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ISSN: 2278-4772

Ayurpharm Int J Ayur Alli Sci., Vol.2, No.4 (2013) Pages 79 - 85

Review Article

GOOD MANUFACTURING PRACTICES OF AYURVEDIC DRUGS

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Received: 28-02-2013; Revised: 11-04-2013; Accepted: 18-04-2013

Abstract

Ayurvedic medicines have a long therapeutic history and are still serving many of the health needs of a large population of the world. However, the quality control and quality assurance still remains a challenge because of the high variability of chemical components involved. Herbal drugs, as a single drug and in combinations, contain numerous compounds in complex matrices in which no single active constituent is responsible for the overall efficacy. This creates a challenge in establishing quality control standards and standardization of herbal drugs. Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks specially two-cross contamination and mix up (unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine) involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP covers all aspects of production: - from the starting materials, premises and equipment to the training and personal hygiene of staff. GMP is the guidelines which, - governs the production, distribution and supply of the drug. So, if we want blunder growth of Ayurveda in International market then proper emphasis should be given on standardization and quality control of medicines.

Key words: GMP, Quality control, Quality assurance.

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Cite This Article

Poonam. Good Manufacturing Practices of Ayurvedic drugs. Ayurpharm Int J Ayur Alli Sci. 2013;2(4):79-85.

www.ayurpharm.com
ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol.2, No.4 (2013) Pages 79 - 85

INTRODUCTION

The therapy which pacifies the diseases and gives rise to other diseases is not a pure therapy; the pure is the one which pacifies without erupting other problems.[1] So from the ancient period emphasis was given on purity of treatment. But in these days most of the Ayurvedic drugs are not fulfilling the quality standards.

Ayurvedic dosage forms are prepared with ausadha (medicines) which are mainly collected from herbal, mineral or animal resources. In ancient times, Ayurvedic physicians prepared medicines for their patients themselves. Today only a handful of practitioners follow this practice and production of Ayurvedic drugs has gone to business class people. In recent years, there has been a great demand for plant derived products in developed countries. These products are increasingly being sought as medicinal products, nutraceuticals and cosmetics.[2] There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines. Due to lack of infrastructures, skilled manpower reliable methods and stringent regulatory laws most of these manufacturers produce their product on very tentative basis.[3] To get more profit, they adulterated and adopted shortcut methods to prepare classical medicines and thus these medicines become substandard. There are around 8000 licensed Ayurvedic pharmacies and the approximate turnover of this industry is Rs. 4500 crores, which accounts for nearly a third of the total pharmaceuticals business in India, which can be considered a very handsome amount.[4]

Many questions are now being raised by the scientific and non scientific community of the world regarding the documentation of safety and efficacy of Ayurvedic Medicines. Hence to control the manufacturing unit, rules and regulation are set and amended time to time by different regulatory authorities. But still, many of the Ayurvedic pharmacies are running in very poor condition which claims more seriousness regarding the implementation of rules both from the authority and from manufacturing sectors. Now the Ayurvedic medicines are under key scrutiny of other world. Government of India has made the GMP mandatory for all units since June 23th 2002. It is now a strategy on production of traditional medicinal formulations, that production be based on thorough analysis of the prevailing conditions during purchase, quality control, packaging and marketing.[5]

Salient Feature of Good Manufacturing Practices

In all the traditional system of medicines the quality assurance aspects are considered as an integral part and they need to be exercised to the fullest extent.[6]

- Gazette Notification GSR 561 (E) Dated: 23rd June, 2000.
- Schedule T' under rule 157 of Drugs and Cosmetics Rule, 1945.[7]
- Applicable to whole of the country with effect from 23rd June, 2000 for New A.S.U. Manufacturing units.
- Units registered prior to 23rd June 2000 are given 2 years time to comply with Individual Vaidyas/ Siddhas/ Hakimas exempted.
- Request for G.M P. certificate will be made on Plain Paper.
- After proper inspection G.M.P. certificate will be issued within 3 months.
- G.M.P. certificate will be given in form EL (under Rule 157 -B) for a period of 3 years.

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ISSN: 2278-4772

G.M.P. for A.S.U. Drugs Objectives to Ensure

- The manufacturing processes have been described to maintain standard.
- Raw materials used by manufacturers are authentic, of prescribed quality and free from contamination.
- Adequate quality control measures are adopted during processing of drugs. .
- The manufactured drug which is released for sale should be of accepted quality.
- Optimization of the efficacy of the product irrespective of the method of manufacturing.
- Manual of methodology, Procedure documented as a manual and kept for reference and inspection.

Components of G.M.P

The manufacturing plant should have adequate space for: Manufacturing process areas, Quality control section, finished goods store, Receiving and storing raw material Office, office for Rejected goods / drugs store.

General Requirements to Establish G.M.P. in Ayurvedic Pharma Industries

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 labelling 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.

Proper drainage system

- Proper sanitary fittings and electrical fixtures for safety
- Furnace and Bhatti section should covered with tin roof
- Proper ventilation/chimney in factory
- Prevention of flies and dust in factory premises
- Proper fire safety measures/ exits should be installed

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

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ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol.2, No.4 (2013) Pages 79 - 85

disposed of after suitable treatment as per guideline of pollution control to be followed.

Containers Cleaning: 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 Stores

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 Metallic origin, Mineral origin. Animal origin, Fresh herbs, Dry herbs or plant parts, Excipients, Volatile oils/perfumes and Flavours, 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/labelling 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 the operations. 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. (Table-1)

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

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Table 1: Space requirement for manufacturing of ASU drugs

S. No.	Category of Medicine	Minimum Space Required
1.	Anjana/Pisti	100 sq. ft.
2.	Churna/Nasya/Manjan/Lepa/Kwatha Churna	200 sq. ft.
3.	Pills/Vati/Gutika/Mathirai	100 sq. ft.
4.	Kupi pakva/Ksara/ Parpati	100 sq. ft.
5.	Kupi pakva/Ksara/Parpati/Satva	150 sq. ft.
6.	Kajal	100 sq. ft.
7	Capsules	100 sq. ft.
8.	Ointment/Marham Pasi	100 sq. ft.
9.	Pak/Avaleh/Khand/Modakllakayam	100 sq. ft,
10.	Panaka / Syrup/ Pravahi Kwathi Manapaku	150 sq. ft.
11.	Asava/Arishta	200 sq. ft.
12.	Sura	100 sq. ft.
13.	Arka/ Tinir	100 sq. ft.
14.	Taila/Ghrita/Ney	100 sq. ft.
15.	Aschyotan/Netra Malham/Panir	100 sq. ft.
16.	Bhatti, furnace, boilers, puta etc.	200 sq. ft.

Infectious diseases. First-Aid facility should be available. Health record of all the employees should be maintained.

Machinery and Equipments

Equipment should be according to the size of operation, nature of product manufactured. Suitable Machinery manually operated; semi-automatic or automatic should be available 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, 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. Proper standard operational procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

Batch Manufacturing Records

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, colour, physical characteristics and chemical tests as may be necessary. 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, equipments 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

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ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol.2, No.4 (2013) Pages 79 - 85

reaction resulting from the use of 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.[8] 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, semi finished 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 the manufacturer 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 minimise 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.[9]

Requirement of Sterile Product

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

Precaution against Contamination and Mix

Manufacturing operations should be carried out in a separate block of adequately isolated building or operating in an isolated area within the building. Use appropriate pressure differential in the process area. The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity. A suitable exhaust system should be provided. Designing laminar flow sterile air systems for sterile products should be provided. 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. 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.[10]

DISCUSSION

Charaka Samhita an Ayurveda text had given emphasis on drug standardization and quality control thousand of year ago itself. Scanning the Ayurvedic literatures for quality control, Acharyas gave emphasis on all the aspects like properties, actions, special actions, origin of the drug, time of collection, method of collection, method of storage, method of

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ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol.2, No.4 (2013) Pages 79 - 85

processing, dose, nature of patient all should be taken in care only then drug will act properly and doctor can get desirable results.[11] So, from the collection of raw material to storage, packaging, supply if all fulfil quality standards only then Ayurvedic drugs can give better results to mankind.

CONCLUSION

Government of India has made the GMP mandatory to develop quality formulations for an Ayurvedic, Siddha and Unani drugs manufacturing units for their global acceptance. Implementation of Good Manufacturing Practice in Ayurvedic pharmaceutical units concern may lead to manufacture of safe and efficacious medicines. GMP also validates the processes involved in Ayurvedic pharmaceutics and also facilitates the functioning of regularity authority and ultimately ensures the safety of Ayurvedic, Siddha and Unani medicines.

REFERENCES

1. Sagar Bhanu PS, Zafar R, Panwar R. Herbal drug standardization.Indian Journal of Pharmaceutical Science and Research; 2005:4(35):19-22.
2. Patel PM, Patel NM, Goyal RK. Evaluation of marketed polyherbal antidiabetic formulations uses biomarker charantin. The Pharma Review 2006;.4(22):113.
3. Naryana DBA, Baba B, Katayar CK. Herbal remedies through GMP/HACCP techniques. The eastern Pharmacist 1997;41(7):21-25.
4. Available from: http://www.qcin.org/documents/Certification_Scheme_AYUSH/ Accessed on:10/04/2013.
5. Shrikumer S, Maheshwari U, Sughanti A, Ravi TK. WHO guidelines for herbal drugs standardization. 2006.
6. Anonymous. Quality Control Methods for Medicinal Plant Materials. Geneva: World Health Organization; 1992.p.492-559.
7. Malik Vijay. The Drugs and Cosmetics Act, 1940. 18th ed. Lucknow: Eastern Book Company; 2006.p.34.
8. Mohapatra Sudhaldev, Rasa Shastra At A Glance. 1st ed. Varanasi: Chaukhamba Krishnadas Academy; 2007.p.123.
9. Lohar DR. Legal status of Ayurvedic Siddha and Unani medicines. New Delhi: Department of Ayush, Pharmacopoeial laboratories for Indian medicines.p.33. [Available online: http://www.plimism.nic.in/Legal_Status.pdf]
10. Available from: http://ayushharyana.gov.in/html/pdf/Schedule-T.pdf Accessed on: 10/04/2013.
11. Caraka. Charka Samhita. Sharma PV, editor: 1st ed. Varanasi: Chaukhambha Orientalia; 1983. p.463.

Source of Support: Nil Conflict of Interest: None Declared