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*for a sustainable future*

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## ZANDU AV SCRIPT

### PRELUDE

According to the Ramayana, India's greatest epic, When Laxman got seriously injured in battle, Hanuman, the monkey God set out in search of the medicinal herb Sanjeevani found only in the Himalayas.

Not wanting to pick the wrong herb he uprooted an entire mountain and flew miles to revive Lakshman.

In today's world one does not have to go to such lengths to get an authentic herbal remedy, thanks to the standardization that goes into the formulation of herbal medicines. Dr. Handa of Zandu Pharmaceuticals will tell us more about it.

### INTRODUCTION

Hello At the outset I, on behalf of Zandu Pharmaceuticals works would like to express my sincerest thanks to ICS-UNIDO for giving us this opportunity to prepare a video film on standardization and quality control of herbal medicinal preparations, to promote herbal remedies in the National Health Care programme.

The World Health Organization promotes encourages the use of herbal remedies because they are easily available, economical, comparatively safe. Moreover people have faith in these remedies. In the recent past there has been a tremendous interest in the west for the use of herbal remedies and this has evoked extensive scientific interest in the quality and safety of herbal drugs.

While emphasizing the role of herbal medicines in the developing countries WHO has laid special emphasis on the quality safety and efficacy of these herbal products.

The most important factor, which stands in the way of the wider acceptance of herbal remedies, is the non-availability and inadequacy of quality control standards.

The difficulty in developing quality control standards for herbal drugs is that the products are either whole plant or a part of the plant or they are poly herbal formulations. Besides this the raw materials in majority of the cases comes from wild sources. The inconsistency caused by various factors such as age and origin of the plant the harvesting period the drying process and storage and so on.

Standardisation therefore embodies the total control and information necessary to guarantee the consistency of the finished final herbal product.

Before we get into the standardisation of herbal medicinal products it would be appropriate to clearly define Herbal Drugs, Herbal Drug preparations and Herbal medicinal products.

Herbal drugs are mainly whole or cut plants or part of plants in an unprocessed state. Herbal drugs are precisely defined by their botanical scientific names .Herbal drug preparations are

obtained by subjecting herbal drugs to treatments such as extraction, distillation, purification concentration etc.

These include powdered herbal drugs, tinctures, essential oils etc.

Herbal medicinal products are medicinal products containing herbal drugs or herbal drug preparations as active substances.

The general protocol followed for standardisation of raw materials are as follows.

Authentication

Post harvest technology.

Determination of Foreign matter.

Macroscopic and organoleptic examination

Microscopic examination

DETERMINATION OF Microbial count

Determination of volatile matter .

Determination of ash value.

Moisture determination

Extractive value.

Isolation of Marker compounds.

Chromatographic profile .

Pesticide residue.

AND

Determination of Arsenic and Heavy metals.

## **AUTHENTICATION**

Authentication includes correct botanical identification and proper care of raw material...

Botanical identification is usually done with the help of herbariums, taxonomic literature, floras, and monographs,. Identification involves establishing correct nomenclature of the species the genus ,the authority and the family

Flow charts, help in the correct botanical identification.

A plant could be an angiosperm or a gymnosperm.

Angiosperms can be classified into monocotyledons or dicotyledons.

In this way by going thru the flow chart a systematic identification of the plant can be done.,

## **Post-harvest technology in medicinal plants**

Harvest technology and post harvest care of the plant material includes

Time of harvesting

Method of harvesting

Grading, curing and value addition

Drying

and

Storage

The time of harvesting is very important for medicinal plants and varies with individual plants.

As a general principle, aerial parts need to be harvested during flowering, underground parts after the aerial parts dry up, and barks should be gathered just after the rainy season.

The method of harvesting depends on the part of the plant to be harvested. In the case of rhizomes, the rhizomes are dug out, made free from roots and mud particles and cut into pieces. These pieces are then dried first under shade and then in direct sunlight.

Harvested produce has to be dried systematically to reduce moisture content and preserve active principles.

The rhizomes are generally graded based on their size. The dried, processed, and graded rhizomes are finally packed in gunny bags and stored in godowns.

Proper storage is essential for retaining the vital principles of the herbs.

For example if Bramhi leaves are stored in polythene bags instead of the recommended storage bags, they get discoloured.

*In the case of Mucuna pruriens, the pods are collected only after they are matured. The maturity of the pods are indicated by the blackening of the pods. The pods are then dried under direct sunlight. Non dried pods are sorted out and then discarded. The dopa seeds are then removed and stored in gunny bags.*

### **Foreign Matter**

To determine foreign matter percentage.

Weigh 100g of the drug sample

Remove foreign matter manually

. Foreign matter constitutes soil, stone, dust, insects, and even plant parts other than what constitutes the drug.

Weigh again and determine the percentage of foreign organic matter (Generally it should not exceed 2 %).

### **Macroscopic & Organoleptic examination**

Macroscopic identity of medicinal plant material is based upon shape, size, and surface characteristics, of the herbal drug.

Wrinkled leaves, should be stretched for macroscopic examination.

Organoleptic examination of herbal drug is done to determine its colour, taste, odour etc. To determine the odour, crush the drug sample and note the odour. If a sample is found to be significantly different in terms of colour, odour, shape, size or taste, from the specifications, it is rejected.

Microscopic examination of the plant drug is essential for the correct identification of the plant material and also to detect adulterants . Microscopic features like the type of stomata, nature of trichomes, vessel thickening, stomatal number, stomatal index and pallisade ratio are of immense value for plant drug standardization.

For Microscopic examination of powdered materials:

- Put the specimen on slide.
- Add water and spread the specimen evenly.
- Stain and place the cover slip
- Observe under microscope

### For Surface study of leaves

Keep the leaf overnight in 20% aqueous potassium hydroxide. Remove the leaf from potassium hydroxide solution and keep it in a mixture of hydrogen peroxide and chloro hydrate for half an hour. Wash with water and stain with 1 % *safranin* and observe.

For in-depth study, one has to examine a section of the specimen. To make a section., select the representative piece of material being examined and cut into suitable lengths.

Thin materials such as leaves, petals, soft slender stems should be bound between two halves of a piece of pith. Cut the section as thinly and evenly as possible.

- Transfer the sections into to a dish containing a solvent comprising of 85% water and 15% Glycerine to prevent dehydration.
- Stain the section with saffranin and then mount in glycerine and observe.

Dried specimens may require softening by soaking in water, ethanol and glycerol..

Prepare transverse sections by cutting at right angle to the longitudinal axis of the material with a sharp blade or a microtome

### **MICROBIAL COUNT**

Medicinal plant materials normally carry a large number of bacteria and moulds, often originating in the soil. Current improper practices of harvesting, drying, handling, storage and processing may cause additional contamination and microbial growth.. All these contaminants can be hazardous to health, if absorbed even in very small amounts.

In the laboratory, the medicinal plant material is examined ,

a)To Determine the Total Viable Count, TVC / gm.

b)To Determine the Yeast and Mold count, YMC / gm.

and

C )To detect presence or absence of *E- coli* and other such microorganisms.

All microbiological operations are carried out in the Laminar Airflow L A F.

- Sterilize washed and cleaned glassware in a hot air oven at a holding temperature of 160°C for not less than two hours. Prepare the media as per standard procedures.
- Sterilize the prepared media in an autoclave at a holding temperature of 121°C for 15 minutes.
- To Pretreat the sample to eliminate anti microbial properties.
- Dilute the sample in sterile Lactose Broth or suitable medium.

### Determination of Total Viable Count

- To determine the total viable count employ the Pour Plate Technique using suitable sterile medium.
- Dilute pretreated material to obtain a colony count of not more than 300 on one plate.
- Incubate at 37 degrees centigrade for five days.
- Count the number of colonies using colony counter and calculate the total viable count per gramme of sample.

Determination of yeast and mould count is similar to the determination of total viable count.

To detect the presence or absence of microorganism pretreat the sample and put into suitable enrichment medium.

Incubate them at 37 degrees centigrade for 5 hours. Take one ml and put it into enrichment medium.

Incubate at 37 degrees centigrade for 27 to 34 hours.

Isolate on suitable selected agar medium plates to obtain the characteristic colony. Confirm the by performing biochemical tests and microscopy.

All glassware and medium are discarded by autoclaving after use.

As per the standard specification of TVC, YMC and presence or absence of specific test organisms the sample is considered passing or failing.

#### **Determination of VOLATILE Matter :**

The determination of volatile matter of the plant drug is done by hydro-distillation.

To determine volatile matter

Weigh 10g of sample in the coarse form.

Transfer it in to the reflux flask of the Clevenger Assembly.

Add about 200ml of distilled water in it.

Put some pumice stones to avoid bumping of the sample.

Arrange the reflux flask and clevenger assembly in the heating mantle.

Slowly increase the temperature of the mantle.

Allow to distill for about 4 to 5 hours for complete extraction of oil.

The oil being heavier than water is collected at the bottom of the graduated tube.

Note the reading of oil collected.

Calculate the percentage of the volatile oil by applying the following formula.

$$\% \text{ of the Volatile Oil} = \frac{\text{Amount of oil collected in ml}}{\text{Weight of the sample in gram}} \times 100.$$

#### **Ash value DETERMINATION**

After receipt of the raw material, the sample is picked up from the container for analysis as per the WHO guidelines. The containers are again sealed and labelled 'Under Test'. The sample is powdered in the grinding mill, it is then passed through the 60 mesh sieve to get homogenous powder for physicochemical analysis.

#### **Determination of ASH :**

Total ash includes both "Physiological ash", which is derived from the plant tissues, and "Non physiological" ash, which represents the residue of the extraneous matter (e.g. sand and soil) adhering to the plant surface.

To determine the percentage of total ash

- 1) Weigh the dry empty silica crucible. Note down the weight (W1).
- 2) Weigh accurately about 2-4g of powdered sample in the crucible. Note down the weight in gram (W2).

- 3) Transfer it to the dessicator.
- 4) After, dessication, keep the crucible on the burner and allow the sample to char.
- 5) Transfer the charred sample into the muffle furnace and adjust the temperature to 600°C.
- 6) Incinerate the sample for about 2-3 hours.
- 7) Transfer to the dessicator to attain room temperature.
- 8) Weigh the crucible with the ash.
- 9) Repeat incineration till you get constant weight of the crucible containing ash. Note the weight in grams Calculate the percentage of total ash by using this formula

$$\text{Percentage of Total Ash} = (W3 - W1) / (W2 - W1) \times 100$$

Where

W1 = Weight of the empty crucible

W2 = Weight of the crucible and sample

W3 = Weight of the crucible and ash

#### Determination of ACID INSOLUBLE ASH :

Acid insoluble ash measures the amount of silica present, especially as sand and silicious earth.

To determine the prescence of acid insoluble ash

- 1) Add 25ml of dilute Hydrochloric acid to the total ash.
- 2) Boil gently for 5min. on hot plate
- 3) Cover with a watch glass. Allow it to attain room temperature.
- 4) Rinse the watch glass with 5ml of distilled water and add this liquid to the crucible.
- 5) Filter through ashless filter paper No.40.
- 6) Give 3 to 4 washings to the residue collected on filter paper, with hot distilled water.
- 7) Check the filtrate for its acidity.
- 8) Go on giving the washings till it becomes neutral to litmus paper.
- 9) Dry the filter paper carefully in an oven kept at 105°C temperature.
- 10) Transfer the residue along with the ashless filter paper into a previously weighed silica crucible.
- 11) Heat the crucible on the burner, char the paper.
- 12) Incinerate in the muffle furnace at a temperature not exceeding 450°C for about 2 hours.
- 13) Transfer it into the dessicator, allow to attain the room temperature, protecting from the moisture in the atmosphere.
- 14) Weigh the crucible with the residue, note the weight in grams (W3).
- 15) Repeat the incineration process till you get constant weight .Note down the same
- 16) Calculate the percentage of Acid insoluble ash by applying the formula :

$$\text{Acid insoluble ash in \%} = (W3 - W1) / (W2 - W1) \times 100$$



Where, W1 = Weight of the empty crucible

W2 = Weight of the crucible and sample

W3 = Weight of the crucible and ash.

### Moisture Determination

Presence of excess water in medicinal plant material will encourage microbial growth. The presence of fungi and insects, could lead to deterioration. Therefore, limits for water content should be set for every given plant material.

#### To determine the moisture content in a given plant material

- 1) Weigh an empty dry LOD bottle. note the weight.
- 2) Weigh exactly 1 to 2 gm of powdered sample and transfer in the previously weighed LOD bottle. Note the weight of LOD bottle containing sample.
- 3) Keep the LOD bottle with the sample for 3-4 hours in an oven at 105°C.
- 4) Transfer to the desiccator to attain room temperature.
- 5) Weigh the LOD bottle again with the sample
- 6) Calculate the Loss On Drying in % by applying following formula.

$$\text{Loss on drying \% w/w} = \frac{W2 - W3}{W2 - W1} \times 100$$

where,

W1 = weight of empty LOD bottle in gm.

w2 = weight of LOD bottle containing the sample before heating.

w3 = weight of LOD bottle containing the sample after heating.

### **EXTRACTIVE VALUES**

#### Determination of EXTRACTIVE VALUES:

The extractable matter refers to the amount of constituents in a given amount of medicinal plant material extracted with solvents. Such extractive values provide an indication of the extent of polar, medium polar and non-polar components present in the medicinal plant material..

*Extractive values can be classified into water soluble extractives and alcohol soluble extractives.*

#### TO DETERMINE THE EXTENT OF WATER SOLUBLE EXTRACTIVES

Weigh 5g of dried powdered sample in a dry stoppered conical flask.

Add exactly 100ml of distilled water.

Put the stopper and shake well frequently for 6 hours.  
Allow to stand for 18 hours  
Filter through filter paper No.1 into a dry conical flask.  
Weigh a dry empty petridish note the weight  
Pipette out exactly 20ml of filtrate representing 1g of crude drug into the petridish.  
Evaporate the filtrate on a water bath at about 80°C-100°.  
Transfer the petridish into an oven and dry it at 105°C for 2 to 3 hours  
Remove the dish out and transfer in the dessicator.  
Cool to attain room temperature and weigh the petridish  
Repeat the heating procedure till you get constant weight, note the weight (W2).  
Calculate the percentage of water soluble extractive by applying the following formula.

Percentage of Water Soluble Extractive =  $(W2-W1) \times 100$  where W1 is weight of empty petridish and W2 is the weight of petridish and water soluble extractives.

#### To determine ALCOHOL SOLUBLE EXTRACTIVES

The same procedure as water soluble extractives is followed.

The only difference being instead of 100ml of water 100 ml of alcohol is used.

Alcohol Soluble Extractive =  $(W2-W1) \times 100$  where W1 = weight of empty petridish and W2 is the weight of the petridish + the alcohol soluble extractives.

#### **ISOLATION OF MARKER COMPOUNDS.**

To isolate a marker compound prepare a plant extract by adding sample to the extractive solvent. Enrich the extract by placing in a water bath. Fix the reflex condenser and remove the solvent by rotary evaporation. Select and load the adsorbent material on to a preparatory glass column. Load the enriched extract on the selected adsorbent. Load the extract on to the packed preparative column and elute the absorbed extract into fractions with different solvents. Collect these solvents and evaluate on thin layer chromatography. Mix the identical fractions and dry the fractions on a rotary evaporator. Repeat the procedure till you get a single marker compound. Characterize the isolated marker compound by IR Spectrophotometry. Characterisation of the compound is also done by IR Spectroscopy, Mass spectroscopy and Nuclear Magnetic Resonance.

#### **HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY (HPTLC)**

Prepare optimized sample needed for loading using, optimized extraction, filtration and enrichment of compounds. Ensure that the sample is subjected to chromatographic separation as quickly as possible.

For HPTLC

Start nitrogen gas flow.

Select the required precoated HPTLC plate and place it on the linomat.

Pre-coated plates with different adsorbent layers are available. Usually plates with sorbent of 0.1-0.25 mm thickness are used.

Load the syringe with the reference solution, select a track and start application.

Then load the sample and repeat the process of application.

Sample application is the most critical step for obtaining good resolution for quantification by HPTLC. The sample should be applied in the form of a spot or a band without damaging the layer.

Take the mobile phase into a glass chamber.

Place the TLC plate with the sample spots in the mobile phase.

Time required for separation will depend on the layer thickness nature and composition of mobile phase. The retention factor can be marked in the finger print of the extract. One of the peaks in the finger print of the extract corresponds to the marker isolated from the same extract.

The retention factor is the distance traveled by the sample divided by the distance traveled by the mobile phase.

After development, remove the plate, from the chamber evaporate the solvent and observe the plate under UV light and mark the UV sensitive bands

The chromatogram thus obtained can serve as "fingerprint" for that sample.

Integrate the peaks from different tracks.

### **HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)**

HPLC is one of the most powerful analytical tools available for the analysis of herbal drugs and phytopharmaceuticals. It is probably a technique with least limitations as almost all types of samples, irrespective of their physical or chemical nature can be analysed with tremendous ease and accuracy.

To start, fill the solvent reservoirs with sufficient solvent. This solvent acts as the mobile phase and is maintained by a pump. Select a suitable column and fix it in the column oven.

Now Place the standard solution in the auto sampler. Integrate the peak of interest after completion of the run.

Place the sample in the auto sampler. The mobile phase carries the sample to the column containing a stationary phase where the sample mixture separates into different components and they get retained in the column for a specific time, which is characteristic for each

component of the sample mixture. Unretained components are eluted first, followed by other components depending on their retention time in the column. Retention time is the time taken for the component to elute from the column. The detector traces the eluted components, which are recorded as peaks and stored by an integrator or a computer.

Integrate the peak of interest after completion of the run. Compare the area of sample with the area of the standard and calculate the percentage of marker compound.

Depending upon the types of compounds requiring separation, the appropriate Normal phase or Reverse phase columns are selected. In normal phase columns, low-medium polar solvents are used while in Reverse phase High to medium polar solvents are used for separation.

The separation of components of a sample mixture is achieved by controlling the following factors :

Mobile Phase composition :

Flow rate :

c. Column length ;and..

d. Detectors :

The most common detection methods in HPLC are based on UV absorption of sample components.

Depending on the selectivity requirements, other detectors based on the properties of the sample are also used, like

Light scattering detector

Refractive index detector

Conductance detector

Fluorescence detector

### **GAS CHROMATOGRAPHY (GC)**

In plant material where the active principles are volatile and thermally stable, Gas chromatography is preferred over HPLC.

Prepare a reference solution.

Prepare the sample solution.

Fix the column.

Straight columns are most efficient but difficult to accommodate, so U-columns or spirals are usually used. Usual diameter for analytical packed columns is 2 mm or 4 mm ID.

Start the carrier gas flow. The carrier gas must be inert to both sample and stationary phase.

Set the temperature for injector and detector.

Injection port should be hot enough to vaporize the sample rapidly. The oven temperature should be 5-10°C lesser than that of the injector and detector.

Start the fuel gas flow.

Light flame on FID

Set the required parameters. (loading)

Inject the reference solution and start the run.

The FLAME IONIZATION DETECTOR yields excellent sensitivity and a wide linear dynamic range.

Integrate the peak of the reference solution

Inject sample. Injection should be rapid so as to obtain minimum bandwidth at start.

Non-polar solutes will remain in a non-polar stationary phase longer than in a polar phase and vice versa. However, columns of intermediate polarity can give good separation for both oxygenated and non-oxygenated materials.

Integrate the peak of interest of the sample solution.

Compare the area of the sample with the area of reference and calculate the percentage of marker compound.

#### Gas Chromatography - Mass Spectrometry :

GC MS is the same as Gas Chromatography except that the carrier gas used is helium and the detector used is Mass Selective Detector.

In GC MS along with the chromatogram we also acquire a mass spectra of the same peak after the completion of the run. We also acquire the molecular structure of the compound.

#### **DETERMINATION OF PESTICIDE RESIDUES**

To analyse pesticide residues the GC operating procedure is followed except that the carrier gas is helium instead of Nitrogen and the reference solution is aldrin instead of menthol. The detector used is an EC Detector.

**DETERMINATION OF ARSENIC AND HEAVY METALS** Environmental pollution and traces of pesticides can contaminate the medicinal plant material with arsenic and heavy metals like cadmium and lead.

**To determine the heavy metal content in a hard herb for example**

Take hard herb and keep it in an oven at 105 C for drying.

After drying, grind it to powder form.

Take 1g from the above powder in a crucible and keep it in a muffle furnace at 250-300C to procure ash.

In a 250 ml conical flask, Mix 30 ml of Hydrochloric acid and 10-ml of Nitric acid to form 40 ml of aqua regia.

To this add the ash and digest it in an electric digester. Cool this and add distilled water to make the volume upto 100 ml.

Filter it and take the reading of the filtrate against a blank on an Atomic Absorption Spectrophotometer.

The following maximum amounts in dried plant materials, are allowed

Lead                    10 mg /kg

Cadmium                0.3 mg/kg

## **SAFETY EVALUATION OF PLANT DRUGS**

### **TOXICOLOGICAL STUDIES.**

Basic facilities required in herbal - drug safety laboratory include, refrigerator weighing scale, microscope hot water bath, microtome bio chemical analyzer, centrifuge, histology processor etc.

The toxicological risk can be evaluated by animal experiments.

Albino rats and albino mice are commonly used because of s their defined health status, genetic homogeneity, low cost, easy maintenance, short life span and availability of large amount of baseline data.

Before any studies are done the rats are weighed because the quantity of the test substance varies according to the weight of the animal. **Short-term safety study** is carried out on mice or rats by giving large single doses in logarithmic proportions.

. These doses are given in liquid form. If the test substance is in solid form like tablets or powder, it is mixed in some inert suspending agent like CMC solution in a known proportion.

The required calculated dose in the solution or suspension form is given to these animals orally with the help of a syringe and a feeding needle. Dermal preparations like balm, liniment etc are tested on the skin of clean-shaven backs of adult rats weighing about 250 g. These preparations are weighed and required dose calculated and applied on the back of each rat and then they are restrained in the rat traps for 24 hours so that the animals cannot lick the test substance and also cannot scratch or mutilate their bodies. This is to ensure that if there are any pathological changes then they will be only due to the test substance. For dermal preparations Draize score tables are used to read the result.

For toxicity studies high doses are used for limited periods of time to exaggerate the possible effects in the shortest period of time to determine the LD 50 value. Higher the LD 50 value safer is the drug.

Maximum tolerated dose MTD is the highest feasible dose, which can be given in a rat or mice that will not produce any toxic symptoms or mortality. If the drug is found to be safe in the acute toxicity test then it is taken up for further study to evaluate the long term toxicity by repeated administration of drug for longer periods

In any of these long term studies all important parameters like weight gain, behaviour, toxic symptoms, state of stools, mortality etc. are observed throughout the drugging period and at the end of the study tests like urine analysis, haematology, biochemistry tests, necropsy, gross pathology, weights of the important organs and histopathology under microscope are done.

#### **GOOD MANUFACTURING PRACTICES (GMP)**

In most countries the manufacturing premises of the pharmaceutical industry units are inspected and approved by the Drug Controller during the course of operations... The quality and safety of pharmaceutical products is ensured by inspection and checks before, during and after manufacture. Some voluntary and some statutory codes have been developed to ensure observance of GMP.

: Building should be located in clean, healthy surroundings, and designed, constructed, adapted, located and maintained to suit the operations carried out within. The walls and floors of the room(s) in which manufacturing operations are carried out shall be impervious to water and be capable of being kept clean.

The manufacturer shall provide adequate working space and adequate room for the orderly placement of equipment and materials so as to minimize mix-ups between different drugs and

raw materials There shall be adequate space in storage areas and wherever necessary controlled temperature and humidity.

: Facilities, systems and procedures should meet a high standard of safety, orderliness, hygiene and comply with loss prevention policy of the organization.

Equipment including services and containers should be designed, to suit the processes and products for which they are used.

Cleaning of equipment may involve use of suitable scrubbers and air pressure. Records of all cleaning operations done periodically shall be maintained.

: All raw materials including crude herbs, herbal extracts, in process material and excipients shall be properly stored in chambers maintained at desired temperatures and humidity..

Procedure of "First In First Out" (FIFO) should be adopted for raw materials.

Records of the receipt, testing and approval or rejection and usage of the raw material shall be adequately maintained.

The batch manufacturing record of each batch of herbal drug manufactured must be maintained.

Manufacturing records are required to provide a complete account of the manufacturing history of each batch of the medicine., Records of finished product produced, and yields obtained, testing of the finished product (if any) packaging records and labeling records shall be maintained.

All packaging materials like bottles, caps and other packaging materials shall be procured and stored properly.

A defined quality control system should exist comprising checking of all incoming materials and finished products. There should be independent overseeing of processes and examining of samples of finished products..

Staff employed must have requisite qualifications, training and must be available in adequate numbers to suit the production processes and products which are produced.

: Suitable arrangements shall be made for the disposal of waste water and other residues from the manufacturing premises in a manner as may not affect the health of the people in the area adversely.



For STABILITY STUDY OF PLANT DRUGS usually a random sample from various batches produced are tested.

The samples are then kept at room temp for a defined period and then transferred to a stability oven set at 37 C. The sample is then transferred to another oven set at 45 C and the results analysed.

Dr.Handa

This documentary is to show live demonstration of different techniques used for the standardisation of herbal drugs for which all facilities available at Zandu Pharmaceuticals works has been utilized.

I sincerely hope it will help impart in house training on standardisation in herbal drug industries in developing countries