SHREE H. N. SHUKLA INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH

B.PHARM

(SEMESTER –VI)

SUBJECT NAME:HERBAL DRUG TECHNOLOGY

SUBJECT CODE: BP603TP

UNIT 5 : GENERAL INTRODUCTION TO HERBAL INDUSTRY

UNIT-V 11 Hours

Content

- Herbal General Introduction to Herbal Industry
- Drugs industry: Present scope and future prospects.
- A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.
- Schedule T – GoodManufacturing Practice of Indian systems of medicine
- Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.

GENERAL INTRODUCTION TO HERBAL INDUSTRY

PRESENT SCOPE OF HERBAL DRUG INDUSTRY:

- Herbs have been known since the era of civilization and are highly esteemed all over the world as a rich source of medicinal agent.
- The popularity of natural products is increasing day by day due to the fact that they are comparatively safe, less toxic, less side effects, easily available and affordable prices when compared to synthetic drugs.
- The herbal drug industry is a very fast growing sector in the international market. In India, various system of medicine like Ayurveda, Siddha, Unani, Homeopathy, Yoga, & Naturopathy are being utilized for the health care of people.

SCOPE OF HERBAL DRUG MEDICINE AND INDUSTRY:

Indian Herbal Market:

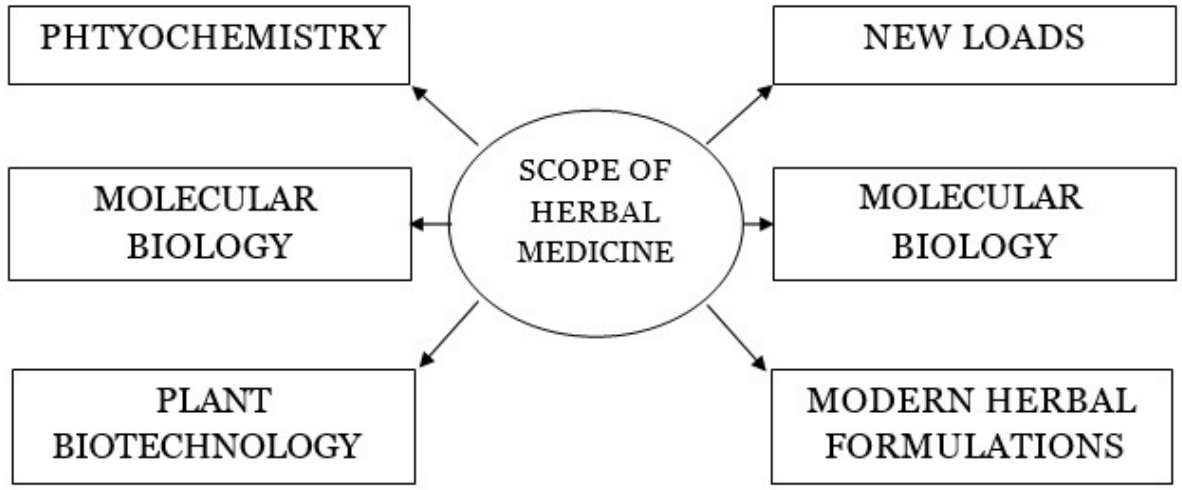
- Herbal drugs constitute a major share of all the officially recognized system of health in India viz. like Ayurveda, Siddha, Unani, Homeopathy, Yoga, & Naturopathy, expect Allopathy
- More than 70% of India's 1.1 billion populations still use these non-allopathic systems of medicine. Currently, there is no separate category of herbal drugs or dietary supplements, as per the Indian Drugs Act.
- In India, raw drugs obtained from around 2,400 plant species. It is the fastest growing market & may attain to 14,500 crore & export to 9000 crore with a CAGR (Compound Annual Growth Rate) of 20% to 25% respectively, according to associated chambers of Commerce & Industry of India (Assocham)
- The "Herbal Industry Biz" has revealed that currently, the Indian herbal market size is estimated at 7000 crores & over 3600 crores of herbal raw materials & medicine are exported by India.
- In India, there are about 8000 medicinal plants are used. Out of which 25 manufacturers are large scale manufacturers. The annual turnover in India was around US $ 300 million for Ayurvedic& US $ 27.7 million for Unani medicine.

INTERNATIONAL SCOPE OF HERBAL MEDICINES:

- According to the World Health Organization (WHO), approximately 25 per cent of modern drugs used in the United States have been derived from plants

- More than 120 active compounds isolated from higher plants are widely used in modern allopathic medicines today and 80% of them show a positive co-relation between their modern therapeutic use and the traditional use of the plants from which they are derived.
- At least 7000 medicinal compounds derived plants, the ingredients of herbal medicine are included in the modern pharmacopeia of drugs.
- WHO estimates that 80 per cent of the world's population currently use herbal medicines for some aspects of primary health care
- They are also highly lucrative in the international market, generating billions of dollars in revenue.
- To cite few examples, annual revenue from herbal medicines and herbal products in Western Europe reached US $ 5 billion in 2003-2004 In china, sales of herbal products totaled US $ 14 billion in 2005
- Herbal medicine revenue in Brazil was USS 160 million in 2007.

FUTURE PROSPECTS OF HERBAL MEDICINE/INDUSTRY:



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. The following leads and development are the future prospects in the herbal drug industry.

- Plant products can also be useful as starting material for the semi synthetic preparation of other drugs. Examples: Plant steroids (Diosgenin): Oral contraceptives, hormones. Microorganisms (Streptomyces genus): Antibiotics (Streptomycin,

neomycin, tetracycline, chloramphenicol) The interest in natural products as a source of new biologically active compounds has expanded due to increasing research and development in phytochemistry.

SOURCE OF DATA:

As Per Association Chamber of Commerce & Industry (ASSOCHAM)

- It has been estimated that 56% of the lead compounds for medicine in British National Formulary are natural products or are derived from them
- With the development in the techniques of molecular biology, there has been an increase of interest in the use of naturally occurring proteins as potential therapeutic agents.
- Several genetically engineered natural products have had a significant impact and more than 20 biotechnology derived products are now in the market

  Example: tissue plasminogen activator is used as a thrombolytic after myocardial infractions Erythropoietin is used to treat anaemia associated with renal failure
- Several colony stimulating factors are used for cancer treatment.

Natural products will continue to be important in the following three areas drug discovery

- As target for production by biotechnology
- As a source of new lead compounds of novel chemical structure
- As the active ingredients for useful treatments derived from traditional system of Medicine.

In the face of the increasing use and fast growing market of herbal medicines and other herbal healthcare products, in both developing and developed countries of the world, policy-makers, health professionals and the public are increasingly expressing concerns about the safety, efficacy, quality, availability, preservation, and further development problem of these herbal products. Public demand has also grown for evidence on the safety, efficacy and quality of the herbal products and traditional medicine (TM) and complimentary alternative medicine (CAM) practices.

However, in order to ensure quality and safety of herbal medicines, their production, sale and use should be officially and legally controlled by established rules and regulations so that herbal medicinal can be used safety for medical and therapeutic purposes and efforts

should be made to raise public awareness about the risks and benefits of using herbal medicines.

Overview on

Plant Based Industries and Research Institutions in India List of research institutions and centers in India

- Government of India also has expressed support and encouragement for the Traditional Indian Medicine (TIM).
- A Separate department for Indian System of Medicine and Homeopathy now known as AYUSH (Ayurveda, Yoga, Unani, Siddha, Homeopathy) was established in March 1995 to promote indigenous systems.
- Priority includes education standardization of drugs, enhancement of availability of raw materials, research and development, information, communication and larger involvement in the national system of delivering heath care
- In the year 1969, the Indian government established a central council for research in Indian medicine and Homeopathy (CCRIMH) to develop scientific research in different systems of medicine.
- As the research in herbal products expanded various government and private research centers developed which are actively engaged in the research and development of herbal medicines.

The following are the list of few research institutions engaged in research in medicinal and aromatic plants in India

Herbal research institutions/ Centers in India

Name of Institute	City
CCRAS (Central Council for Research in Ayurvedic and Siddha)	New Delhi
RRL (Regional Research Laboratory) (CSIR)	Jammu-Tawi
NBRI (National Botanical Research Institute)(CSIR)	Lucknow
Gujarat Ayurveda University	Jamnagar
Bhavan's SPARC	Mumbai
National Institute of Ayurveda	Jaipur
Arya Vaidya Shala	Kottakal
Interdisciplinary School of Health Sciences	Pune
Banaras Hindu University	Vanarasi
CIMAP (Central Institute for Medicinal and Aromatic Plants)	Lucknow
ICMR (Indian Council for Medical Research)	New Delhi
National Medicinal Plants Board	New Delhi
Regional Medical Research Centre (ICMR)	Belgaum
PERD Centre (Pharmaceutical Education and Research Development)	Ahmedabad
CCRUM (Central Council of Research in Unani Medicine)	New Delhi
NISCOM (National Institute of Science Communication)	New Delhi
IMPCOPS (Indian Medical Practitoners Co-operative Pharmacy & stores Ltd.)	Chennai
IHMMR (Indian Institute of History of Medicine and Medical Research)	New Delhi
Zandu Foundation	Mumbai
CDRI (Central Drug Research Institute) (CSIR)	Lucknow
IMPLANT Centre (Inter-University Medicinal Plant Laboratory for Analysis, Nurture and Therapeutics)	Rajkot

LIST OF FEW HERBAL DRUG INDUSTRIES IN INDIA

NAME	CITY
Ansar Drugs Laboratories	Surat (Gujarat)
Acis Laboratories	Kanpur (UP)
Allen Laboratories Pvt. Ltd.	Kolkata
Basic Ayurveda	Ghaziabad
Dabur India Ltd.	Ghaziabad
Herbals (APS) Pvt. Ltd.	Patna
Herbo-Med (Pvt. Ltd.)	Kolkata
The Himalaya Drug Co.	Mumbai
Shipachem	Indore
Hamdard (Wakf) Laboratories	Delhi
Zandu Pharmaceutical works Ltd.	Mumbai
ShhriBaidyanathAyurvedBhavan	Patna
Charak Pharmaceuticals	Mumbai
Biocon India Pvt. Ltd.	Bengaluru
Cipla Research Centre & Factory	Bengaluru
Government Quinine Factory	Mungpoo
Vicco Laboratories	Nagpur
Nagarjuna Herbal Concentrates	Kerala
Shree Dhootapapeshwar Ltd.	Mumbai
Sandu Pharmaceuticals Ltd.	Goa
PatanjaliAyurved	Uttarkhand
Sri Sri Ayurveda	Bengalore

SCHEDULE T – GOOD MANUFACTURING PRACTICE OF INDIAN SYSTEMS OF MEDICINE

COMPONENTS OF GMP (SCHEDULE - T) AND IT'S OBJECTIVES:

GMP:

- Good Manufacturing Practice (GMP) is a production and testing practice that helps to ensure a quality product.
- GMP guidelines are not prescriptive instructions on how to manufacture products.
- These are a series of general principles that must be observed during manufacturing.
- When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements.
- It is the company's responsibility to determine the most effective and efficient quality process.

OBJECTIVES:

The Good Manufacturing Practices for ASU Drugs as described in Rule 157 of Drugs & Cosmetics Rules1945 with conditions as specified in Schedule T/GMP are to ensure that: Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination

- The manufacturing process is as has been prescribed to maintain the standards Adequate quality control measures are adopted
- The manufactured drug which is released for sale is of acceptable quality
- 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 Practice (GMP)

BASIC PRINCIPLES OF GMP:

Many countries have created their own GMP guidelines & procedure. These GMP guidelines remain more or less similar to the ultimate goals of safeguarding the health of the patient as well as producing good quality medicine.

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language.
- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language.

SCHEDULE T:

Requirements (GMP) of factory premises forAyurvedic, Siddha, Unai drugs For getting a certificate of "Good Manufacturing Practices" of Ayurveda, Siddha-Unani drugs, the applicant shall made application on plain paper, providing the information on existing infrastructure of manufacturing unit, and the licensing authority shall after verification of the requirement as per Schedule "T" issue the certificate within a period of 3 months in form of 26-E.

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

COMPONENTS OF GMP:

GMP schedule for ISM manufacturing units is quite elaborate and broadly covers each and every component of manufacturing process. Different components of GMP are given below in order of appearance in Schedule – T.

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II.

PART-I

Factory Premises:

The manufacturing plant should have adequate space for:

• Receiving and storing raw material

• Manufacturing process areas

• Quality control section

• Finished goods store

• Office

• Rejected goods/drugs store.

GENERAL REQUIREMENTS:

Factory Premises:

I. Location and surroundings

II. Buildings

III. Water Supply

IV. Disposal of Waste

V. Containers Cleaning

VI. Stores (Raw materials, packing materials, Finished goods stores)

VII. Working Space

VIII. Health, Clothing, Sanitation and Hygiene of Workers

IX. Medical Services

X. Machinery and Equipment

XI. Batch Manufacturing Records

XII. Distribution records

XIII. Record of Market Complaints

XIV. Quality control

REQUIREMENTS FOR STERILE PRODUCT:

A. Manufacturing area

B. Precautions against contaminations and mix

FACTORY PREMISES:

Location and surroundings:

Location and surroundings of the pharmacy should be situated where there is:

➢No open sewage

➢No drainage coming from public areas & pubic lavatory

➢No factory fume

➢No excessive soot and smoke and dust

Buildings:

➢Hygienic conditioned.

➢No cobwebs/insects/rodents.

➢Adequate light & ventilation.

➢No dampness or Moisture on floor and walls.

➢Wall & floors should be even.

➢Premises used for manufacturing, processing, packaging and labeling should be in conformity with the provisions of Factory Act.

➢Compatible with manufacturing Operations.

➢Adequate working space.

➢ Logical placement of equipment to avoid risk of mixing, cross contamination and risk of omission of a control step. Designed, constructed and maintained well to prevent entry of insects/rodents.

➢ Interior surface should be smooth, easy for cleaning and disinfection.

➢ Mooring should be smooth and even so as not to permit retention or accumulation of dust or waste products.

Water Supply:

The water used in manufacturing should be pure and of potable quality. Adequate supply of water is required for washing the premises and containers.

Disposal of Waste:

In the manufacturing section and laboratories the waste water and residues which might the prejudicial to the work as well as public health shall be disposed of after suitable treatment as per guideline of pollution control to be followed.

Containers Cleaning:

In factories where operation involving the use of containers such as glass bottles, vials and jars are conducted. Adequate arrangement for washing, cleaning & drying of containers.

Stores:

It should provide adequate space for stores of different type of material such as raw material, packing material and finished products. Store should have proper ventilation and should be free from dampness.

Raw Materials:

• Raw material store should have appropriate containers which would protect the quality of raw materials and prevent from contamination or rodents and Insect infestation.

• Suitable cabins for raw material of

➢Mineral origin

➢Metallic origin

➢Animal origin

➢Fresh herbs

➢Dry herbs or plant parts

➢Excipients, Volatile oils/perfumes and Flavors

➢Plants extracts, Exudates/Resins etc.

• Each container used for raw material storage should 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.

• Label of raw material should clearly indicate Batch No or Lot No, and date at receipt of the consignment.

• All raw materials shall be sampled and got tested either by the in-house quality control technical person or by laboratories approved by the Government and should be used only on approval after verifying.

• Records of the receipt, testing and approval or rejection should be maintained.

Packing Materials: All packing materials such as bottles, Jars, capsules etc. should be stored properly. All Container and Closure lids should be properly cleaned and Dried before packing the products.

Finished Goods Stores:

• The finished goods transferred from the production area after proper packaging should be stored in proper shelves 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 the finished product quality described, then it will be Moved to **Approved Finished Goods Stock** area.

• Only approved finished goods should be dispatched as per marketing requirements.

Distribution records should be maintained as required. Specific storage conditions should be provided for special drugs.

Working Space:

• The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of theoperations.

• Facilities for easy and safe working, facilities to minimize or eliminate mixing up of the drugs should be provided. To prevent cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

Health, Clothing, Sanitation and Hygiene of Workers:

• Workers should be free from contagious diseases.
• Workers should use proper uniform suitable to work.
• Hands should be covered with cloth or synthetic covering.
• Personal cleanliness, clean towel, soap, scrubbing brushes, separate lavatories for men and women and facility for changing of clothes and cupboards to keep clothes/belongings should be maintained.

Medical Services:

▪ Annual medical check-up of all employees should be done to ensure freedom from Infectious diseases.
▪ First-Aid facility should be available.
▪ Health record of all the employees should be maintained.

Machinery and Equipment:

• Equipment should be according to the size of operation, nature of product manufactured.
• Suitable Machinery manually operated; semi- automatic or automatic should beavailable in the manufacturing unit.
• 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 ease in movement of workers and orderliness in operations a suitably adequate space will be ensured between two machines or rows of machines.
• These Equipment have to be properly installed and maintained with proper cleaning.
• Proper standard operational procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

Batch Manufacturing Records:

• Ayurvedic, Siddha, Unani drug manufacturer should maintain batch manufacturing record of every manufacturing.
• List of raw materials used, Quantity obtained from the store, tests conducted during the various stages of manufacture like taste, color, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurvedic, Siddha and Unnai.

• 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.

• Details of transfer of manufactured drug to the finished product store along with record of the finished product, packaging etc. should be maintained.

• All manufacturing records should be duly signed by Production and Quality Control Personnel respectively.

• It should be essential to maintain the record of date, manpower, machine, equipment used along with in process record of various shodhana (purificatory procedures of poisonous drugs), Bhavana (trituration) in terms of internal use.

Distribution Records:

Records of sale and distribution of each batch of Ayurveda, Siddha and Unani Drugs should be maintained in order to facilitate prompt and complete recall of the batch, if necessary.

Record of Market Complaints:

• Manufacturers should maintain a register to record of the complaints as well as corrective action initiated to prevent recurrence regarding the products.

• Once in a period of six months, the complaint records have to be sent to the licensing authority.

• Register should be available for inspection during any inspection of the premises.

• Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha, Unani drugs should be maintained in separate register.

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 pharmacopoeia standard.

• There should be 150 sq. feet area for quality control section.

• For identification of raw drugs, reference books and reference samples should be maintained. Manufacturing record should be maintained for the various processes. To verify the finished products, controlled samples of finished products of each batch will be kept for 3 years.

• To supervise and monitor adequacy of conditions under which raw materials, semifinished products and finished products are stored.

• Keep record in establishing shelf life and storage requirements for the drugs.

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

• The record of specific method and procedure of preparation, that is, Bhavana, Mardana and Puta (earthen pits) and the record of every process carried out by themanufacturer shall be maintained.

• 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.

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

• Quality control section will have a minimum at 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.

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

REQUIREMENT OF STERILE PRODUCT

Manufacturing Areas:

Manufacturing area for the production of sterile of Ayurvedic, Siddha, Unani product, separate enclosed area should be provided. This area should be aseptic, dust-free, moisture less and should have bacteria free air supply.

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.

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 same premises an additional area of 400 sq. feet will be required.			
1	Anjana/Pisti	100 sq. feet	Kharal/mechanized/motorizedKharal, End runner/Ball–mill,Sieves/Shifter.
2	Churna/Nasya/Manjan/Lepa/KwathChur	200 sq. feet	Grinder/Disintegrator/Pulveriser/Powdermixer/Sieves/Shifter.

3	Pills/Vati/ GutikaMatirai 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 andsugar coating, polishing pan in case of sugar-coated tablets, mechanized chattoo (formixingguggulu)
4	Kupipakava / Ksara/ Parpati/ LavanaBhasmaSatva/SinduraKarpu/ Uppu/ Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/ Patila, Flask, MultaniMatti/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 /MarhamPasai	100 sq. 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/Lakaya	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 /PravahiKwathManapaku	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 MalhamPanir/KarnBindu/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

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.

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	ItrifalTirya/majoon/ Laooq/JawarishKhamiras	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. storagetank,Boiling Vessel, Gravity filter, Bottle filling machine, Bottle washingmachine, 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, SilBatta, 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 fillingmachine, hot airoven 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. Thiswill have proper ventilation, removal of smoke, prevention offlies, insets, dustetc	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	Microscopic 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 microscope
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	Magneticstirrer		

How

	toDownlo
13	Hot air oven
14	Refrigerator
15	Glass/Steel Distillation Apparatus
16	LPG Gas Cylinders with Burners
17	Water Bath (Temperature controller)
18	Heating Mantles/Hot plates
19	TLC Apparatus with all accessories (Manual)
20	Paper chromatography apparatus with accessories
21	Sieve size 10 to 120 with sieve shaker
22	Centrifuge Machine
23	Dehumidifier
24	pH Meter
25	Limit Test Apparatus