aquaculture, Bhubaneswar, Odisha
- Dr. B.V Rao Institute of Poultry Management and Technology, Pune, Maharashtra
- Kerala University of Fisheries and Ocean Studies (KUFOS), Panagadh, Kerala
- Central Avian Research Institute, Bareilly, Uttar Pradesh

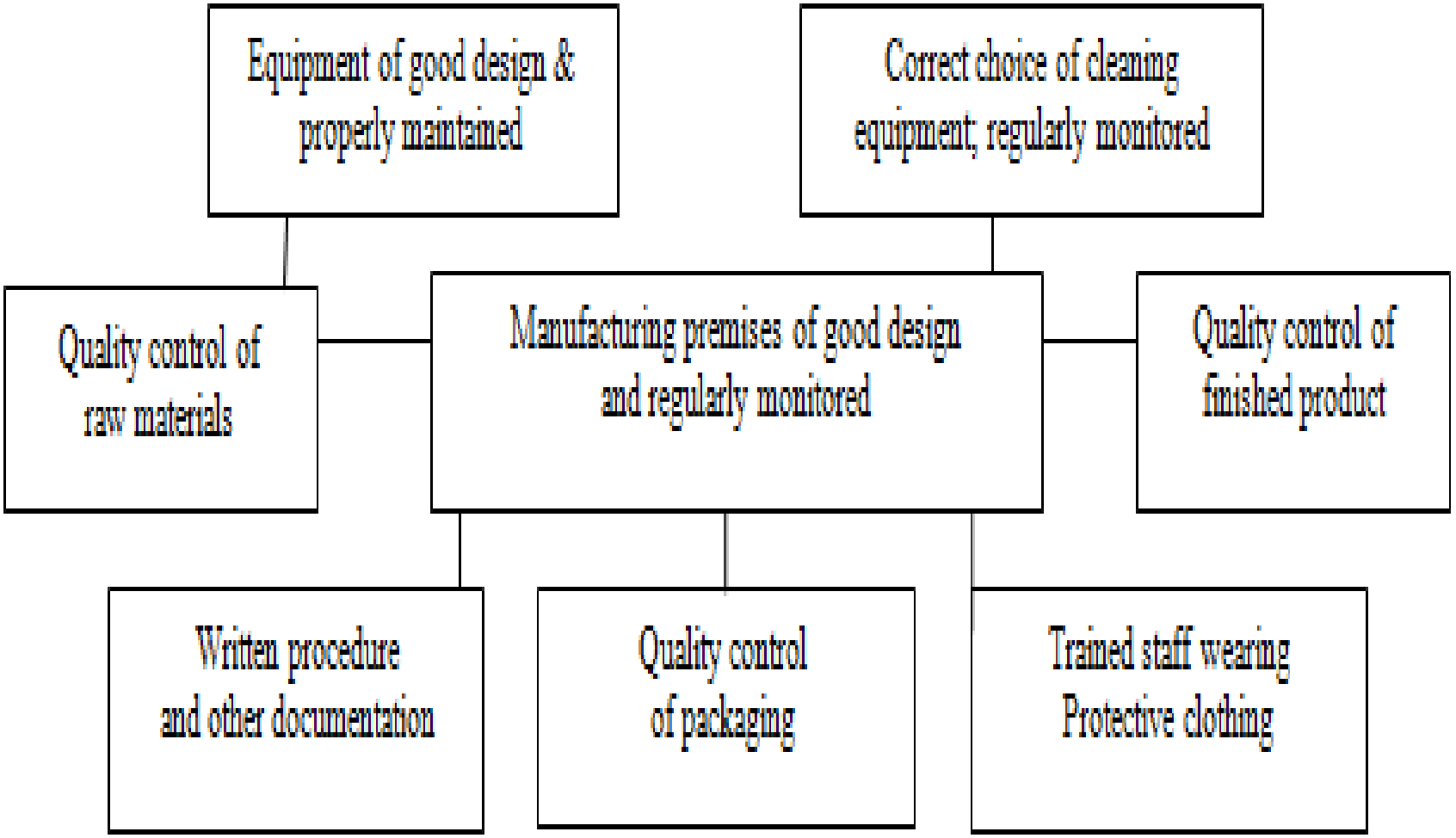
- Directorate of Sorghum Research, Hyderabad, Andhra Pradesh
- Central Arid Zone Research Institute, Jodhpur, Rajasthan
- Central Potato Research Institute, Shimla, Himachal Pradesh
- Central Plantation Crops Research Institute, Krishnapuram, Kerala
- Indian Institute of Crop Processing Technology, Thanjavur, Tamil Nadu
- Indian Institute of Vegetable Research, Varanasi, Uttar Pradesh
- Central Sheep and Wool Research Institute, Avikanagar, Rajasthan
- Indian Institute of Horticultural Research, Bangalore,
- National Research Centre on Meat, Boddupal, Hyderabad
- Directorate of Cashew Research, Puttur, Karnataka Lucknow, Uttar Pradesh
- Central Institute for Cotton Research, Nagpur, Maharashtra
- Central Institute for Research on Cotton Technology (CIRCOT), Mumbai, Maharashtra
- A National Research Center on Plant Biotechnology, Pusa Campus, New Delhi
- Tamil Nadu Veterinary and Animal Sciences University, Chennai, Tamil Nadu
- National Institute of Veterinary Epidemiology and Disease (NIVEDI. Bengaluru Karnataka
- Indian Institute of Soil Science, (IISS), Bhopal, Madhya Pradesh
- Department of Zoology, University of Delhi, Delhi
- University of Agricultural Sciences, Bellary Road, Bangalore
- Sugarcane Breeding Institute, ICAR, Coimbatore, Tamil Nadu
- National Institute of Plant Genome Research (NIPGR), New Delhi

B.
Schedule T- Good Manufacturing Practice of Indian Systems of Medicine

Schedule T

- Herbal drugs are regulated under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945 in India, where regulatory provisions for Ayurveda, Unani, Siddha medicine are clearly laid down.
- Department of AYUSH is the regulatory authority and mandate that any manufacture or marketing of herbal drugs have to be done after obtaining manufacturing license, as applicable.
- Schedule "T" of the act lays down the good manufacturing practice (GMP) requirements to be followed for the manufacture of herbal medicines.

Components of GMP



The Objective of 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.

PART-I
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 or any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust or smoke.

1.1(B) Buildings- The building 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.

(iv) Provided with proper drainage system in the processing area.

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) **Disposal of Waste-** From the manufacturing sections and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off after suitable treatment as per guidelines of pollution control authorities to render them harmless.

1.1(E) **Containers' Cleaning-** In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate arrangement 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(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 are 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.

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

(i) Adequate facilities for first aid;

(ii) Medical examination of workers at the time of employment and periodical checkup thereafter by a physician once a year, with particular attention being devoted to freedom from infections.

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 team 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 machinery and equipments and machinery recommended is indicated in Part II-A.

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 and 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).

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.

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.

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 Ayurveda, Siddha and Unani pharmacopoeial standard. 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.

The quality control section shall have the following facilities:

(a) There should be 150 sq feet area for quality control section.

(b) For identification of raw drugs, reference books and reference samples should be maintained.

(c) Manufacturing record should be maintained for the various processes.

(d) To verify the finished products, controlled samples of finished products of each batch will be kept till the expiry date of product.

(e) To supervise and monitor adequacy of conditions under which raw materials, semi finished products and finished products are stored.

(f) Keep record in establishing shelf life and storage requirements for the drugs.

(g) Manufacturers who are manufacturing patent proprietary Ayurveda, Siddha and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.

(h) 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.

(i) 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.

(j) All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.

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. 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.

(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. 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.

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

S. No.	Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
		1200 Square feet covered area with separate cabins or partitions for each activity. If Unani medicines	
1.	Anjana/Pisti	100 sq. feet.	Kharal/mechanized/ motorized Kharal, 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/LavanaBhasma Satva/Sindura Karpu/ Uppu / Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/ Patila, Flask, Multani Matti/Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Mufflefurnace(Electrically operated), End/Edge Runner, Exhaust Fan, Wooden/ S.S.Spatula.
5.	Kajal	100 sq. feet	Earthen 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 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.
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 plusDistillation 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/Kam 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
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

S. 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 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 steel trays/ container for storage and sugar coating, polishing
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 50-100 kgs. 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, furnace boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc.	200 sq. ft	