

Learning from the past: Review of the Central Council for Research in Homoeopathy Quarterly Bulletin 2002 (volume 24) and 2003 (volume 25)

AUTHOR'S NOTE

We are what we remember. If we lose our memory, we lose our identity, and our identity is the accumulation of our experiences. By following our stream of consciousness, we look for lost time and things past. Some reminiscences become anchor points that can take another scope with the wisdom of hindsight. Central Council for Research in Homoeopathy Quarterly Bulletin (CCRH), Volume 24 and 25 supports in anchoring of the past vital information and disseminate it for the present.

Volume 24 (1 and 2)

The issue highlights the excerpts from the papers presented in a two day seminar of developing an interface between CCRH and homoeopathic pharmaceutical industry held on 27th September, New Delhi in 2001 with a view to give a wider publicity among the homoeopathic fraternity.

Present scenario of homoeopathic pharmaceutical industry and problems faced by them

Babu Mukesh, Manager, Quality Assurance, Dr Willmar Schwabe India Pvt. Ltd., Noida (UP) in his session on first day covered the present scenario of homoeopathic pharmaceutical industry and problems faced by them. Babu Mukesh, Manager, Quality Assurance, Dr Willmar Schwabe India Pvt. Ltd., Noida (UP) in his session on first day covered the present scenario of homoeopathic pharmaceutical industry and problems faced by them. He stressed upon the use of Indian Systems of Medicine and Homoeopathy which had surged by about 70% since 1989 and is expected to grow 30% annually owing to high cost, serious side effects of allopathic medicines, and recognition of alternative systems of medicine by the World Health Organization (WHO). The other reasons for its growth have been also emphasized in his article. The issues responsible for a lower growth rate of homoeopathic pharmaceutical industry were also highlighted. He added upon the major challenges faced i.e nonavailability of quality raw drug material, market of medicines made from units having no control on raw material, environmental factors, and methods for manufacturing finished products. Further, to achieve good quality products, enforcement and implementation is required in the areas of raw material control, process control, environment control, and availability of qualified staff.

Quality control in homoeopathic pharmaceutical industry

Bhar D.S, Director, M/s Hapco, Kolkata in his session addressed upon the importance of availability of standard quality medicine to humanity for which stringent quality

control measures in manufacturing of pharmaceutical products are necessary. The manufacturing of quality medicine entails proper testing of the raw material used and the finished preparation. Homoeopathic Pharmacopoeia of India (HPI) has set standards for raw drug material to be used in the preparation of homoeopathic medicines, but only those standards are not enough to establish proper identity or quality of raw materials, especially in the case of botanical drugs. A few more parameters such as "Ash content" and "Assay of Principle Active Constituents" were required to be incorporated.

Apart from these for finished preparations, color of mother tinctures may be incorporated to discourage unscrupulous manufacturers from adding coloring matter. Further, selection of proper material for the manufacture of containers to be used in homoeopathic industry is also of much importance. In HPI, the standard of container to be used for storage and dispensing of medicines has not been set. However, a comparative study shows superiority of glass over polymers used in the manufacture of containers used.

Good manufacturing practice and homoeopathic pharmaceutical industry

Good manufacturing practice (GMP) is not only important for allopathic industry stressed upon the fact that also it is doubly important for homoeopathic industry, as the medicines that we use were in very small quantities which requires by definition, purity, and perfect measurement of qualities. The concept of GMP was mooted around 1967 in the World Health Assembly which has since become WHO. Many changes have taken place since then. Among other changes, the latest version takes account of the International Standards Organization (ISO)-9000 series quality systems' standards setup by the ISO. In Homoeopathy, no guidelines have been laid down; however, some principles are set out for Homoeopathy in Schedule M-1 of the Act, relating to licensing of industrial units. GMP is a precondition for entry into the business of manufacturing homoeopathic remedies and staying in it. If India hopes to be a global player in the field of Homoeopathy, establishment of GMP in homoeopathic manufacturing practices is a must.

He added that for establishment of GMP, a considerable investment has to be involved in the treatment of water, use of noncontaminating vessels made of standard stainless steel; minimum testing equipment to distinguish good quality raw material from bad ones and control of atmosphere to bring air purity where manufacture is carried on. However, while allowing time for universal adoption of GMP standards, the

government can consider introducing measures to recognize manufacturers who observe such standards. A mark such as Agmark or ISP or ISO 9000 can be awarded to companies which fulfill GMP requirements which will enable consumers, institutional buyers, and homoeopaths to distinguish between products with standards of excellence and others.

Homoeopathic pharmacopoeia committee

Singh S.P., Deputy Adviser (Homoeo), Govt. of India talked about the Homoeopathic Pharmacopoeia and its related issues. The Homoeopathic Pharmacopoeia Committee (HPC) was constituted in September 1962 on the recommendations of the Homoeopathic Advisory Committee and Homoeopathic Sub-Committee of the Drugs Technical Advisory Board on the question of control of homoeopathic drugs under Drugs and Cosmetics Act, 1940 and Rules 1945. The term of the HPC was initially for 3 years which was extended from time to time.

The functions of the HPC are to prepare pharmacopoeia of homoeopathic drugs whose therapeutic usefulness have been proved on the lines of the American, German, and British homoeopathic pharmacopoeia; to lay down principles and standards for the preparation of homoeopathic drugs and testing of their identity, quality, and purity; to prepare homoeopathic pharmaceutical codex. The priority of the HPC is to fix standards up to the level of mother tincture or equivalent. Seven volumes of HPI have been published and Seventy-four meetings of the HPC have been held so far. HPI has become official in terms of Schedule II of the Drugs and Cosmetics Act, 1940 and Rules. The government on the advice of Drug Technical Advisory Board has also amended Schedule "K" of Drugs and Cosmetics Rules, 1945 to facilitate the availability of certain homoeopathic medicines through licensed pharmacies.

Drug standardization and homoeopathic pharmaceutical industry

Mazumdar K.P., Chairman, Homoeopathic Pharmacopoeia Committee briefed about standardising homoeopathic medicines in his lecture. The ideal of any homoeopathic pharmacopoeia is to give to the manufacturer-specific directions with respect to collection, identification, preparation, and preservation of the source material and finished product and ensure to the physician the availability of a standard drug material. Effects of the homoeopathic drugs are qualitative and not quantitative. He talked about the different developmental stages of the plant can alter the constituents of a particular specimen although morphologically correct, and therefore efforts should be made to fix the developmental stage as one of the parameters for collection. Standardization of source material is therefore very imperative. If there is any doubt in coming to a conclusion, it will be necessary to conduct a fresh proving, after standardizing the drug substance.

He added that Hahnemann classified the drug material into nine classes, but while critically reviewing, we find that the classification sounds arbitrary and without logic. To overcome this situation, mother tinctures have to be prepared in accordance with the modern method described in

Homoeopathic Pharmacopoeia of United States (HPUS). He supplemented this by stating that the mosaic of the various constituents is important and is controlled by the genetic makeup of the species concerned. This mosaic is responsible for the quality of its action. While maintaining the standards of the drug substance which are very essential, methods devised should be simple wherever possible and reproducible. But wherever simple method may not be possible then recourse to elaborate method. Cost need not sacrifice the scientificity of the end product.

Pharmacological aspects in drug standardization

Singh K.P., Drug Standardization Unit, Ghaziabad on second day of seminar discussed upon the topic in his session. Further, in medical practice, it is very much essential to standardize the dose of a drug which when administered clinically to a patient should have produced a desirable degree of therapeutic effect without having any untoward or side effects. Standardization of a drug can be done by chemical assay, microbiological assay, and bioassay. Chemical assays employ thin-layer chromatography, high-performance liquid chromatography, ultraviolet, infrared, atomic absorption, spectrophotometry, mass spectroscopy, nuclear magnetic resonance, etc., whereas microbiological assays employ turbidimetric or tube assay method and cylinder-plate or cup-plate method. The principle of bioassay is to compare how much of a sample of a drug being tested produces the same biological response as a given quantity of a standard preparation, provided that both sample and standard are tested in identical conditions in all respect of time, environmental factors, and biological media used. Actual potency of a sample cannot be judged; only approximate potency with a confidence limit (95% or 99%) can be calculated using statistical analysis (standard deviation of the mean, standard error of the mean, Student's *t*-test, Chi-square test, and analysis of variance).

Quality control of homoeopathic medicine is done by pharmacological screening of homoeopathic drugs for toxicity, pyrogens, and sterility. In homoeopathy, sterility test is done for those preparations which are prepared in aqueous solution and are used topically mainly for eyes.

Botanical studies and homoeopathic medicine – an assessment of their integration

Bhatnagar A.K., Professor, Department of Botany, Delhi University talked that there is considerable scope for botanical resource development for homoeopathic drugs in India. The credibility of homoeopathy depends not only on the quality of medicines available over-the-counter but also on the genuine, authentic plant material of consistent characteristics required for preparation of standard drugs in accordance with prescribed procedures and proportions. Recent experimental studies indicate that there exists considerable genetic diversity within a plant species with respect to its active constituents.

Tribal and village communities in India use a large number of plants for medicinal purposes and Value of ethnobotanical information is now being realized. Manufacturers of

homoeopathic drugs must utilize this information for realizing the full potential of our natural wealth without damaging it. Homoeopathic system of medicine is least demanding on plant resources despite its dependence on them. Unlike other systems, it requires small quantities of material which can be used to treat a large number of people. Pollution has become a serious hazard to many medicinal plants. We need to dig deeper into our long healing traditions and rich reservoir of medicinal plants to unearth new drugs that can cure the ills of humanity without disturbing the ecological equilibrium of the planet.

Medicinal plants identification and cultivation for quality manufacturing of homoeopathic drugs

Baburaj SD, Survey Officer, Survey of Medicinal Plants and Collection Unit, Ooty in his paper highlighted about a large number of drugs in the homoeopathic system of medicine which were derived from plants. Many drugs are plants used as such or their derivatives by way of active principles.

Usage of plants calls for strict adherence to pharmacopoeial standards and proper identification of plants for maximum pharmaceutical efficacy. Departure from such guidelines can result in palpable mistakes and consequent degradation in quality and therapeutic efficacy as well as loss of reputation for the manufacturer. Problems and pitfalls to be avoided are highlighted in this paper.

He stressed upon the importance of proper identification and selection of correct parts of plants in appropriate seasons, adhering to prescribed procedures, be it preparation of mother tinctures or any other pharmaceutical preparations, and ensuring quality medicines with maximum therapeutic efficiency. Stability in botanical nomenclature would ensure research workers and other technical personnel in their search for research literature as well as to ensure whether the proper plant is utilized in each drug.

Good manufacturing practices in Homoeopathy

Vidyaprakash S in his session discussed that Homoeopathic system of medicine is going to be the largest accepted health-care system throughout the world. It is safe, simple, nontoxic, natural, and economical. He emphasized that GMP should be introduced as part of the law, but before implementing the law, government has to interact with large and small scale manufacturers. Suggestions for implementing good GMP were discussed in his presentation.

He added that the government should take immediate steps incorporating CCRH and Homoeopathic Pharmacopoeia Laboratory (HPL) to start a back potency and herb supplying cooperative society including the manufacturers. Recommendations for the changes in the Drugs and the Cosmetics Act should be initiated by the government. Separate drugs control department for homoeopathy should be started in all states.

Volume 24 (3 and 4)

Drug proving special - IV

The issue highlights the methodology adopted for drug proving by the Council. The provings conducted were based on

Drysdale method of proving, i.e., double-blind method where the proving master and prover are blinded. Drugs in potencies to be proved were procured from M/s Hahnemann Publishing Co. Pvt., Ltd., Calcutta by Central Drug Proving Cum-data Processing Cell (CDPC), CCRH Headquarters, New Delhi. The CDPC prepares the phial of globules of different potencies and mother tincture and identical placebo. Medicines were coded, sealed, and sent to the proving master at drug proving centers for proving. Each prover was assigned a code number of CDPC. All provers undergo pretrial and posttrial medical examination before and after proving. The drug in each potency was administered in 4 doses/day for 14 days. The prover makes a record of the signs and symptoms and reports to proving master who interrogates the prover and makes observations. The collected data were sifted, analyzed, and compiled after eliminating symptoms generated by placebo. After unblinding, the final compilation is done after discarding symptoms experienced by controls. The collected and compiled data were then placed before the subcommittee on drug proving, followed by the approval of the Scientific Advisory Committee of CCRH for approval. The drug pathogenesis was published for the profession in the Quarterly Bulletin, and the same was also provided to the clinical verification units.

The issue includes pathogenesis of ten drugs namely, *Acid butyricum*, *Arsenicum bromatum*, *Chromium kali sulphuratum*, *Euphorbia lathyris*, *Ocimum canum*, *Oxytropis lamberti*, *Rauwolfia serpentina*, *Ricinus communis*, *Staphylococcinum*, and *Tribulus terrestris* proved by the Council at its Institutes and units undertaking Drug Proving Research Programme. The details related to proving centers, period of proving, potencies, order of proving, number of provers, staff involved in proving, and pathogenesis evolved of each drug after proving have been elaborated. The pathogenesis was written as per the Kent Schema in detail giving prime importance to the mental symptoms. The first figure(s) in pathogenesis denotes the potency of the drug proved, and the second figure denotes the number of the provers who reported the symptoms. The verified symptomatic data from all the units were collected and compiled at the headquarters and published in the form of monograph/research articles.

Volume 25 (1 and 2)

Clinical verification special - II

Clinical verification is the process of evaluating the clinical applicability of newly proved drugs and drugs with fragmentary data (partially proved drugs). The process helps in establishing the clinical validity of data collected through drug proving on healthy human beings and also guides to reliable indications for therapeutic application in the future use. Council has undertaken clinical verification of 65 drugs which include drugs of indigenous origin and proved by CCRH. The data available in the Materia Medica and compiled from proving was used for a prescription. The Institutes/units engaged in Clinical Verification Research are Clinical Verification Units at Ghaziabad, Vrindavan (Uttar Pradesh); Patna (Bihar), Clinical Research Units (H) Jammu (Jammu and Kashmir),

Homoeopathic Drug Research Institute, Lucknow, Regional Research Institute (H), New Delhi, and Homoeopathic Research Institute for Malaria, Jaipur. The cases were taken from the outpatient department (OPD), and the drug nearest to the symptomatology was prescribed. All cases of each drug were analyzed with respect to the response after prescription and follow-up at the end of trial.

This special issue contains clinically verified data of ten drugs namely *Boerhaavia diffusa*, *Caesalpinia bonducella*, *Carica papaya*, *Hydrocotyle asiatica*, *Jaborandi*, *Nyctanthes arbor-tristis*, *Saraca indica*, *Sarsaparilla*, *Terminalia chebula*, and *Viscum album*. The drugs are incorporated in the Clinical Research Programme of CCRH so that their efficacy in particular disease conditions can be evaluated in comparison to existing drugs mentioned in the literature.

Volume 25 (3 and 4)

A review of scope of animal experimentations in homoeopathy

Singh K.P. highlighted the scope of animal experimentations in homoeopathy in this article. Till to date, research in homoeopathy throughout the world is mainly confined in the human either for proving in healthy volunteers or for clinical verification/clinical efficacy in diseased individuals. Few reports regarding the usage of homoeopathic medicines in veterinary practice, particularly in pet animals were also available in the literature.

Maliekal (1996) had reported that *Kalium muriaticum*, *Phytolacca decandra*, *Hydrastis canadensis*, and *Carcinosinum* could reduce tumor formation in mice while Chaudhary (1980) had shown that *Kalium phosphoricum*, *Calcarea phosphorica*, and *Ferrum phosphoricum* all in 30 potencies, were effective in the cure of artificially induced fibrosarcoma in Swiss mice. Some of the important areas where experiments on animals carried out by the author and his associates along with few homoeopathic medicines which were found to be effective in animal experimentation which are reported in different annual reports of the laboratories are being compiled and reported in this article.

During the course of acute and subacute toxicity study in mice and rats, gross effect of homoeopathic drugs on the central nervous system, namely, alertness, passivity, motor incoordination, equilibrium maintenance, spontaneous motor activity, posture, and behavior was observed. Excerpts from the homoeopathic medicines showing hypoglycemic and hypocholesterolemic effects on albino rabbits, antiulcerogenic and ulcerogenic effects in adults albino rats, and antifertility effects in albino mice unveils the usefulness of homoeopathy as a veterinary medicine. Singh *et al.* in his experiment had shown wound healing capacity of *Calendula officinalis* (Marigold) in artificially produced superficial circumscribed wounds on the back of the rat approximately 2 cm in diameter aseptically under pentobarbitone anesthesia.

Pharmacognostic studies of the seeds of Ulex europaeus Linn.

The authenticity of crude drugs is of prime importance for the preparation and quality of the finished products in

Homoeopathy. *Ulex europaeus* Linn. (English: gorse, furze, and whin) of family *Fabaceae* is a spiny weed, introduced in India from England and naturalized at the higher altitudes of the Nilgiri, Plani, and Kodaikanal hills of South India; it is also cultivated in Shimla hills as a winter fodder. Gupta H.C. in this paper highlights the macroscopic and organoleptic characters, qualitative microscopical studies on transection and longitudinal sections, power studies, and micrometry for evaluating the seeds of *U. europaeus* Linn. in view of obtaining the specific diagnostic characters for quality assurance of the medicine in homoeopathy.

Pharmacognostical studies on stem and leaves of Mirabilis jalapa Linn.

Mirabilis Jalapa Linn. vernacular name Gul Abbas of family *Nyctaginaceae* is a perennial herb or undershrub, native of America, grown for ornamental purpose throughout India. The plant is widely used in various ailments and also as a substitute and adulteration of Jalapa. This paper by Gupta H.C. highlighted the microscopical studies in terms of qualitative and quantitative characterization of various tissues organized in stems along with macroscopic study of leaves of *M. jalapa* have been undertaken. The study was undertaken to evolve the specific parameters to determine the purity and quality of the basic drug material before preparation of medicine.

A study of lesser known drug Anthrakokali

This paper by Ray R.K. and Rai Y underlined the study which was undertaken to verify the symptoms available in the literature, to complete the drug picture and to explore the full potential of a lesser known partially proved drug - *Anthrakokali* in 6C and 30C potency. In the study, One thousand seven hundred and four patients were registered; 1019 patients (59%) improved, 281 (16.49%) shown no improvement while 404 (23.4%) did not report. Both the potencies were equally effective in acute and chronic affection. The drug has shown its action in all the affections, but it has special affinity to skin manifestations and has emerged as an antipsoric drug. The study confirmed the symptoms available in the literature are a reliable indication of drug, a number of new symptoms have also been observed which have been mentioned as additional symptoms.

Gallic acid - case reports

Gallic acid (C₇H₆O₅), a derivative of tannic acid, obtained from galls or Oak apples is a well-known astringent. In the past, it has been found effective in pulmonary hemorrhage with a history of tuberculosis and excessive menstruation. In the proving, symptoms are weakness with irritability, excessive dryness of mouth and throat, sense of contraction of anus, jerking of limbs, and itching of skin. Prakash A and Vichitra AK presented two cases of hemoptysis treated with gallic acid have been presented in this article. The article highlights the chest symptoms mentioned in the homoeopathic literature by Allen T. F., William Boericke, and Clarke J. H. and has been clinically verified in these two cases.

Nyctanthes and fever

Prakash A and Vichitra AK had undertaken the Clinical verification of *Nyctanthes* was undertaken on the basis of available symptomatology in the literature on 1051 patients in OPD. The literature shows its efficacy in fever. The drug was proved by Dr. S.C. Ghosh in cases of bilious and remittent fevers, rheumatism and sciatica, and constipation of children. The study shows that *Nyctanthes* possess the antipyretic effect. It is efficacious in intermittent fever with chill and also been used in fever without chill with predominant bilious symptoms, increased thirst, constipation, and dull headache. The drug was found effective in Q, 6C, and 30C potencies in repeated doses. *Nyctanthes* Q has been found effective in acute cases and 6C and 30C in chronic fever.

Efficacy of lesser known homoeopathic drugs on skin disorders

In homoeopathic literature, a large number of drugs have been mentioned having special affinity for skin ailments. This study by Singh J.P focuses on the clinical efficacy of some indigenous drugs (*Calotropis gigantea*, *Hydrocotyle asiatica* [*Centella asiatica*], and *Hygrophila spinosa*) whose fragmentary data are available on skin diseases, especially on ringworm, exfoliative dermatitis, and urticaria, respectively. The medicines were prescribed on the basis of totality of the symptoms in 6–200 potencies depending on age, constitution, and intensity of the disease. In cases of exfoliative dermatitis and urticaria, 30th potencies were found to be more effective, whereas in cases of ringworm, 6th potency was found to be very effective. The drugs

have been proved to be good for treatment of aforesaid conditions.

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