

## Guidelines For Stability Study report

قررت اللجنة الخاصة بتسجيل مستحضرات التجميل-مستلزمات طبية-مبيدات حشرية منزلية ومطهرات بجلسة  
٢٠١٠/١٠/٢٦ الموافقة على ال Guidelines for stability study report المقدمة استنادا لقرار اللجنة العلمية  
المتخصصة لتقييم دراسات الثبات الخاصة بالمستلزمات الطبية

### Guide Lines for stability study report:

*According to ASTM F 1980-02 and ISO 11607*

*1-Protocol of stability study (shelf life) including, but not limited to, the following:*

- a) Sampling rationale*
- b) In case of family products, rationale for selecting a product for stability study "considering worst case conditions" should be clarified*
- c) List of equipment used in the stability study and its calibration status*
- (d) Qualified personnel (mention name and title*
- e) Tests to be performed and their sequence*

*2-Package specification*

*3-Batch record of the product used in the stability study*

*4-Technical performance used as a sample preferably harmonized standards*

*5-Testing results report*

*6-Sterilization and Packaging verification at zero time and at the end of the stability study*

*7-Product description and intended use*

*8-In case of colorant material, medicinal substance, animal tissue or human blood derivative used, provide evidence of composition stability*