EMERGING QUALITY CONTROL PERSPECTIVES FOR AYURVEDIC DRUG

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ABSTRACT

Ayush system of medicines based Herbal Pharmaceutical industry (ASU & H drug mfg) is having great potential and opportunities in India for development in future because of global acceptability of the medicinal plants & their value added products in Domestic & International Market as Ayurvedic, Unani and Siddha medicines, Herbal Nutraceuticals, Herbal Cosmeceutical, Herbal Health drinks, Dietary Health Supplements, Medicinal Plants / Crude Drugs, Herbal Extracts / Concentrates, Veterinary Medicines, Health Foods. India is rich with 771468 registered Ayush practitioners, 8667 licensed Ayurvedic drug manufacturing units. Quality Control/Assurance is the department, which controls all activities at various level of manufacturing as National & International standard. Ministry of Ayush continues to lay emphasis on up gradation of AYUSH educational standards, Quality control and standardisation of drugs, improving the availability of medicinal plant material, research and development and awareness generation about the efficacy of the system domestically and internationally. There are various issues & challenges related to drug quality for ASU&H Pharmaceutical Industries in India. It needs proper attention of policy makers and regulator & academia. Complete Implementation of GMP (schedule T) norm/guidelines and quality control/assurance procedure and activities is a big challenge for ensuring quality of drug.

INTRODUCTION

Opportunities for Ayurvedic Medicines

Ayush system of medicines based Herbal Pharmaceutical industry (ASU & H drug mfg) is having great potential and opportunities in India for development in future because of global acceptability of the medicinal plants & their value added products in Domestic & International Market as Ayurvedic, Unani and Siddha medicines, Herbal Nutraceuticals, Herbal Cosmeceutical, Herbal Health drinks, Dietary Health Supplements, Medicinal Plants / Crude Drugs, Herbal Extracts / Concentrates, Veterinary Medicines, Health Foods. India is rich with 771468 registered Ayush practitioners (as on 1.4.2016)[2] in India; out of these 419217 (54.4%) belong to Ayurveda and there were 8667 licensed Ayurvedic drug manufacturing units (as on 1.4.2016) in the country; out of these 99.5 % were controlled by non Govt bodies eg. Ayurvedic drug now day to become more popular globally.[9] There may be several positive causes of global popularities & acceptance of herbs based Ayurvedic drugs. e.g. 1.Easy accessibility & approach for Ayurvedic drug mostly time tested for their efficacy. 2. Cost effective and affordable. 3. Most of ISM drugs of Herbal origin are safe to use. “Assume to be no side effect”. 4. Increasing awareness about AYUSH systems due to it emphasize on Prevention of Diseases & Promotion of Health as it Considered Body, Mind and Soul as one unit & Ayush Healthcare also provided complete Disease management. 5. Increasing public awareness for adverse effects of synthetic drugs Total Global Market of herbal product[4] Natural Products) is estimated aprox. 62 billion USD($) [5]. The Compounded annual growth of Pharmaceutical industry[6] is estimated as 17.8%. Assumption By 2050 herbal market is expected to reach US $ 5 trillion Worth of Domestic market[7] of Ayurvedic, Siddha, Unani and Homeopathy Medicines is estimated by 15000-20000
Classical Ethical product (P&P) OTC Herbal

Ayu intended to modulate certain of evolution it is presumed that. Life in was created in March 1995 on step. The final -Vatta, Pitta- d to the, he last 15 years. As consumers have -Arogya- these make body diseased. For this Ayurveda emphasis role in the operation of life (known as Nidra
Dhatumal kriya, Prasana Atmaendriyaman Svasthyaiti

Classical Ayurvedic System of Medicines

Ayurveda is conceived as the union of body, senses, mind

1. To upgrade the educational standards of Indian systems of Medicine and Homoeopathy colleges in the country.
2. To strengthen existing research institutions and to ensure a time-bound research programme on identified diseases for which these systems have an effective treatment.
3. To draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems.
4. To evolve Pharmacopoeial standards for Indian systems of Medicine and Homoeopathy drugs.

AYUSH Ministry, Govt. of India

The Ministry of AYUSH[8] was formed on 9th November 2014. Earlier it was known as the Department of Indian System of Medicine and Homeopathy (ISM&H) which was created in March 1995 and renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003, with a view to provide focused attention for the development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.

Objectives of Formation of AYUSH Ministry[9]

1. To upgrade the educational standards of Indian Systems of Medicines and Homoeopathy colleges in the country.
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4. To evolve Pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs.

Ayurvedic System of Medicines

Ayurveda[10] is a word made of Ayu = Life and Veda = knowledge; which means a particular branch which tells about the knowledge of Ayu. In the beginning of Creation as per theory of evolution it is presumed that first of all plants come into existence, followed by animals. Ayurveda is the natural healing system of India, which literally means ‘the science of Life’.

According to Ayurveda “The Life is result of better combination & coordination of Satva (mind), Atma (Soul), Indriya (Senses Organ); Every person want good health because Heath (Arogya) is base of Chatur-Prurusharth-Dharma, Artha, Kama, Moksha. Life in Ayurveda is conceived as the union of body, senses, mind and soul. The living man is a made up from the three humours (Vata, Pitta & Kapha), seven basic tissues (Rasa, Rakta, Mansa, Meda, Asthi, Majja & Shukra) and the waste products of the body such as faeces, urine and sweat. According to Surshruta “ Sama dosa, Sama Agni, Sama Dhatumal kriya, Prasana Atmaendriyaman Svasathyaiti-dhiyate” As per Ayurveda general health of individual person is directly related to proper equilibrium of The Siddhambha of Body (Vatta, Pitta, Kapha) & Ahar (diet), Nidra (proper sleep), Brimhchariya, which are well known as Upastmbha of life. They play very important role in the operation of life (Ayu), Improper utilization of these make body diseased. For this Ayurveda emphasis on preserving and promotion of health of individuals as well as on the treatment of illness through natural resources. Its diagnostic method, therapeutic procedures, the use of drug formulation(by combination of herbs, plants, trees, mineral, metals & animal product as per diseases) with their dosage and manner of taking were all very systematized, based on long standing observations & experience of the our ancient Achariya.

Production Process/Operation Management

Production/operations management[11] (P/OM), as a functional field of management, has developed rapidly during the last 15 years. As consumers have become more discerning and competition more intense, manufacturing organizations have been presented with a wide variety of panaceas including; just-in-time (JIT), total quality management (TQM), manufacturing resources planning (MRP II), flexible manufacturing systems (FMS) and computer-integrated manufacturing (CIM), ISO, Six Sigma process Approach etc.

The general process involved in the manufacture of drug products consists of a series of unit operations/process, each intended to modulate certain properties of the material being processed[12] for example Ayurvedic tablet manufacturing require following manufacture process step to product tab eg. Material Procurement, Mt. Storing, Material Indenting, Weighting, Preprocessing (Cleaning, Grading, chopping, Cutting), Size reduction, Dry Mixing, Wet mixing, drying, Milling, Sieving, Sizing, lubrication, tab compression, Coating, Primary packing, Secondary packing etc. The manufacture of drug substance, or API (active pharmaceutical ingredient), involves several unit operations/processes. Typically, it involves several stages of complex traditional process/reactions as per classical Ayurvedic texts or Ayurvedic pharmacopoeia. In which different functional groups are attached to the starting raw material. The products formed after each stage of reaction are termed as intermediates. In many cases, some downstream processing of the reaction mixture such as filtration, distillation etc. is also conducted prior to the next reaction step. The final reaction mixture or finished goods/medicines, also termed as the powder, Decoction, Extract, mother liquor, goes through multiple steps of downstream processing to produce the desired active in solid form – Tab, Powder, Granules, Capsule, Syrup, Cream, ointment Asava, Arogya, Avelha etc. These steps almost always include Size reduction, Mixing/Homogenation filtration, distillation, precipitation (reactive crystallization), crystallization, drying and milling.

Quality Control/Assurance for ASU Drug Industry

Quality Control/Assurance is the department, which controls all activities at various level of manufacturing as National & International standard. Quality Control is a part of quality management focused on full filling quality requirement. Quality Assurance providing confidence that quality requirement will be fulfilled. QC is defect detection & product oriented however QA is defect prevention & process oriented. QC is actually testing process and QA is its verification.
Ministry of Ayush continues to lay emphasis on up gradation of AYUSH educational standards, Quality control and standardization of drugs, improving the availability of medicinal plant material, research and development and awareness generation about the efficacy of the system domestically and internationally.

There are various issues & challenges related to drug quality for ASU&H Pharmaceutical Industries in India. It needs proper attention of policy makers and regulator & academia. Complete Implementation of GMP (schedule T) norm/guidelines and quality control/assurance procedure and activities is a big challenge for ensuring good quality of drug; hence we first need to understand what is quality.

What is Quality?

Word “Quality” derived from Latin word ‘quails” means of which kind. Quality is denominator of a product or its acceptability to consumers & regulatory authority. It is degree to which a “set of inherent characteristics that fulfil customer requirement. Reasons for quality becoming a cardinal priority for most organizations as it is needed for providing confidence that quality requirement will be fulfilled.

What is Quality Control- Control on entire production process with the set-norm/Standards is carried out by the Quality Control/Assurance Department. QC/QA is the department, which controls all activities at various level of manufacturing as National & International standard.

Quality Control

QC is a part of quality management focused on full filling quality requirement.

Quality Assurance

QA providing confidence that quality requirement will be fulfilled.

Process oriented. QC is actually testing process and QA is its verification.

Production Process & Quality Control: Relevance for Pharmaceutical Industry

Ayurvedic Industry comes under schedule “T” of Drug & Cosmetic Act 1940 & Rule the under 1945. It have certain guidelines for production process and their quality control which are collectively known as GMP. Quality Control is the part of GMP concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

Customers -General Quality Perspectives

As Ayurvedic classics “Bhisak, Dravya, Upasthata, Rogi Pad Chatushtyam” mean Bhisak (Vaidya/Ayurvedic Physician), Dravya (Drugs), Upasthata (supporting staff), Rogi (patient) are the main four pillar of Ayurvedic system of medicines. All should be good as per described Guna. Vaidyas are technically skilled for Ayurvedic treatment concept as well knows to how drug manufacturing. In old time medicines was prepared by Vaidya itself by taking/collecting highest quality Raw material; mostly in fresh form and dispensed at the same time. That time there is no issues about drug efficacy, preservation, safety, issues etc. time has been passes. Medicines prepared by commercial manufacturing house. It involve third party other than user (customer). That why customer looks fulfilling their product requirement. Relatively simpler approaches to quality viz. product inspection for quality control and incorporation of internal cost of poor quality into the selling price, might not work for today's complex market environment. Everyone defines Quality based on their own perspective of it. Typical responses about the definition of quality would include: [16]

1. Perfection
2. Consistency
3. Eliminating waste
4. Speed of delivery
5. Compliance with policies and procedures
6. Doing it right the first time
7. Delighting or pleasing customers
8. Total customer satisfaction and service

Why QC/QA Needed

There are several reason for requirement of QC/QA Implementation in Ayurvedic Pharmaceutical industry as it is needed for

- Identification of drug
- Purity of drug
- Safety of drug
- Strength of drug
- Efficacy of drug
- For Ayurvedic Physician, To cure disease, drug is only tool, So, medicine would be good in quality & high standard.
 ✓ The product meets the standards and expectations of medical professionals and regulatory agencies around the world.
 ✓ The product performs as claimed.
 ✓ The product can be successfully made consistently.
 ✓ To follow GMP/GLP/WHO\(^{19-20}\) CoPP/ISO etc. standards Given by regulatory agencies/authority

**Sections Works Under Q.C/QA**
Q.C. work every where throughout manufacturing processor for producing good quality product by following three department
- Department of Pharmacognosy
- Department of Chemistry
- Department of Pharmacology
- Department of Microbiology

**Methodology of Q.C./QA**
The quality assessment tests is carried out by Quality control and Quality assurance Dept. during the drug manufacturing can be done in three main stages under GMP and GLP norms.
- proper Sampling and testing of raw material only good quality material are accepted otherwise substandard material rejected.
- Sampling and testing of mid products(extracts etc.) at different stages.
- In process Quality control during Production for such controlled parameter like-Temperature, Relative humidity (RH), pressure Etc.
- Sampling and testing of finished products (powder, tablets, Bhasmas etc.).

**A) Methodology of Testing of Crude Drugs**
The quality assessment shall be done by Quality control and Quality assurance Department through proper sampling as per sampling plan. Sample should be taken before production; only complies material with regard to standards laid down in pharmacopeia/In-house protocol should be releases for production.

Testing Protocol of Raw drugs (as per API/UPI Monograph/testing protocol)\(^{[21-34 & 42-45]}\)

a) Identity-

i) Pharmacognosy Profile (Macroscopic/ Microscopic)

- **Macroscopic examination:** Visual examination as Size, Colour, Surface, Characteristics, Texture and Other examination as Odour, Taste.
- **Macroscopic examination:** Preparation of sample, Inspection by microscopy, Inspection by colour filter of ground glass, Histo-chemical detection, Section study(T.S./L.S.).

ii) Chemical identification

iii) TLC/ HPTLC FP profile

b) Purity-Physico-Chemical profile (as above as applicable as per dosage form).

c) Strength-Active marker/Assay (wherever required)

d) Safety –

i) Heavy metal profile (Lead, Mercury, Arsenic, Cadmium)

ii) Microbiological limit testing (Total Aerobic Bacterial count, Total yeast /mould count and Presence of pathogens [Salmonella, P. aeruginosa, E.coli, S. aureus])

iii) Aflatoxins (B1, B2, G1, G2)

iv) Pesticide residue

**B) Methodology of Testing of Compound Drugs**
The quality assessment shall be done by Quality control and Quality assurance Department through proper sampling as per sampling plan. Sample should be taken from In-process stage and finished product from Quarantine area. Only complies finished product with regard to standards laid down in pharmacopeia/In-house protocol should be releases for dispatch for end user.

QC/QA Technical person should also ensure about compliance of other regulators requirement such as Label claim under rule 161 of drug & cosmetic act. As drug name, formulation & composition, Drug mfg Ref, main therapeutic indication/uses, dose, vehicle, direction of use (if any), self life, caution/warning (if any), storage condition etc.

**Testing Protocol of drugs (as per API/UPI Monograph/ testing protocol)**\(^{[35-41 & 42-45]}\)

a) Description

b) Identity-Pharmacognosy Profile (Macroscopic/ Microscopic- wherever required)

- Chemical identification (Wherever required)
  - TLC/ HPTLC FP profile (Wherever required)

- Purity-Physico-Chemical profile* (as above as applicable as per dosage form)

- Strength-Active marker/Assay (wherever required)

- Safety –

  i) Heavy metal profile (Lead, Mercury, Arsenic, Cadmium)

  ii) Microbiological limit testing (Total Aerobic Bacterial count, Total yeast /mould count and Presence of pathogens [Salmonella, P. aeruginosa, E.coli, S. aureus])

  iii) Aflatoxins (B1, B2, G1, G2)

  iv) Pesticide residue

There are various physicochemical testing employed for drug profiling which is depend on the specific characteristics of drug/dosage form or testing protocols given in Ayurvedic Pharmacopoeia of India (API), Unani Pharmacopoeia of India (UPI), Siddha Pharmacopoeia of India (SPI), USP (United state Pharmacopoeia), IP (Indian Pharmacopoeia) etc as 1) Determination of foreign matter, 2) Determination of Ash value (at 500-800°C), 3) Determination of extractable matter, 4) Determination of water & volatile matter, 5) Determination of Moisture content (L.O.D. at 110°C) 6) Determination of bitterness value, 7) Determination of haemodynamic activity, 8) Determination of Tannins, 9) Determination of swelling index, 10) Determination of foaming index, 11) Determination of pesticide residue, 12) Determination of Total chlorine & phosphorous, phosphates, 13) Determination of arsenic & Heavy Metal, 14) Determination of Bulk density, 15) Determination of...
Radio-active contamination, 16) Comparative TLC/ HPLC/ HPTLC/ GC-MS, 17) Determination of in-organic content by ICP etc various tests may be carried out for Quality control as per need according to dosage from.

Stability study also be carried out for QC/QA work for 1) Real time Stability studies (to see the changes in the quality standards at various intervals is found suitable for ascertaining the shelf life of the ASU medicines) in standard Storage Condition- Temp. 30°C ± 2°C, Relative Humidity: 60% ± 5 % for 1/6/12/18/24 /30/36months as per stability study testing protocol

**Instruments used in QC/QA Process**

Various common instrument used in the quality control/Assurance activities as Ph meter, Single Distillation unit, Double distillation unit, Soxhlet assembly, Water bath, Viscometer, Tinto meter, Bulk density apparatus, Polari meter, Referectometer, Microscope, Titration unit, Hot air oven, Magnetic stirrer, Filtration unit, I.R. Moisture balance, Karl fischer tritrator, Muffle furnace, Vacuum evaporator, Dissolution apparatus, Friability apparatus, Hardness tester, Top loading balance, Autoclave, B.O.D., Incubator, Laminar flow, Microbiological colony counter, Antibiotic Zone Reader. In drug standardization work so many ultramodern instrument also used frequently as & when they are application as Paper chromatography setups, Column Chromatography apparatus, Double beam Spectrophotometer, HPTLC Unit, HPLC Unit, LCMS, G.C. with detector, GCMS, ICP-MS etc.

**Documentation Required for QC/QA**

Documentation is a reliable (written) record that can be used, at a future time, to clearly and completely recreate an activity, event, or process. There are several Documentation Rules as Use permanent blue or black ink, Record information directly on proper form, Record information immediately after completion of step, process, or observation, Use proper date and signature formats, Correct ‘errors in documentation’ promptly and properly. There are 9 Characteristics of a properly produced Document as Permanent, Legible, Accurate, Prompt, Clear, Consistent, Complete, Direct, and Truthful.

In manufacturing unit, QC, QA dept. should be maintained following record & documentation. eg. Sample receiving register, Reagent & chemical stock register, Lab. Manual, Quality plan, Instrument manual and SOPs (standard operating Procedures) for Instrument Handling & maintenance, STP (Standard Testing Procedures), Instruments logbook, Calibration records, reagent/solution standardization record, and WI (Work instruction having knowledge of OQ (Operation Qualification), IQ (Installation Qualification), DQ (Design Qualification), PQ (Performance Qualification) , QC, QA Technical person must know state of art instrumentation technique.

**Process Mapping of QC/QA**

Input:
1. Validated Procedures.
2. Equipment
3. Standards /References

4 Specifications

**Procedure:**
1. Laboratory test manual
2. Standard Testing Procedures (STP)
3. Standard operating Procedures (SOP)
4. Work Instruction

**Maintaining:**
1. Standardization
2. Calibration
3. Verification

**Out Put:** - Test Reports (COA)

**Step Taken by M/O Ayush for Improving Quality of ASU& H Drugs**

Various solid steps\(^{47-51}\) have been taken for Improvement in drug quality by strengthening of drug enforcement / regulation by Ministry of AYUSH, Govt. of India in last decade for mainstreaming Ayush system of medicines in India as.

- Separate chapter and rules for Ayurveda, Siddha and Unani drugs in Drugs & Cosmetics Act, 1940.
- Drug Technical Advisory Board (ASUDTAB) for matters related to quality control and standardization.
- Drugs Consultative Committee (ASUDCC) for securing uniform administration of the legal provisions in different states.
- Licensing of manufacturing units and drugs mandatory.
- Compulsory Good Manufacturing Practices (GMP) schedule “T”.
- Central Government empowered to prohibit manufacture and sale of certain drugs in public interest.
- Government Drug Analysts- Qualifications and Duties.
- Appointment of Drug inspectors.
- Penalty for manufacture, sale etc. of drugs in contravention of Act.
- To prescribe methods of drug testing and analysis.
- Listing of schedule E drugs – poisonous materials.
- Definition of misbranded, adulterated and spurious drugs for punitive action.
- Labelling/Packing provisions under rule 161 of Drugs & Cosmetics Act.
- Establishment of research councils eg. CCRAS, CCRUM, CCRH, CCRS) for quality research and development of pharmacopoeial standards.
- Establishment IMPCL for mfg pure & authentic drug as per pharmacopoeia for Govt. supply.
- Recognition of private and public drug testing laboratories (39) for sample analysis.
- Compulsory testing and Certification for export.
- Approval for separate ASU & H drug controller.
- Various initiative taken by Govt under COE, IC, NMPB scheme of Ayush Ministry.
Establishment of PLIM, HPL, State DTL (27), Latest setup of PCM&H.

- Regulation of Drug Control cell & Implementation of API/UPU/SPI/HP of Raw Materials as well as finished Medicines. Publication of AFI, NFUM for drug manufacturer for the consistent & uniform quality of the drug.

**General Difficulties/Challenges for Q.C. Activities** [46-53]

- Lack of awareness & up to date knowledge of QC/QA procedures & GMP norm.
- Lack of Up to date Infrastructure / state of the art machinery, automation in process, Technical manpower, Poor Formulation & Development (F & D) initiatives for process & product development.
- Instrument & basic setup as per GMP is too costly.
- Poor R & D activities and lack of Awareness in the field of R & D in Ayurveda.
- Raw drug unavailability in proportion of demand.
- Increasing number of endangered medicinal plants (Red Data Book).
- Commercialization (High cost of product) Drug Adulteration.
- Availability of Skilled technical traditional Ayush professional with scientific background.
- Lack of Scientific documentation, SOPs, STPs, CCP (Critical control Point), Validated data on drug Manufacturing.
- Lack of Process and Product standardization & Validation date.
- Lack of complete drug standards. Limitation in standards of raw material and finished product.
- Everywhere Commercialization even with the drug, which is the need of health; One's need to be work with oriented motto/charity for human welfare; rather than business oriented approach which makes product adulterated/spurious. It needs implementation of GMP, Ayush mark, QCI, GLP, GPP, GAP, GCP, Organic certification etc. on ground levels. It will require investment at initial level.
- Comparative Poor Statutory regulation as allopathic drug, Shortage of Drug enforcement infrastructure & manpower.

**Role of Govt. to regularize Q.C. Activities**

The national health authorities (Ministry of AYUSH, Govt. of India and State Licensing Authorities/ Drug controller) should ensure that all ASU &H Drugs subject to their control are in conformity with Quality, Safety, Efficacy and that all premises and practices employed the, manufacturing and distribution of these product comply with GMP standards, So as to ensure the continued conformity of the product with these requirements until such time as they are delivered to the end user.

**CONCLUSION**

In view of the cited facts we can conclude & way forwards for ISM drug mfg industry or AYUSH Academia as

- The global interest in traditional medicine of India especially Ayurveda is increasing with the result of that herb based single and compound formulations market is growing very fast.
- The international and national ministries/ organization/institutions have emphasized on quality products for safe use by the consumers. Therefore, mandatory regulations for authentic use of herb under legal provisions of respective countries have been imposed.
- Govt must be re-structuring & strengthen the existing Drug enforcement infrastructure.
- We should promote cultivation of MAPs (Medicinal & Aromatic Plant) & Development of Common raw material sourcing centre (Herbal Mandi) is essentially required. Rigorous effort to be done for conservation of rare & endangered plant.
- Development of GMP/QC & QA training Centers.
- Publication of various Book/manual on GMP/QC & QA. Regular seminar, workshop, ROTP program for awareness of GMP/QC & QA standards.
- Initiatives & Incentive for Quality accreditation.
- ASU Drug manufacturing needs more assistance from Govt from deferent Dept.

There are other many suggestion may be taken from various stack holder of AYUSH system of Medicines; Lets joint hand to all Industry-Academia-Student-Policy maker for the development & well-being of our Ayush System of Medicines.

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