FORMULATION AND EVALUATION OF THE HERBAL INGREDIENTS AND OFFICIAL HERBAL DRUGS

Classification of the ingredients

1)Solid
2)Semi solid
3)Liquid or Oil herbal

- Solid Herbal Ingredients: Senna,Digitalis,Cinchona,ipecacuanha,Ginger etc….
- Semi solid Herbal:Aloes,Acacia,Tragacanth,Guar gum etc…
- Liquid or Oil Herbal:Castor oil,Almond oil,Cedar oil all types of oil include in the Oil herbal..

FORMULATION OF HERBAL INGREDIENTS

- ✓ **For the Solid preparation**: Drugs are cleaned and dried. They are coarsely powederd, weighed as per formula, and then mix well..

- ✓ **For the Semi solid preparation**: the preparation generally have liquids, sugar or sugar candy, powders or certain drugs, oil and honey..
  Sugar or sugar candy dissolved in the liquid and strained to remove the foreign particles. This solution boiled over a moderate fire.when pressed between two figers or when it sinks in water without getting easily dissolved, it should be removed from the fire. Fine powders of drugs are then added in small quantities and stirred continuously and vigorously to form a homogenous mixture. Oil is mentioned is added while the preparation is still hot and mixed well. Honey , if mentioned is added when the preparation is cool and miwed well..

- ✓ **For the Liquid preparation:** for this preparation generally steam distillation method is used. The drugs are cleaned and coarsely powdered. Some quantity of water is added to the drugs for soaking and kept over-night. This makes the drugs soft and when boiled releases the essential volatile principle easily. The vapour is condensed and collected in a receiver. In the beginning, the vapour consists of only steam and may not contain the essential principles of the drugs. It should therefore be discarded. The last portion also may not contain therapeutically essential substance and should be discarded. The aliquots collected in between contain the active ingredients and may be mixed together to ensure uniformity of the product..

SUGGESTED EVALUATION METHODS

- ✓ As mentioned earlier that the expiratory date can not be used for the herbal formulations.

- ✓ This guidelines details out simple quality assessment parameters as a means of evaluating "the best before use date"

♦ EASIEST METHOD TO PREDICT DATE IS

1. To decide requisite condition and parameter to be monitored during
   Processing
   Packing
   Storage condition
2. Selection of packing material
3. Exposing packs to challenging conditions to study behavior of formulation in

A. STEPS

1. Batch size of at least 5% of the regular production batch is taken for testing.
2. Samples from one to three batches are selected.
3. The properly closed selected packs with one or more intended packing material proposed for packing the formulation is recommended for such study.
4. Adequate numbers of sample are required.
5. If more than one packaging material are to be studied test for each packaging material is required with the same batch.

B. CHALLEGING CONDITION FOR STORAGE OF PACKS FOR ACCELERATED STUDIES

- AT 45 ± 2 0 C
- AT 40 ± 2 0 C / 75% ± 5% RH
- For comparison purpose one set of sample to be stored in a refrigerator below 25 0C
- Samples are to be evaluated on pre decided parameter at 0, 1, 2, 3 and 6 months.

C. REAL TIME STUDY

- Temperature = 30 0 C ± 2 0 C
- Relative humidity = 65% ±5%
- For long period of time.

- Samples are evaluated at 0,3,6,12,18,and 24 months

D. PARAMETERS TO BE EVALUATED

1. Appearance
2. Colour
3. Odour

4. Taste
5. Particle size
6. Flowability
7. Viscosity
8. Clarity
9. pH
10. Moisture content
11. Sedimentation
12. Flocculation
13. Emulsion breakage
14. Friability
15. Hardness
16. Extractive Values (in selected solvents)
17. Volatile matter contents
18. Free fatty acids/ acidity
19. Peroxide values
20. Microbial parameters
    - Total viable count (TPC)
    - Yeast and mould count (YMC)
    - Coil form count and other pathogens
21. Specific parameters applicable to formulation / dosage form

E. HOW TO DETERMINE THE CRITICAL PARAMETER

- ✓ Done by intentionally exposing the formulation to such conditions promoting their degradation and determining the critical parameter.

- ✓ eg. Churna have moisture content 3.5 % when it increase up to 7-10 % start to look different and can start degradation.