

## Stability considerations of Dosage forms

**Stability:** is defined as the extent to which a product retains, within specified limits, and throughout its period of storage and use (shelf-life), the same properties and characteristics that it possessed at the time of its manufacturer.

**Factors that affect products stability:**

- 1- Temperature
- 2- Light
- 3- PH-level
- 4- Humidity
- 5- And many other factors related to manufacturing.

Table (1) : physical instability for all dosage forms

Dosage form	Evidence of physical instability
<b>Solid dosage forms</b>	
Hard and soft gelatin capsules	Hardening or softening of the shell, release of gas such as a distended paper seal .
Coated tablets	Cracks, mottling or tackiness in the coating and clumping of tablets.
Uncoated tablets	Cracks, mottling, swelling, discoloration and fusion between tablets.
Dry powders and granules	Caking into hard masses or discoloration
Effervescent tablets, granules or powders	Swelling of the mass or development of gas pressure.
<b>Liquid dosage forms</b>	
Solutions , elixirs and syrups	Precipitation or formation of gases or evidence of microbial growth.
Emulsions	Breaking ( separation of oily phase that is not easily dispersed )
Suspensions	A caked solid phase that cannot be re-suspended after shaking or presence of large particles ( crystals ).
Sterile liquids ( parenteral solutions or ophthalmic solutions )	Presence of any sign of contamination like change in color, cloudiness and surface film.
Tinctures	Precipitation
<b>Semisolid dosage forms</b>	
Creams	Emulsion breakage, crystal growth, shrinking due to evaporation of water and gross microbial contamination.
Ointments	Change in consistency, separation of excessive amount of liquids and formation of granules.
Suppositories	Excessive softening ,dryness or hardening ,

Table (2): In use shelf-lives for in-sterile medications

**Tablets and capsules**

Blister Packed/Single Unit Dose	Manufacturer's Expiry
Bulk Packs	1-Year from date of opening
Exceptions: Products susceptible to atmospheric moisture, GTN	

**Liquids**

Preserved	Internal and External 6-Months (local policy may direct 3-months for internal liquids)
Extemporaneously Prepared to a BP Monograph or EDS Formula	4-Weeks from date of manufacture
Diluted Preserved liquids	2-Weeks
Preserved with Chloroform	2-Weeks

**Creams**

Packed in Tubes	3-Months (local policy may direct 1-Month for Unpreserved creams)
Packed in Jars/Pots	1-Month
Diluted Commercial Preparations	2-Weeks
Extemporaneously Prepared in a suitable base	4-Weeks from date of manufacture

**Ointments**

Packed in Tubes	6-Months
Packed in Jars/Pots	3-Months
Diluted Commercial Preparations	4-Weeks
Extemporaneously Prepared in a suitable base	8-Weeks from date of manufacture

Table (3): In use shelf-lives for sterile medications

sterile creams and ointments for application to wounds and burn	24 hours
ophthalmic use	5-days for antibiotics)
	4- weeks

References:

- 1- U.S Pharmacopeia . Volume 28(1),page112.  
[http://www.pharmacopeia.cn/v29240/usp29nf24s0\\_c1191.html](http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1191.html) , access date: 18, 3, 2014
- 2- World Health Organization . WHO Expert Committee on Specifications for Pharmaceutical Preparations - WHO Technical Report Series, No. 863 - Thirty-fourth Report  
<http://apps.who.int/medicinedocs/en/d/Js5516e/15.7.html>
- 3- <http://ebookbrowse.net/storage-stability-in-use-shelf-lives-of-non-sterile-medicines-pdf-d21317960>

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