KNOWLEDGE OF SHELF LIFE OF DRUGS (AYURVEDIC)

PRESENTED BY

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Introduction

- Ayurveda is a natural gift to humanity for its betterment. Since ancient time human have feeling himself as a part of the Mother Nature, thus there was no problem in accepting the natures gift for his benefit. This seems to be the origin of the eternal health science; every thing in the nature can be beneficial but cannot be used in raw form which leads to development of art of modification for improving its beneficial effect & eliminating the unwanted aspects.

  Thus to achieve these aspects different dosage forms of a drug were developed which comes under the umbrella of Ras Shastra and Bhaishjya Kalpana.
Objectives of Ayurveda are...

- Prevention, Promotion & Maintenance of Health in Healthy
- Treatment of Diseases.

It specifies that, Ayurveda deals with the Health Promotive, Preventive, & Curative aspects of life in a most comprehensive way.
Four Folds Of Chikitsa..

Also known as chikitsa chatushpada.....

- Physician
- Drug
- Patient
- Attendent

Drug (Medicine)....is very important among them...
Qualities Of Perfect Medicine...

- Bahuta (Abundance)
- Yogya (Applicability)
- Anekvidh kalpana (Utility in various forms)
- Sampat (wholesome)
Drug....

- All medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of diseases or diagnosis in the human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of ASU system of medicine specified in the first schedule of D & C Act 1940
Source Of Drugs

• Herbal / Plant origin.

• Animal origin.

• Mineral origin.
Basic Pharmaceutical Formulation

Panchvidh Kashaya Kalpana..

- Swarasa
- Kalka
- Kwath
- Him
- Phanta
Panchvidh Kashaya Kalpana..

- THE AYURVEDIC FORMULATIONS RANGE WIDELY FROM FRESHLY EXTRACTED PLANT JUICE TO EYE DROPS, OINTMENTS, SURGICAL THREADS ETC. HOWEVER THERE ARE FIVE BASIC CLASSICAL FORMS TERMED AS ‘PANCHAVIDHA KASAAYA’ (SAARANGADHARA SAMHITAA - MADHYAMA KHANDA 1/1, 1983) FROM WHICH ALL OTHER DRUG FORMULATIONS OR FORMS ARE DERIVED OR DEVELOPED. ......
THE FIVE BASIC FORMS ARE:

- ‘SWARASA’ - THE EXPRESSED JUICE,
- ‘KALK’ - A FINE PASTE OBTAINED BY GRINDING FRESH OR WET GRINDING DRIED PLANT MATERIAL,
- ‘KWAATH’ - THE DECOCTION,
- ‘SHEET’ OR ‘HIMA’ - THE COLD WATER INFUSION
- ‘FAANT’ - THE HOT WATER INFUSION.
THE FIRST TWO FORMS ARE PREPARED FROM FRESHLY COLLECTED PLANT MATERIAL AND ARE DIRECTLY PUT TO PATIENT USE, WHEREAS THE LAST THREE FORMS ‘KWAATH’, ‘SHEET’ AND ‘FAANT’ ARE AQUEOUS EXTRACTS PREPARED FROM THE DRIED PLANT MATERIAL
Basic Classification Of Ayurvedic Drugs...

- **Solid** –
  Churna, Vati, Parpati, Varti, Bhasma, etc

- **Semisolid** –
  Avleha, Lepa, Ghruta, Paka etc.

- **Liquid** –
  Swaras, Him, Phant, Ark, Aasava, Drops, Oil, Syrups etc
Action Of Ayurvedic Drugs Is Due To...

- Ras
- Gun
- Virya
- Vipak
- Prabhava
The general belief that Ayurvedic medicines do not have any expiry date and their shelf life is infinite is not true. Ayurvedic medicines generally made of herbs and minerals, do tend to lose their herbal medicinal qualities over a period of time. As a consumer of Ayurvedic medicine, it is very important for you to know about the expiry date of Ayurvedic medicine.
The rule 161 (B) of Drugs and Cosmetics Act, 1940 and rules their under has made it mandatory to print the manufacture and expiry date of all ayurvedic, siddha and unani (ASU) drugs from April 1, 2010 onwards. "Under no circumstances, consumers should buy these drugs after their expiry date.”
Definition Of Expiry Date Of Medicine

• The time from the date of manufacturing of the medicine to the time till which the medicine has sufficient potency to bring about the desired therapeutic action can be termed as shelf life or expiration date.

• When put in simpler words, the time till which the medicine has sufficient strength to bring about the desired action is termed as expiry date or shelflife.
Shelf Life Also Known As Saviryata Avadhi

In Ayurvedic classics, Saviryata avadhi term is mentioned in context of the time period during which the Virya (potency) of any drug remain unaffected due to environmental / microbial deterioration.

Whereas in Contemporary system, the term shelf life is used to indicate the time period during which an finished pharmaceutical product (FPP) is expected to remain within the approved stability specifications, provided that it is stored under the conditions defined on the container label.
There is no clear idea about shelf life of different Ayurvedic formulations in the classical texts before of 11th century A.D.
Sharangdhar Samhita (51-53)

गुणहीनं भवेद्वर्षादृध्वं तडूपमौषधम्।
मासहृयातथा चूर्णं हीनवीर्यत्वमापनयात्।।५१।।
हीनतं गुटिकालेहि लभेते वत्सरात्यरम्।
हीना: स्थुर्गृहेनीष्टुलायश्चतुर्मासाधिकात्तथा।।५२।।
अोषध्यो लघुपाकः स्वरूपीयो वस्तरात्यरम्।
पुराणः स्थुर्गृहुर्ष्ट्रा आसवा धातवो रसः।।५३।।

जंगल से लाई काशौधियां (Medicinal recipes) एक वर्ष के बाद गुणहीन हो जाती हैं, 
दो माह बीतने पर चूर्ण (Powder) हीनवीर्य अर्थात् गुण में न्यून (Less) हो जाता है, गुटिका 
(गोली) (Pills) और लेह (confections) एक वर्ष के बाद गुण में कम हो जाते हैं। धूत और 
तेल (oil) १।६ मास (Month) के बाद गुणहीन हो जाते हैं, जिन व्रूपों (मेहूं, जौ, चना आदि) 
के दाने खेत में अच्छी तरह नहीं पकते हैं वे एक वर्ष के बाद तत्वविहीन हो जाते हैं। किंतु 
आसव (Fermented Liquors), धातु (Metal) एवं रस (Mineralrecipes) औषधियां जितनी पुराने 
होते जाते हैं, उतने ही उत्तम (more Potent) हो जाते हैं।
As per Different Ayurvedic Classics:

Saviryata Avadhi of different pharmaceutical formulation is as:

- Swarasa, Kalka, Kwath - one Prahara (3 hrs)
- Anjana – one Prahara (3 hrs)
- Churna (powder) – 2-3 months.
- Vati – 1 year
- Ghruta and Taila – 16 months
- Asava- Long term stability
- Guda and avaleha – 1 year
- Dhatu(Metallic preparation)- Long term stability
- Ras(Mercurial preparation)- Long term stability
Concept of Virya (Strength/Potency).

- The concept of Virya explained in ancient Ayurvedic literatures is very clear and it denotes the main property which is solely responsible for all the therapeutic actions of the drug. Saviryata Avadhi is indicative of that specific period during which the virya of the drug remain above certain threshold provided that it is stored in mentioned conditions. Beyond that time limit the drug may lose its potency up to some extent but it is not completely devoid of it.
Labelling.....

- Drugs and cosmetics act 1940 and rules ,1945
- Rule 161
- Name of drug.
- Net contents.
- Name and address of manufacturer.
- Licence no.
- Batch no.
- Mfg date.
- Expiry date.
- Ayurvedic medicine
- If for external use then 'EXTERNAL USE ONLY'
- 'Not to be sold' 'Physician sample' 'Govt, supply'
The Government of India has established the shelf life period of the Ayurvedic medicines, which is found below...

under Rule 161-B of Drugs and cosmetics act 1940
(GSR 764(E) dt 15.10.2009 amendment)
SHELF LIFE...

Ghan vati / Avaleha / Taila / Oral Liquid Syrup / Khand / Pak / Grannules

3 Years
SHELF LIFE...

Lepa Churna & Guti / Capsules / Lepa malahar (Ointments) / Liniment / Gels / Lotions / Creams

3 Years
SHELF LIFE...

Gutika containing Kasth aushadhi (Vati-Guti, Pills, Tablets except Gutika with Rasa)

3 Years
SHELF LIFE...

Capsules made of soft gelatin containing Kashtha aushadhi

3 Years
SHELF LIFE...

Churna / Kwath Churna / Ghrita / Varti, Shwet Parpati

2 Years
SHELF LIFE...

Arka / Eye Drops

1 Year
SHELF LIFE...

Svarna Bhasma / Rajata Bhasma / Abhraka Bhasma / Godanti / Shankha Bhasma

No Expiry Date
SHELF LIFE...

Rasaushadhis / Parpati / Kupipakva Rasayana / Pisti & Bhasma /Asava – Arista

No Expiry Date
SHELF LIFE...

Mandura - Lauha

10 Years
SHELF LIFE...

Guggulu / Dravaka / Lavana / Kshara / Nag, Vang & Tamra Bhasma

5 Years
SHELF LIFE...

Guggulu / Dravaka / Lavana / Kshara / Nag, Vang & Tamra Bhasma

5 Years
SHELF LIFE...

Gutika / Tablet containing Kasth aushadhi and Rasa, Uprasa, Metallic Bhasma & Guggulu

5 Years
SHELF LIFE...

Capsules made of hard gelatin containing Kashtha aushdhi with Rasa, Bhasma, Parada-Gandhak

5 Years
As Per Govt Of India....... 

Above mentioned expiration date is for the medicines when brought in sealed condition. However, if you have opened the jar of medicine and are using it, then you need to empty it a little faster. Hence we should be more careful about expiration date of ayurvedic medicine, once after opening the jar.
Factors responsible for the expiry date of medicine

... is largely dependant upon

- The quality of herbs and ingredients used in the Ayurvedic medicine.

- The nature of herbs used in a formulation – wet or dry.
Factors responsible for the expiry date of medicine.....

• The dosage form of the Ayurvedic medicine (Powder, Vati, Ghruta, Avleha, Kwath, Taila etc)

• Usage of particular herbs that usually contribute to the anti oxidant / natural preservative property to the Ayurvedic medicine
Longer Stability Of Ayurvedic Drugs....

Important points are...

- Quality of raw material.
- Packaging.
- Quality control and Quality assurance.
- Storage conditions.
As per reference in charak samhita a drug should be packed in such a type of vessel which has Anuroop Guna that is the packing material should not interfere with physical, chemical or biological property of the drug being packed inside. Beside this some of indications are found for the air tight packaging of churna, taila etc. So it has a great role in obtaining a product of suitable purity and potency because unsatisfactory packaging permits or fasten the degradation in the product. Any package must possesses sufficient quality so that environmental hazard like temperature, Moisture, infestation, contamination and exposure to air can be avoided.....
Certain Photosensitive drugs must be protected from light there are numerous types of transparent, opaque and coloured containers available for packaging. Amber glass will usually screen out the ultraviolet radiation very effectively and is usually the colour recommended for protection from light.......

The Most important point in the evaluation of the stability study of a product is its storage conditions. It should simulate the conditions under which the drug substance or drug product is subjected from manufacturing up to its final application. Storage conditions are derived from real climatic situation because most of the chemical reaction follow logarithmic and not linear functions. This characteristic must be taken into consideration while defining the appropriate conditions. .....
STORAGE CONDITIONS...

- Hence, the present packaging and storing technology development are playing a great role in the comparatively longer stability of the raw of finished drug materials. Nowadays, the Ayurvedic industries are also utilizing these technology for the packaging and storage of their formulations which ultimately enhance the self life of the product.
THANK YOU