SAVIRYATA AVADHI

(Shelf Life of Ay. Dosage form)

Shelf Life

Typically the shelf life of a medicine is that period during which the potency of medicine drops a certain amount - often 10 percent.

Shelf Life As Per Classic

- xq.kghua Hkosn o"kkZnw/oZa rnzwiekS"k/ke~A

---SHARANGDHARA

vkS"k/;kS y?kqikdk% L;qfuZohZ;k oRljkRije~A

--- SHARANGDHARA

ekl};kÙkFkk pw.kZa ghuoh;ZRoekIuq;kr~A
ghuRoa xqfVdkysgkS yHksrs oRljkr~ ije~A
ghuk% L;q% ?k`rrSyk|k'prqekZlkf/kdkÙkFkkA
iqjk.kk% L;qxqZ.kS;qZDrk% vklok /kkroks jlk%A

--- SHARANGDHARA

Sl. No.	NAME OF GROUP OF AY. MEDICINE	SHELF LIFE(yrs)
1.	Churna, kwatha churna	2 years
2.	Gutika except gutika with rasa	3
3.	(i)Gutika tablet containing Kashta aushadhi (ii) gutika tab containing kashta aushadhi and Rasa bhasma and guggulu	3 5
4.	Rasayoga (only rasa/bhasma) Rasayoga (along with herbs/gugguls)	10* 5*
5.	Asava arista	10 yrs*
6.	Avaleha	3
7.	Guggulu	5
8.	Mandura-lauha	10*
9.	Ghrita	2

10.	Taila	3
11.	Arka	1
12.	Dravaka, lavana,kshara	5
13.	Lepa churna	3
14.	Danta manjan powder	2
15.	Danta manjan paste	2
16.	Lepa gutika	3
17.	Lepa malhar	3
18.	Varti	2

19.	**Ghana vati**	**3**
20.	Kupipakwa rasayana	10 yrs*
21.	Parpati	10 yrs*
22.	Sweta parpati	2
23.	Pisti and bhasma	10 yrs*
24	Sharkar	3
25.	Naga , vang & tamra bhasma	5
26.	Capsule made of soft gelatin	3
27.	Capsule made of hard gelatin	5

28	Syrup/ liquid oral	3 years
29	Ear/ nasal drops Eye drops	2 1
30	Khand/granules/paka	3
31	Dhoopan- inhalers	2
32 33.	Pravahi kwath (along with preservatives) Satva (derived from plants)	3 2*

Method of evaluation of Shelf Life

Evaluation of Physico chemical and organoleptic characters along with actives of the formulation (medicine)

1. Generally ICH guidelines are followed in India.
2. Countries are classified in different group as per the climatic conditions in the respective country

Conditions recommended for stability studies in India

For accelerated and Room temperature studies in Stability chambers in the same packaging as intended for the marketing.

- 30 ± 2 ^{0}C/70 ± 5 RH - For RT
- 40 ± 2 ^{0}C/75 ± 5 RH - For Accelerated Study

Climatic Zones

Climatic Zone	Definition	Storage Conditions
I	Temperate climate	21ºC/45% RH.
II	Subtropical and Mediterranean climate	25ºC/60% RH.
III	Hot, dry climate	30ºC/35% RH
IV	Hot, humid climate	30ºC/70% RH

Testing frequency(general)

Study	Storage condition	Minimum time period for data submission
Long term*	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH	Every 3 months for first yr, (0,3,6,9,12 months), every 6 month for 2nd yr, 18, 24 months), annually there after
Intermediate**	30°C ± 2°C/65% RH ± 5% RH	6 months(0, 6, 9, 12 months)
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 month (0, 3, 6 month)

- 1.Assessment of samples of different interval of stability study and comparison with initial results.

- 2. If the sample clears for the accelerated stability study it can be marketed.

Evaluation of stability

- based on testing a minimum of at least three batches of the drug,
- An Ayurvedic drug can be considered to be stable if “no significant change” occurs during at any time of testing at accelerated storage condition or at real time storage condition.

“Significant change” for a drug is defined as

1. A + or - 20 per cent change from the initial assay value (If the drug is analyzed for its marker). A + or - 15 per cent change from the initial assay value (If the drug is analyzed for its active compound).
2. Appearance of new spots in Identification by TLC or completely disappearance of existing spot.
3. The physico-chemical parameters (moisture, ash, particle size) shall not vary beyond 25 percent of the initial value.
4. Failure to meet the acceptance criteria as per individual monographs or specification.

Factors influencing shelf life of the drugs

Extrinsic factors

- 1, Heat
- 2. Light
- 2. Moisture

Intrinsic Factors

- 1. Dosage form
- 2. Preservative
- 3. Ingredients compliance
- 4. Products internal attributes

Ayurvedic Methodology which can enhance the shelf life of products

1. Bhawana
2. Manual pill making
3. Avartana of Tailas – Rancidity &Trans Fat

Ways to enhance the shelf Life of Drugs

- 1. Preservative
  A. Suitable - pH
  B. Quantity
  C. Preservative Efficacy Test

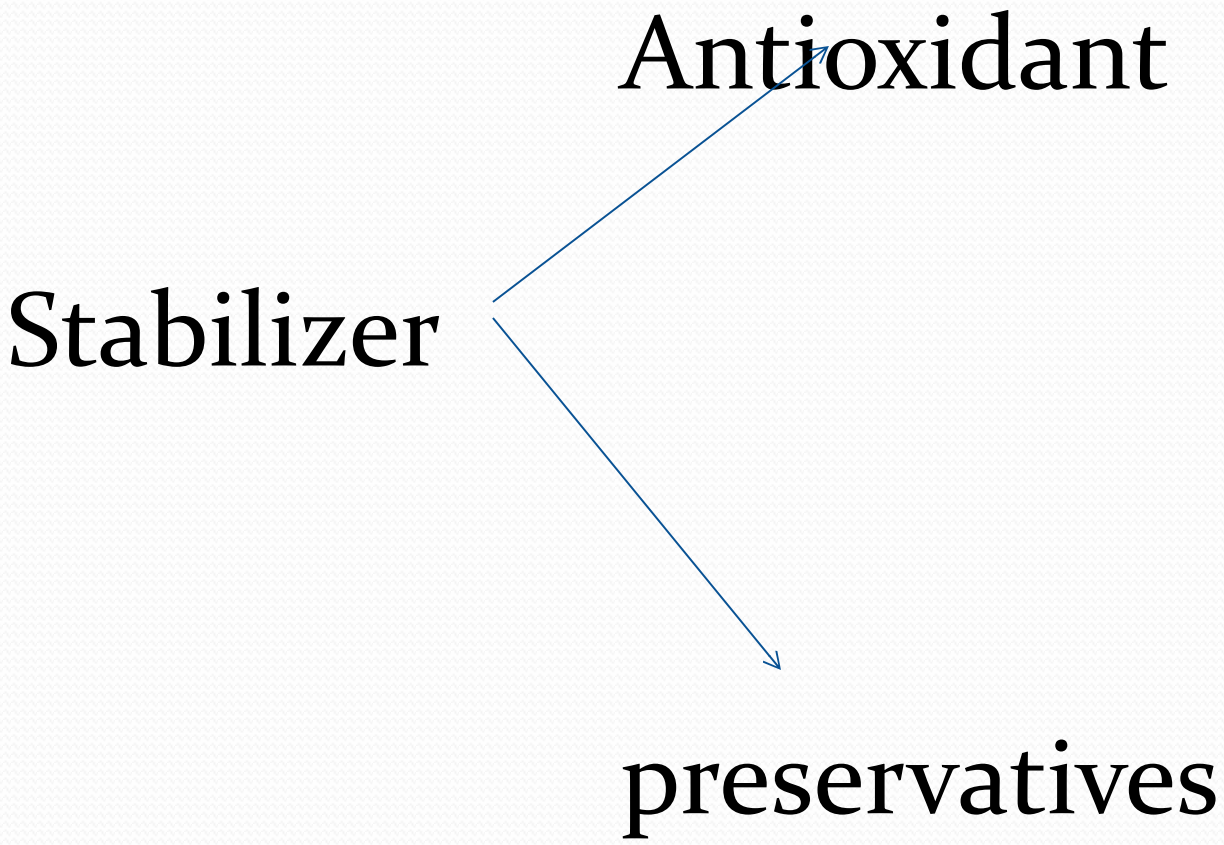
- 2. Packing
  A. Glass - Amber colour
  B. HDPE
  C.PET
  D. Laminate/Pouches

- 3.Storage Condition
  (Store in a cool and dry Place away from the sun light)

Stability of Ay. Drug

- Stability of a drugs may be defined as the capability of a particular formulation in a specific container to remain within the physical, chemical, microbiological, therapeutic and toxicological specifications.

- The substances which are used to control these stabilities are known as stabilizers.


Antioxidant
Stabilizer
preservatives

ANTIOXIDANT

- An antioxidant is a substance which is added to a pharmaceutical formulation to prevent the oxidative degradation of drugs. The antioxidants have great affinity for oxygen and when they are added to formulation they compete for it affording protection to other oxygen sensitive drug.

Ideal Antioxidant

An ideal antioxidant should be stable and effective against a wide range of pH , colorless , nontoxic, nonirritant , thermo stable and compatible with ingredients and packing material.

commonly used antioxidant are ....

- sodium bisulphate
- sodium metabisulphate
- sodium thiosulphate
- ascorbic acid
- ascorbyl palmitate hydroquinone,
- Propyl gallate,
- tocopherols.

Preservatives-

Preservatives are substances that commonly added to various foods and pharmaceutical products in order to prolong their shelf life. The addition of preservatives to such products, especially to those that have higher water content, is essential for avoiding alteration and degradation by microorganisms during storage.

Choice of preservatives:

- effective against a wide range of micro-organisms.
- compatible with other ingredients of the formulation.
- soluble in aqueous phase when used in emulsions.
- non toxic.
- free from odour and taste.
- preserved the preparation and remain stable for shelf life of the product.

Types of Preservative

Class I-

common salt, sugar, dextrose, glucose, spices, vinegar or acetic acid, honey, edible vegetables oil.

Class II-(Permissible for food items and Drugs)

commonly used preservatives

No single preservative posses all the qualities. Therefore it becomes necessary to use a combination of preservatives to prevent the growth of microorganisms.

- benzoic acid and sodium benzoate 0.1-0.2%
- salicylic acid 0.1%
- phenol 0.2-0.5%
- chlorecresol 0.05-0.1%
- alcohol 15-20%
- chlorbutanol 0.5%
- phenyl mercuric nitrate 0.001%
- benzylkonium chloride 0.01%
- Phenyl ethyl alcohol 0.5%
- methyl paraben and propyl paraben 0.1-0.2%

SCHEDULE FF
(See Rule 126-A)
Standards for Ophthalmic Preparations

provisions of the labelling laid down in the rules on container:

(i) The statement 'Use the solution within one month after opening

the container'.

(ii) Name and concentration of the preservatives, if used.

(iii)The words 'NOT FOR INJECTION'.

Permissible agents for ASU drugs

On the recommendation of ASUDTAB, the amendment to Rule 169 of D & C Rule 1945 for permitting excipients, preservatives, antioxidants, flavoring agents, chelating agents etc in ASU drugs was carried out.

Notification has been issued in this regard on 23rd October, 2008.

Thank you