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REVIEW ARTICLE

Establishment of an Herbal Industry in India

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ABSTRACT

Indian herbal market is one of the fastest growing market and may attain to 14500 crore by 2012. The herbal industry biz potential has revealed that currently the indian herbal market size is estimated at Rs. 7000 crore and over Rs. 3600 crore of herbal raw materials and medicines are exported by india. The herbal products become very popular now a days and found more application in medicinal treatment across the world. This review article focuses on current status of indian herbal industry. It also provides an insight on regulation of herbal industry in india.

Key Words: Herbal raw materials and mediciens

INTRODUCTION

India has the world's oldest as well as largest tradition of systems of medicine. The Indian Systems of Medicine includes the systems originated in India as well as outside but got adopted in India in course of time. The various systems are Ayurveda, Siddha, Unani, Homoeopathy, Yoga, and Naturopathy. They have become a vital part of the culture and traditions of India. Indian traditional knowledge on herbal medicine and vast plant biodiversity has a great potential in this sector.

The codified Indian system of medicine puts to use raw drugs obtained from around 2,400 plant species. The number of raw drugs in trade is still less i.e. 1289 botanicals obtained from 960 plant taxa. The highest proportion of the traded medicinal plant species is used under the Ayurvedic system[1].

Herbal Market

Indian herbal market is one of the fastest growing market and may attain to Rs.14,500 crore (Rs 145,000 million) by 2012 and exports to Rs.9,000 crore (Rs 90,000 million) with a CAGR of 20% and 25% respectively, according to findings of the Associated Chambers of Commerce and Industry of India (Assocham).

The 'Herbal Industry Biz Potential' has revealed that currently, the Indian herbal market size is estimated at Rs.7000 crore (Rs 70000 mn) and over Rs.3600 crore (Rs 36000 mn) of herbal raw materials and medicines are exported by India. The reasons cited for the unexpected growth comprises setting up of Herbal farm clusters by the government for improving quality of drugs and promotion of exports, doubling the cultivation of medicinal plants by converting existing farmland, continuous focus for R&D on product and process development and effective marketing of herbal products, the study said.

Indian Herbal Industry:

As per study commissioned by the Associated Chamber of Commerce and Industry (ASSOCHAM), the herbal products become very popular now a days and found more application in medicinal treatment across the world [2].

The study also revealed that Indian herbal products are more popular among the Indian Diaspora; however, a need is being felt to make them popular among the locals in foreign lands.

Markets	Present Demand	Projected Demand (for 2015)
Europe	US$ 35 Billion	US$ 70 Billion
North America	US$ 6.5 Billion	US$ 25 Billion

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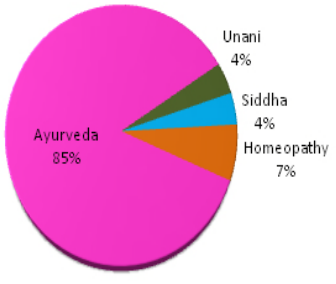
China	US$ 4.0 Billion	US$ 12 Billion
India	US$ 1.5 Billion	US$ 3 Billion
Others	US$ 13 Billion	US$ 30 Billion
Total	US$ 60 Billion	US$ 140 Billion

The recent surge in use of herbal medicines has led to a huge requirement of raw materials by the industry. The turnover of AYUSH industry is estimated to be more than Rs 8800 crore. The domestic market of Indian systems of medicine & Homoeopathy (ISM&H) is of the order of Rs 4000 Crore with a total consumption of all botanicals to a figure of 177000 MT, which is expanding day by day. The total annual turnover of the Ayurvedic drug manufacturing industry is estimated to be around Rs.3, 500 Crore. Besides this, there is also a growing demand for natural products including items of medicinal value/pharmaceuticals, food supplements and cosmetics in both domestic and international markets. India with its diversified biodiversity has a tremendous potential and advantage in this emerging area.

Manufacturing Units

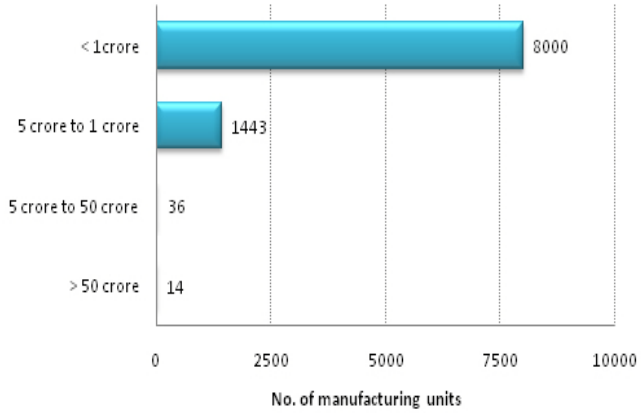
The increased demand of herbal medicines has led to a sudden increase in herbal manufacturing units. There is a complex of large number of manufacturing units using herbal material for various purposes. Whereas the largest number of such manufacturing units are registered as 'pharmaceuticals', there are others that are engaged in making plant based cosmetics and food supplements. Even within the pharmaceutical units, there are manufacturers of Ayurveda, Siddha, Unani and Homeopathic formulations (**Fig 1**) with a few even making western medicines. Another group of manufacturing units is engaged in making extracts and distilling oils for use by other industries and for exports. Raw materials for all these diverse industries are largely derived from wild sources. These manufacturing units:

Fig 1: Proportion of manufacturing units of different systems



***Source**: Dept of Ayush (data as on 01/04/07*)

Fig 2: **Herbal manufacturing units**



***Source**: Demand & supply, NMPB 2008*

There are total of 9,493 manufacturing units, of which mostly are small scale units (8,000) having an annual turnover of less than one Crore. Some of the well known industrial houses with annual turnover of more than 50 Crores are Dabur, Zandu, Himalaya, Shree Baidyanath, Arya Vaidya Shala etc. Though the number of manufacturing units with higher turnover is less, still they are the ones which consume about 35 % of the total raw material used [3].

Establishment of herbal industry:

Regulations

Health authorities and governments of various nations have taken an active interest in providing standardized botanical medications. Government of India has also plunged into this opportunity and initiated some regulations in this sector.

To ensure and enhance the quality of ASU medicines, the Government of India has notified Good Manufacturing Practices (GMP) under Schedule 'T' of the Drugs and Cosmetics Act 1940 which also ensures raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination. The guidelines for Good Agricultural Practices (GAP) seek to lay down a cultivation programme designed to ensure optimal yield in terms of both quality and quantity of any crop intended for health purposes. Quality of raw material being watched over by following GAP and GACP, for manufacturing and marketing the prepared drugs, government has formulated the Drugs and cosmetics act, 1940. It is an act to regulate the

import, manufacture, distribution and sale of drugs and cosmetics. This act was basically initiated for chemical drugs but later in the year 1969 a separate chapter relating to Ayurveda, Siddha and Unani drugs was inserted by act 13 of 1964. Laws are partly same as those for conventional pharmaceuticals. Later on this was again modified with some substitutions in the year 1983, 1987, 1994 and 2002[4]. The schedules and rules pertaining to Ayurveda, Siddha and Unani systems in the act are:

Schedules:

- First Schedule substituted by act 13 of 1964 came into force w.e.f 1-2-1969. The schedule lists the standard Indian pharmacopoeias to be followed for manufacturing Ayurveda, Siddha and Unani drugs. About 57 books of Ayurveda (with insertions in 1987, 1994, 2002), 29 of Siddha (1987), 13 of Unani Tibb system are listed.
- Second Schedule came into force w.e.f 15.09-64. It states about the standard to be complied for manufacturing drugs. (Subs. by Notifn. No. G.S.R. 885, dated the 4th August, 1973, Gazette of India, Pt. II, s. 3(i), p. 1643.)
- SCHEDULE-E(1) : List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine (Added by Notfn. No. 1-23/67-D dt. 2-2-1970) differentiated into vegetable, animal and mineral origin.
- SCHEDULE T: Good Manufacturing Practices (GMP) for ayurvedic, siddha and unani medicines. (Ins by G.S.R. 561 (E) dt 23-06-2000 and subs. by G.S.R. 198(E), dt. 7.3.2003.). Under Schedule "T" of the drugs and cosmetics act 1940, the government has made it mandatory for all manufacturing units to adhere to GMP.

Rules:

- Rules: Part XVI (Parts XVI, XVII and XVII added by S.O. 642, dt. the 2-2-1970 (w.e.f. 21.2.1970) Manufacture for sale of ayurvedic (including siddha) or unani drugs. It notifies about how to acquire license, loan for establishing a unit and also on the identification of raw materials and its purity.
- Part XVIA: Approval of institutions for carrying out tests on ayurvedic, siddha and unani drugs and raw materials used in their manufacture on behalf of licensees for manufacture for sale of ayurvedic, siddha and unani drugs (Ins. by G.S.R. 701(E), dt. 27-7-2001 and subs. by G.S.R.73 (E), dt. 31-01-2003.)
- Part XVII: Labelling, packing and limit of alcohol in ayurvedic (including siddha) or unani drugs. (Subs. by G.S.R. 904(E), dt. 2.11.1992.)
- PART XVIII: Government analysts and inspectors for ayurvedic (including siddha) or unani drugs.
- PART XIX: Standards of ayurvedic, siddha and unani drugs (Ins. by G.S.R. 519(E), dt. 26.6.1995.)

PART XVI—MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS [5].

1. If Ayurvedic drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.
2. An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic drugs shall be made in Form 24-D to the Licensing Authority along with a fee of rupees sixty. Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry: Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees thirty.
3. A fee of rupees fifteen shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.
4. Loan Licence- An application for the grant of renewal of a loan licence to manufacture for sale of any Ayurvedic drugs shall be made in Form 25-E to the Licensing Authority along with a fee of rupees thirty.
5. Explanation—For the purpose of this rule, a loan licence means a licence which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licence in Form 25-D: Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one

month of such expiry: Provided further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case the fee payable for renewal of such licence shall be rupees thirty plus an additional fee of rupees fifteen.

6. A fee of rupees seven and paisa fifty shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.
7. A licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25-D. The licence shall be issued within a period of three months from the date of receipt of the application.
8. A loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25E.
9. The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.
10. Certificate of renewal—the certificate of renewal of a licence in Form 25-D shall be issued in Form 26-D.
11. Certificate of renewal of a loan licence.—the certificate of renewal of a loan licence in Form 25-E shall be issued in Form 26-E[6].
12. Duration of licence—An original licence in Form 25-D or a renewed in Form 26-D, unless sooner suspended or cancelled shall be valid up to the 31st December of the year following the year in which it is granted or renewed. Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry after payment of the additional fee of rupees thirty, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.
13. Duration of loan licence—An original loan licence in Form 25-E or a renewed loan licence in Form 26-E, unless sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed. Provided that if the application for the renewal of a loan licence is made in accordance with rule 153-A, the loan licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if the application for its renewal is not made within three months of its expiry.
14. Conditions for the grant or renewal of a licence in Form 25-D—Before a licence in Form 25-D is granted or renewed in Form 26-D the following conditions shall be compiled with by the applicant, namely: —

(1) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T. [A 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 the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule 'T' issue the certificate within a period of 3 months in form 26-E-I].

(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent tec hnical staff consisting at least one person, who is a whole time employee and who possesses the following qualifications, namely—

(3) The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture if Siddha drugs and Unani drugs shall have qualification in Siddha or Unani, as the case may be.

15. Conditions of licence.—a licence in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely—

(a) The licensee shall maintain proper records of the details of manufacture and

of the tests, if any, carried out by him, or by any other person on his behalf, of the raw material and finished products.

(b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, to take samples of the raw material as well as finished products, and to inspect the records maintained under these rules.

(c) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.

16. Conditions of loan licence.—a licence in Form 25-E shall be subject to the conditions stated therein and to the following conditions, namely—

(a) The licence in Form 25-E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

(b) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other person on his behalf, of the raw materials and finished products.

(c) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the Rules have been observed.

(d) The licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed.

17. Cancellation and suspension of licences—

(1) The Licensing Authority may, after giving an opportunity to show cause within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act and the Rules made there under.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

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Annexure I

FORM 24-D[7]

Application for the grant / renewal of a licence to manufacture for sale of Ayurvedic drugs

1. I / We …….. of ……..hereby apply for the grant / renewal of a licence to manufacture Ayurvedic drugs on the premises situated at…….
2. Names of drugs to be manufactured (with details)
3. Names, qualification and experience of technical staff employed for manufacture and testing of Ayurvedic drugs ……..
4. A fee of rupees……..has been credited to the Government under the head of account…….and the relevant Treasury Challan is enclosed herewith.

Date…… *Signature*……..
(Applicant)

NOTE—The application should be accompanied by a Plan of the premises.

FORM 24-E [8]

Application for grant or renewal of a loan licence to manufacture or sale Ayurvedic Drugs

I / We*……..of**…….hereby apply for the grant / renewal of a loan licence to manufacture Ayurvedic Drugs……..on the premises situated at……..
C/o ***……..
2. Names of drugs to be manufactured (with details).
3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic (including Siddha) or Unani drugs in the manufacturing premises.
4. I / We enclose,
a) A true copy of a letter from me / us to the manufacture concern whose manufacturing capacity is intended to be utilized by me / us.
b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me / us and that they shall maintain the registers of raw materials and finished products separately in this behalf.
c) Specimen of labels, cartons of the drugs proposed to be manufactured.
A fee of Rs……..has been credited to Government under the head of account…….and the relevant Treasury Challan is enclosed herewith.

Date…… *Signature*……
(Applicant)

* Enter here the name of the proprietor, partners or Managing Director as the case may be.
** . Enter here the name of the applicant firm and the address of the principal place of business.
*** Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the letter operates.

FORM 25-D [9]

Licence to manufacture for sale of Ayurvedic drugs

No. of Licence……..

1…….is / are hereby licensed to manufacture the following Ayurvedic drugs on the premises situated at…….under the direction and
Supervision of the following technical staff: —
a) Technical staff (Name)
b) Names of drugs (each item to be separately specified).
2. The licence shall be in force from……..to……
3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act,1940.

Date…… *Signature*……
Designation……

Conditions of Licence
1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the form with the changed constitution.

FORM 25-E [10]

Loan Licence to manufacture for sale Ayurvedic Drugs

1. Number of Licence…….
2……..of……is hereby granted a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani drugs, on the premises situated at……C/o……under the direction and supervision of the following expert technical staff.
a) Technical staff
b) Names of drugs (each item to be separately specified)
3. The licence shall be in force from…….to……
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue……. *Signature*…….
Designation……..

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
3. This licence shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the form with the changed constitution.

FORM 26-D [11]

Certificate of renewal of licence to manufacture for sale of Ayurvedic drugs

1. Certified that licence No…….granted on the……to Shri/ Messers……..for the manufacture of Ayurvedic/Siddha/Unani drugs at the premises situated at……..has been renewed from…….to…….
2. Name of technical staff…….
3. Names of drugs (each item to be separately specified).]

Date…… *Signature*…….
Designation……

FORM 26-E [12]

Certificate of renewal of loan licence to manufacture for sale of Ayurvedic / Siddha or Unani Drugs

1. Certified that Loan Licence No……..granted on the……to…….for the manufacture of Ayurvedic / Siddha or Unani drugs at the premises situated at……C/o……..has been renewed from…….to…….
2. Name of technical staff……..

Date……. *Signature*……..
Designation……..

FORM 26-E-1

(*Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurveda,*):

Certified that manufacturing unit licensee, namely ……...situated at …… State …….. Licence No. …… comply with the requirements of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetic Rules, 1945.

This certificate is valid for a period of three years.

Dated :…..
Place : ….
Licensing Authority for Ayurveda/Siddha/ Unani Drugs.

Signature ……..
Designation ……..

Annexure-II

PART - I

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

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.N	Category of Medicine	Minimum manufacturing space required.	Machinery/equipment recommended.
(1)	(2)	(3)	(4)
		1200 sq. ft. covered area with separate cabins or partitions for each activity. If Unani medicines are manufactured in same premises an additional area of 400 sq. ft. will be required.	
1.	Anjana/Pisti	100 sq. ft.	Kharal/mechanized/motorized Kharal, End runner/Ball-Mill Sieves/Shifter.
2.	Churna/ Nasya Manjan/ Lepa Kwath Churn	200 sq. ft.	Grinder/Disintegrator/ Pulverisar/Powder mixer/ Sieves/Shifter.
3.	Pills/Vati/ Gutika Matrica and tablets.	100 sq. ft.	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, mechanized chattoo, (for mixing of guggulu) where required.
4.	Kupi pakva/ Ksara/ Parpati/	150 sq. ft.	Bhatti, Karahi/stainless steel vessels/Patila flask, Multani Matti/Plaster of Paris, Copper

	Lavana Bhasma Satva/ Sindura Karpu/ Uppu/ Param		Rod, Earthen container, Gaj Put Bhatti, Muffle furnace (electrically operated) End/ Edge Runner, Exhaust Fan, Wooden/S.S. Spatula.
5.	Kajal	100 sq. ft.	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. ft.	Air conditioner, De-humidifier, hygrometer, thermometer, capsule filling machine and balance.
7.	Ointment/ Marham Pasai	100 sq. ft.	Tube filling machine, Crimping medicine/Ointment mixer, End Runner/Mill (where required), S.S. Storage container, S.S. Patila.
8.	Pak/Avaleh/ Khand/ Modak/ Lakayam	100 sq. ft.	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. ft.	Tinctum press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, Filter press/Gravity filter liquid filling machine, P.P. Copping machine.
10.	Asava/Aristha	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.

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8. Added by G.O.I. Notification No.GSR 376 (E) dtd 20.7.1978.
9. Added under G.O.I. Notification No. 1-23/67-D, dtd 2-2-1970
10. Added by G.O.I. Notification No. GSR 376 (E), dtd 20.7.1978
11. Ins. by G.O.I. Notification No. 1-23/67-D, dtd 2-2-1970.
12. Ins. by G.O.I. Notification No. GSR 376 (E), dtd 20.7.1978