STANDARDISATION OF HOMOEOPATHIC DRUGS : A PHARMACEUTICAL PERSPECTIVE

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The primary emphasis of Homoeopathy is on therapeutics, the treatment and cure of the disease. In Homoeopathic philosophy ideal cure is rapid, gentle and permanent restoration of health with safe methods and holistic approach.

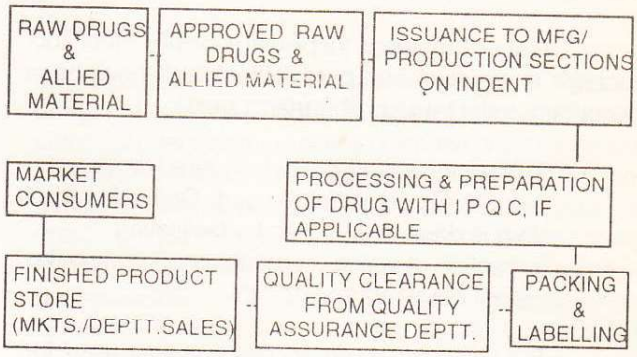
Therefore a quality drug can only give the desired therapeutic response. Therapeutic efficacy of any drug depends upon purity and quality of crude as well as finished drug/product. Hence standardisation is a term used to cover the subject of conformity to fixed standards or to evaluate in comparison to a fixed standard. It is a process to fabricate a uniform and rational product. Alternatively we can say that quality cannot be achieved in the absence of standards.

Homoeopathic medicines as defined under Drug Rule 2 (d d) of Drugs & Cosmetics (D&C) Act at present reads as follows:

"Homoeopathic medicine includes any drug which is recorded in Homoeopathic provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic Pharmacy and covers combinations of ingredients of such Homoeopathic medicine but does not include a medicine which is administered by parenteral route".

Standardisation is also required in men, materials, methods and procedures employed in production of drugs. Quality assurance is a statutory requirement for Homoeopathic drugs as manufacturing, sale, distribution, possession and transport of these drugs comes under the purview of D & C Act.

A schematic flow diagram showing general plan of manufacturing and allied activities in a pharmaceutical manufacturing company is given below.



So in the array of pharmaceutical procedures procurement of authentic raw material is the first step.

Parameters for Raw Material

Considering the various sources of raw materials in Homoeopathy viz. botanical, biological or mineral origin, the drugs may have different parameters.

The parameters, in general, can be summarised as below:

1. Botanical/Biological/Microbiological/Chemical Names etc.
2. Description.
3. Identification.
4. Part used.
5. Assay.
6. Preparation.
7. Chemical/Biochemical reactions.
8. Limit tests/solubility/M.P./B.P./Assay for chemicals
9. Macroscopy/Microscopy/Distribution for botanical drug,
10. Habitat.
11. History & Authority
12. Caution/Toxicity.
13. Storage.

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Similarly the second phase in the manufacturing unit is analysis of raw materials on the basis of above standards and their issuance in batch wise manner from approved raw material store, to production sections on their indent.

Manufacturing section has a standard methodology for preparation of a pharmaceutical product with the help of standard equipments.

General methods for preparation of mother tincture are maceration and percolation which have been described under various pharmacopoeias.

- For organised, air dried, powdered drugs process of percolation is used. Comminution of drug is done to a degree for facilitating extraction of active constituents containing the widest range of constituents.

- For unorganised drugs, maceration is done for about 14 days as per method of Homoeopathic Pharmacopoeia of India (H.P.I.)

Further potentisation of tincture and raising to higher potentised derivatives is a part of production activity. It is done in accordance with Hahnemannian or Hering's principles as mentioned in Homoeopathic Pharmacopoeia of India. Sometimes fifty millesimal potencies are also prepared which is also official in H.P.I.

After processing/preparation of mother tinctures & potencies, they are subjected to filling/packaging in final containers/bottles followed by as per drug rules.

Final container is subjected to quality assessment in Q.C. labs. for various statutory tests of contents and labelling requirements. Packaging material such as bottles/cartons/closures are also subjected for Q.C. tests.

Parameters for Finished Products

1. Alcohol content
2. pH value
3. Wt. per millilitre
4. Total solids
5. % max (Max. absorbance in U.V. range)
6. Identification Tests
   - Colour reactions
   - T.L.C. / Co -T.L.C.
7. Assay
8. Absence of foreign matters
9. Absence of abnormal toxicity
10. Sterility in selected categories

After getting quality clearance from the quality assurance sections, production section releases the batch of drugs to Marketing/Sales Deptt. of the manufacturing units to meet the demand from consumer/market for that product.

Currently all the procedures coming in the domain of pharmaceutical manufacturing should comply with Good Manufacturing Practices, precisely known as GMP for aesthetic and ethical products/drugs so that goal enunciated by the slogan "Health for all by 2000 A.D." is achieved.

Substances belonging to the animal and vegetable kingdom possess their medicinal qualities most perfectly in their raw state. [142]

Organon of Medicine - Aphorism 266
Samuel Hahnemann
