EDITORIAL FOR OCTOBER 2014

QUALITY CONTROL IN HOMOEOPATHY

Quality control is total procedure for providing the standard medicines to the patients. Quality control is a procedure through which a raw material is transformed to a drug and the finished product till it is used by the patient. One of important function of Quality Control department is to establish specifications for raw materials, packing materials, intermediates and finished products to assure the quality.

In India the Homeopathic Pharmacopoeia Laboratory (HPL) (1975) under the ministry of Health and Family Welfare, Government of India. is responsible for quality control and standardization of homoeopathic drugs.

Homeopathic Pharmacopoeia India (HPI) is the book we need to refer, it has total 1016 monographs, once the homoeopathic pharmacopeia laboratory brings out its standards it is later reviewed by Homeopathic pharmacopoeia committee and finally the results are published Homoeopathic pharmacopeia. Homoeopathic pharmacopeia codex publish in 2004 contain detail of 1000 drugs.

What does Pharmacopeia contain?

It contains monograph of each drug e.g. details for identification, details for collection, part to be used, method of preparation, assessment of purity and limits of impurity.

For Quality Control and Standardization one be very vigilant for the following

- Analysis of finished products,
- Comparison with standards and analyzed, testing of purity manufacturing
- Dispensing
- Handling and packaging of medicines
- Identification of adulterants
- Machinery
- Manufacturing area,
- Monitoring industrial waste
- Packaging
- Processing different methods of preparation,
- Sampling of raw materials
- Storing

- Utensils

What is the aim of Quality Control?

The main aim is to give standardised medicine to our patients.

Quality can be defined as the status of a drug that is determined by identity, purity, content, and other chemical, physical, or biological properties, or by the manufacturing processes. Quality control is a term that refers to processes involved in maintaining the quality and validity of a manufactured product.

In general, quality control is based on three important pharmacopoeial definitions:

Identity: Is the herb the one it should be? Purity: Are there contaminants, e.g., in the form of other herbs which should not be there? Content or assay: Is the content of active constituents within the defined limits?

There are two types of standardization

In the first category, “true” standardization, a definite phyto-chemical or group of constituents is known to have activity. Let's examine the alkaloid of Nux vomica -they are as follows The composition of TAF and MTAF were determined by HPLC analysis. The results showed that

Strychnine, Brucine, and Brucine N-oxide accounted for 42.35 ± 2.22%, 20.56 ± 0.95%, and 0.091 ± 0.007% in TAF (n = 5), respectively, while the corresponding percentages changed to 18.05 ± 1.07%,

40.67 ± 1.15%, and 0.250 ± 0.029%, respectively, in MTAF (n = 5). It was obvious that most of the

strychnine was removed from MTAF and the ratio of brucine to strychnine changed from 1:2.05 to 2.2:1. The percentage of other alkaloids except strychnine and brucine were 38.09% and 41.29% in TAF and MTAF, respectively. HPLC chromatographs of TAF and MTAF are shown in Figure 2. In addition, compared to TAF, the yield of brucine in MTAF was calculated to be 92.69%.

The other type of standardization is based on manufacturers guaranteeing the presence of a certain percentage of marker compounds; these are not indicators of therapeutic activity or quality of the herb.

Strict guidelines have to be followed for the successful production of a quality drug.

The following are the parameters for Quality Control and standardization of Drugs

- Raw materials
- Manufacturing process,
- Finished products and
- Storage and packaging

In raw material following factors needs to be taken care of

1. Medicinal

Minerals, Herbs and animals etc

Microbes, pathological products, healthy tissues, drugs

2.Non medicinal (vehicles)

Alcohol, Lactose ,Sugar ,White petroleum jelly etc.

The quality of raw materials are ascertained and standardized referring HPI.

In case of raw material resources it is mandatory to follow the guidelines of

GAP- Good Agricultural Practices,GHP- Good Harvesting Practices,GHP- Good Laboratory Practices

Also taking care of incoming raw material,transfer,sorage,sampling,identification,purity testing and looking after the whole manufacturing process .

Finally the need of our hour is a smart packing, I am not happy with homoeopathic pharmacies dispensing medicines in a plastic bottle they do not look at all attractive and very often the cap of the bottle is defective, here one needs to learn from western countries.