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Review of Homoeopathic Pharmacy in the Light of Quality Control

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ABSTRACT

In today's era adulteration of any product is burning issue. InHomoeopathy Quality of Medicine is the Vital Factor. Quality can bedefined as the status of the drug that is determined by identity, purity,content and other physical, chemical, biological properties, or by themanufacturing processes. Quality should not only be tested at the endbut must be carried out right from the moment of receipt of rawmaterials, right through processing, till the final packaging.Homeopathic medicines are often prepared from natural and syntheticsource materials. Two issues are decisive for the quality ofhomeopathic preparations: Determining the authenticity and the originof the starting materials according to the homeopathic tradition and defining themanufacturing procedure. The quality of Homoeopathic Medicine ascertained andstandardized as specified in HPI. By this literary study one can state that the Homeopathicpreparations with the help of Quality Control have atherapeutic relevance, pure, safe, costsaving and having standards with quality specifications thus beneficial to physician and patient.

KEYWORD: Quality, Quality Control, Homoeopathic Pharmacy, Manufacturing Process, Goodmanufacturing Practices.

INTRODUCTION

Homoeopathy has a holistic approach to healing, with as its central tenet that "like cures like"(in Latin: similia similibus curentur). Homoeopathy has its own views on illness, and its owndiagnostic and treatment principles, as well as products and practices.[1] In Homoeopathy Quality of Medicine is the Vital Factor. Medicines are greatest weapon of mankind to fight against diseases and death. Quality control is the only tool to ensure highest quality and purity of medicine. In the beginning of 20th century the drug industry was nonexistent in India and drugs were imported from abroad. Demand of drugs increased during and after the First World War and cheap drugs was imported in large volume. Thus increase in demand of drug resulted in production of cheaper and inferior drugs by some Indian companies to compete with imported drugs. To control the situation, Drug and cosmetic Act-1940 passed. The drug rules were framed in 1945 to give effect to provision of act. The homoeopathic pharmacopeia Laboratory (HPL), Ghaziabad, was set up in Sept. 1975 as a quality monitoring apex body. Its main functions are to set standards and drug testing laboratory at national level. Quality can be defined as the status of the drug that is determined by identity, purity, content and other physical, chemical, biological properties, or by the manufacturing processes. Quality control is the term that refers to the process involved in maintains the quality and validity of manufactured product. Quality should not only be tested at the end but must be carried out right Quality of Medicine is the Vital Factor. Medicines are greatest weapon of mankind to fightagainst diseases and death. Quality control is the only tool to ensure highest quality andpurity of medicine. In the beginning of 20th century the drug industry was nonexistent inIndia and drugs were imported from abroad. Demand of drugs increased during and after theFirst World War and cheap drugs was imported in large volume. Thus increase in demand ofdrug resulted in production of cheaper and inferior drugs by some Indian companies tocompete with imported drugs. To control the situation, Drug and cosmetic Act-1940 passed.The drug rules were framed in 1945 to give effect to provision of act. The homoeopathicpharmacopeia Laboratory (HPL), Ghaziabad, was set up in Sept. 1975 as a quality monitoringapex body. Its main functions are to set standards and drug testing laboratory at national level.Quality can be defined as the status of the drug that is determined by identity, purity, contentand other physical, chemical, biological properties, or by the manufacturing processes.Quality control is the term that refers to the process involved in maintains the quality andvalidity of manufactured product. Quality should not only be tested at the end but must becarried out right from the moment of receipt of raw materials, right through processing, tillthe final packaging. Quality Control is not only laboratory procedures, but also theprocedures through which a raw material is transformed to a drug and the finished product tillit is used by the patient. It's one of important function is to establish specifications for rawmaterials, packing materials, intermediates and finished product to assure the quality andsafety.[2,3]

MATERIALS AND METHODOLOGY

Material: Type of study- Literary study. For thorough understanding of this topic available literature has referred.Method: Extensive theoretical study was done from various source books of Homoeopathic Pharmacy, Homoeopathic Pharmacopoeia of India all volumes, Encyclopedia of Homoeopathic Pharmacopoeia of India all volumes, journals, research papers, articles, internet sites and previous work done etc. on this topic if any.

REVIEW OF LITERATURE

1) QUALITY CONTROL OF RAW MATERIAL a) All incoming raw material are transformed to the store. b) Each incoming material is marked with coding reference. c) Samples of raw material are analyzed. d) Identification of adulterants is done. e) The raw materials are compared with f) standards. g) Purity testing done. h) Equipment's are inspected for microbial contamination. i) After completion of manufacturing process, representative sample of finished product is analyzed.[3,4]

2) QUALITY CONTROL OF FINISHED PRODUCTS It includes: Alcohol content determination, Weight per ml, Specific gravity, pH value, Total solids, λ Max, Fluorescence analysis, Chromatography.

3) IN-PROCESS QUALITY CONTROL The In-process quality control includes every step of preparation from raw material to finished products. It is critical in ensuring the purity and safety of Homoeopathic Medicines. The system of quality control is even more vital in the manufacturing process than with their allopathic counterparts. In case of highly diluted and potentised medicines care should be taken in every step of manufacture to maintain the quality and reliability of the final product.[5,6] It is mandatory for the manufacturers to have GMP (Good Manufacturing Practices) Certificate.

4) QUALITY CONTROL OF FINISHED PRODUCTS

Finished homoeopathic products must meet quality standard. Finisdone. Equipment's are inspected for microbial contamination. i) After completion ofmanufacturing process, representative sample of finished product is analyzed.[3,4]

5) PACKING AND LEBELING OF HOMOEOPATHIC MEDICNES

a) The words 'HOMOEOPATHIC MEDICINE'. b) The Name of the medicine with Potency.c) Name and Address of the manufacturer or distributor. d)If alcohol is present, alcoholcontent in % by volume of ethyl alcohol shall be stated on the label. e) Instructions forstorage f) Instructions for usage. g) Manufacturing Date of the batch of medicine. h) ExpiryDate of the batch of medicines. i) Batch number, by which details of manufacture of theparticular batch is understood. As products are prepared in batches, batch number helps intracing out the entire batch in case of defect. k) Manufacturing License Number or 'Mfg. Lic.No.' is the license number of the manufacturer and indicates that the authority grantinglicense is satisfied with the conditions and that it is competent in manufacturinghomoeopathic medicines.[9,10]hed product should undergo all possible sorts of physical and chemical tests.[7,8] Homoeopathic Pharmacopoeia Laboratory (HPL) suggested some preliminary standards for finished products.

6) MODERN ANALYTICAL TECHNIQUES ADOPTED FORSTANDARDIZATION 1) Spectroscopic Analysis 2) Infra-Red Spectrometry 3) Ultraviolet and Visible Spectrometry 4) Romen Spectrometry 5) Nuclear Magnetic Resonance 6) Gas Chromatography 7) X-ray Diffraction 8) Atomic Absorption Spectrometry 9) High Performance Liquid Chromatography 10) Gas Liquid Chromatography.

RESULTS AND DISCUSSION

Quality Control procedures are procedures for standardization, by which the quality of a medicine is tested. The quality should not only be tested at the end but must be carried outright from the moment of receipt of raw materials, manufacturing, till the final packaging,labeling, storage and distribution. Homeopathic medicines may be based on toxic source materials from animals or plants. In their fresh form they are prone to microbiological contamination. From the safety point of view it is important to note that, although homeopathic treatments often utilize ultra molecular dilutions of the starting material (above Avogadro's number), there are also homeopathic medicines of lower dilution which contain molecules that may be active in the biochemical sense. Hence, homeopathic medicines are ingeneral considered to be safe when administered, but toxicological aspects should not be neglected especially when using lower dilutions of unsafe starting material. Identification andquantification of active substance and toxicological testing of the final homeopathic product is mandatory. In such cases the quality should be demonstrated by complete validation of the manufacturing and dilution process.[11,12] Plant materials may be contaminated with pesticides and heavy metals. The properties of homeopathic medicines can be compromise by accidental or intentional contamination by the vessel or bottle in which the dilution is made. In today's era adulteration of any product is burning issue. So the solution of this problem is Quality Control.

CONCLUSIONAs a conclusion one can state that the Homeopathic preparations with the help of Quality Control have a therapeutic relevance, are pure, safe, cost saving and having standards with quality specifications thus beneficial to physician and patient.

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