

# GPC-CHEMEXCIL

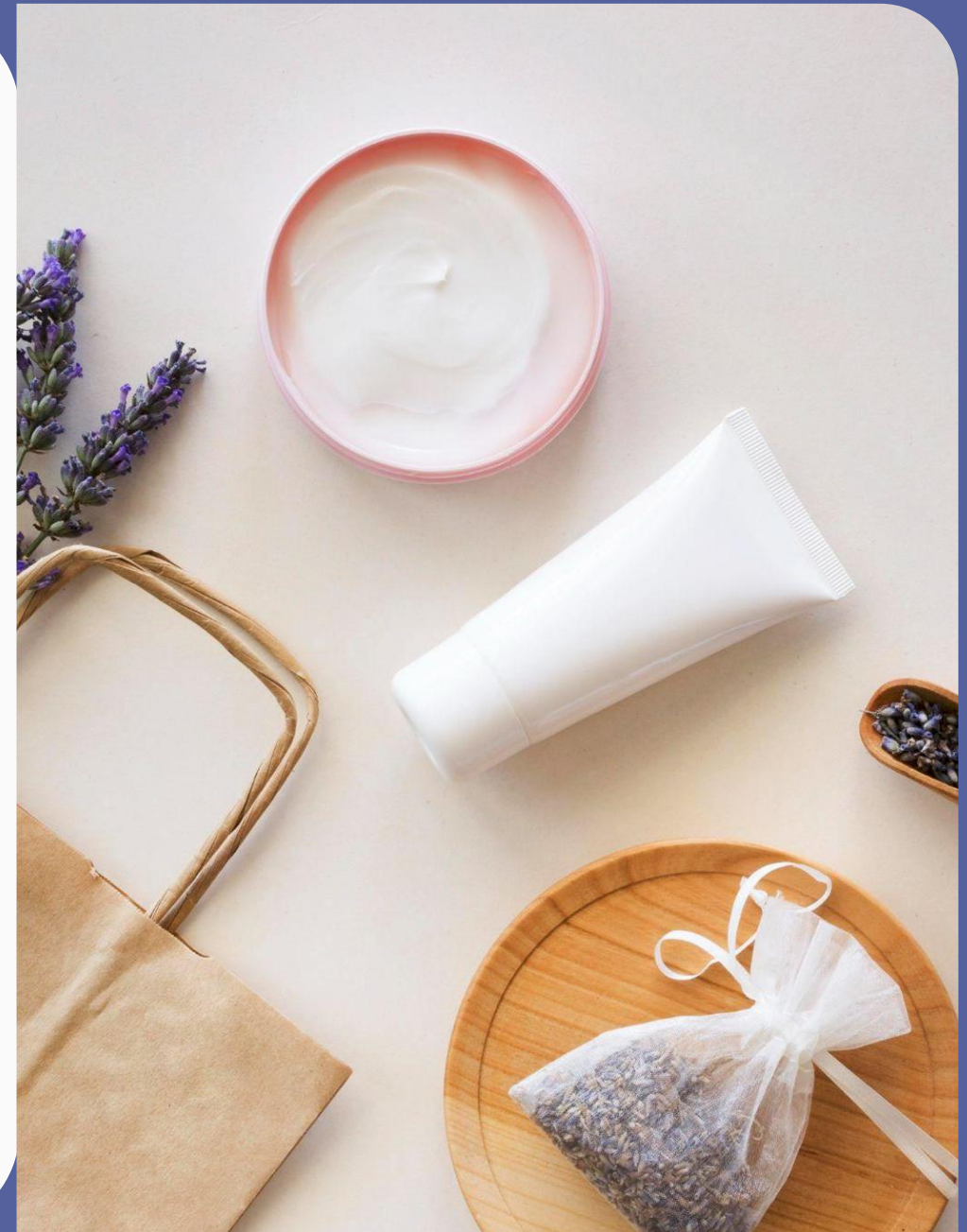
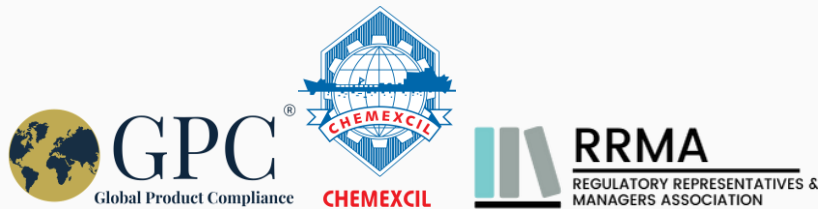
## COSMETIC PRODUCT SERIES

# Stability Testing and Shelf Life of Cosmetic Products

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Anders Bergqvist, GPC Europe AB

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# An overview of Cosmetics Rule 2020

# Cosmetics rule 2020 (1)

- **Ministry of Health and Family Welfare (MHFW)**
- published on 15 December 2020
- came into force immediately as a subset of the existing Drugs and Cosmetics Rules, 1945
- A framework to regulate cosmetics separately from pharmaceuticals
- Regulating import, manufacture, labelling, sale and distribution of the products in India

## Highlights of the Rules:

- Licensing Authority – Drug Controller General of India (DCGI) – responsible for import of cosmetics, grant approval to the laboratories
- Central Cosmetic Laboratory – for analysing and testing the samples
- Import, manufacture for sale or for distribution
- Labelling and packaging standards
- Also need to comply with the Bureau of Indian Standards (BIS) (according to Schedule 9)



# Cosmetics rule 2020 (2)

Chapter 1 – Definition, Objectives and Scope

Chapter 2 – Authorities, Officers and Laboratory

Chapter 3 – Import and Registration

Chapter 4 – Manufacture of Cosmetics for sales or distribution

Chapter 5 – Permission for import or manufacture of New Cosmetics

Chapter 6 – Labelling, packaging and standard for sale or distribution of cosmetics

Chapter 7 – procedure of sampling for test or analysis, seizure and report

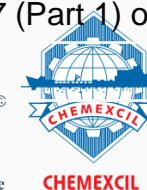
Chapter 8 – Approval of laboratory for carrying out tests on cosmetics and their raw materials

Chapter 9 – Miscellaneous



# Cosmetics rule 2020 (3) New Schedules

Sr. No.	Schedules	Description
01.	First Schedule	Authorisation from manufacturer
02.	Second Schedule Part-I	Information and undertaking required to be furnished by the manufacturer or his authorised importer or distributor or agent with the application form for import registration certificate.
03.	Second Schedule Part-II	Information and undertaking required to be furnished by the manufacturer with the application form for grant of manufacturing licence or loan licence
04.	Third Schedule	Fee payable for licence, permission and registration certificate.
05.	Fourth Schedule	List of categories of cosmetics for import
06.	Fifth Schedule	Fee for test or analysis by the Central cosmetics laboratories or by the state laboratories
07.	Sixth Schedule	Undertaking for the import of cosmetics to be submitted by the importer with application form for Import Registration Number
08.	Seventh Schedule	Good manufacturing practices and requirements of premises, plants and equipment for manufacture of cosmetics
09.	Eighth Schedule	Manufacturing and raw material records
10.	Ninth Schedule	Standards for cosmetics (BIS)
11.	Tenth Schedule Part-I	List of colourants allowed for use in cosmetic products as given under IS: 4707 (Part 1) of BIS
12.	Tenth Schedule Part-II	List of colours permitted to be used in soaps



# BIS related compliance requirement

Standards for cosmetics in finished form should conform to the Indian Standards specifications laid down from time to time by the **Bureau of Indian Standards (BIS)**.

- Skin Powders IS :3959
- Skin Powder for infants IS :5339
- Tooth Powder IS :5383
- Toothpaste IS :6356
- Skin Creams IS :6608
- Hair Oils IS :7123
- Shampoo, Soap – based IS :7669
- Shampoo Specification IS : 7884
- Hair Creams IS :7679
- Oxidation hair dyes, Liquid IS :8481
- Cologne IS :8482
- Nail Polish (Nail Enamel) IS :9245
- Aftershave Lotion IS :9255
- Pomades and Brilliantines IS :9339
- Depilatories Chemicals IS :9636
- Shaving Creams IS :9740
- Cosmetic Pencils IS :9832
- Lipstick IS :9875
- Toilet Soap IS :2888
- Liquid Toilet Soap IS : 4199
- Baby Toilet Soap IS : 10523
- Shaving Soap IS :5784
- Transparent Toilet Soap IS :11303
- Lipsalve IS: 10284
- Powder Hair Dye IS: 10350
- Bindi (Liquid) IS : 10998
- KumKum Powder IS: 10999
- Henna Powder IS : 11142
- Bathing Bars IS:13498
- Sindoor IS: 14649
- Liquid foundation make-up IS 14318
- Coldwax-Hair remover IS : 15152
- Face pack IS: 15153
- Kajal IS : 15154
- Oxidation Hair Dyes (Emulsion type) IS: 15205
- Cream Bleach IS:15608
- Hair Shampoo for Babies- Specification IS:17117



**Bureau of Indian Standards**  
The National Standards Body of India



**GPC**  
Global Product Compliance



**RRMA**  
REGULATORY REPRESENTATIVES &  
MANAGERS ASSOCIATION

# SHELF LIFE

- Shelf life: the length of time you can expect a product to stay safe for use
- “Use before” or “date of expiry”: the date upto which the cosmetic shall retain its characteristics as per standards at proposed storage condition stated on the container, label or package
- CHAPTER VI: LABELLING, PACKING AND STANDARDS FOR SALE OR DISTRIBUTION OF COSMETICS  
Have “use before” or “date of expiry” written on both inner and outer labels
- Stability test

Source: Cosmetics Rules, 2020.



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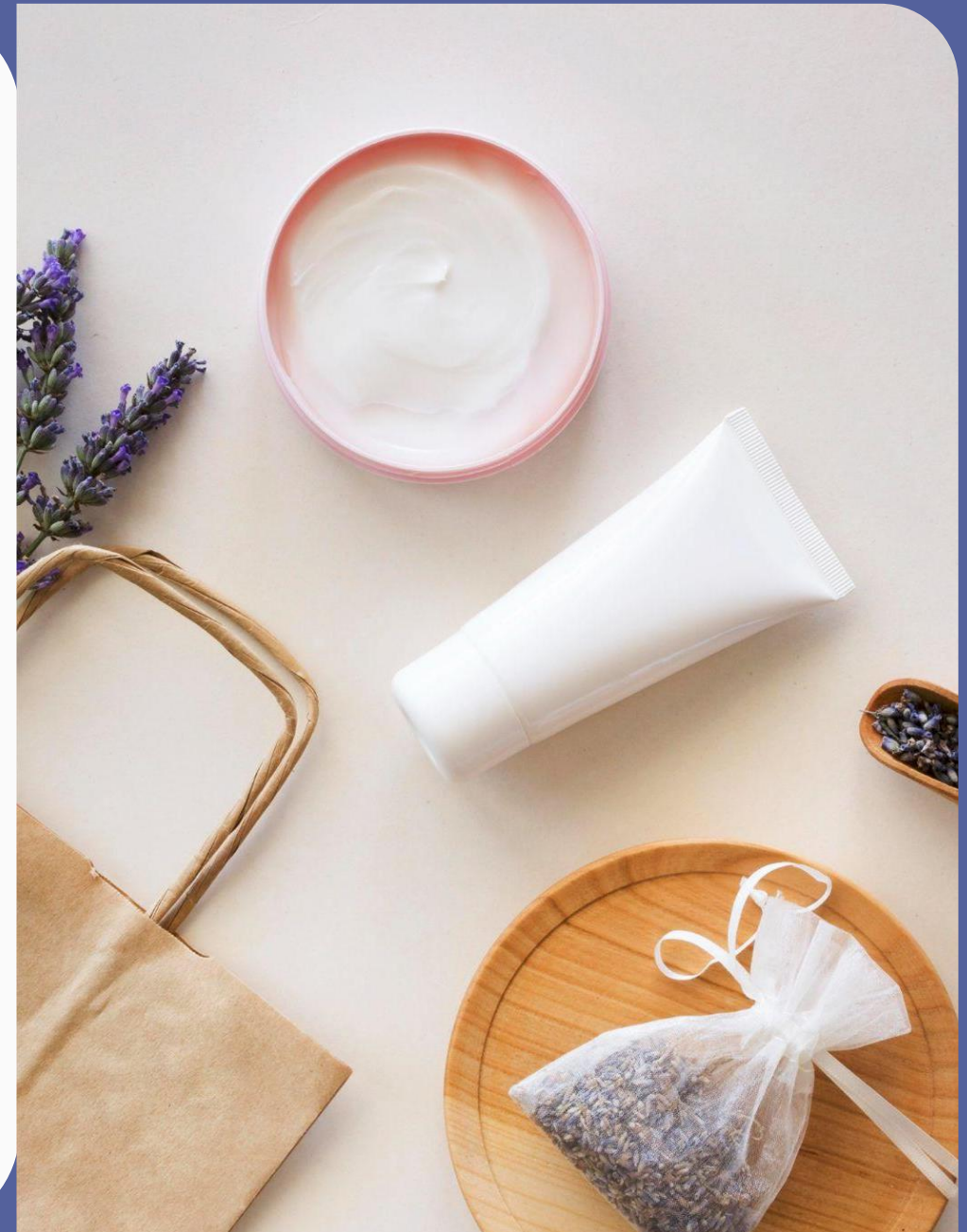
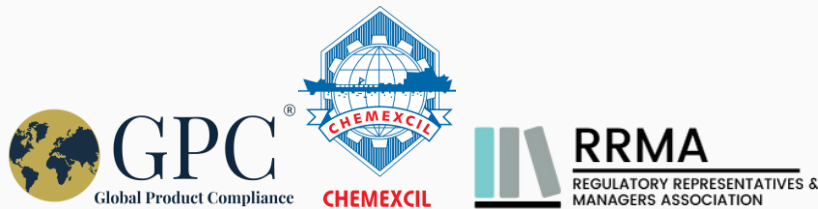
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## KEY DISCUSSION POINTS

- When/why is stability testing necessary?
- Microbiological stability
- Physical and chemical integrity
- Packaging compatibility
- What is considered a significant change?
- Shelf life
- Summary, Q&A session

# WHEN IS STABILITY TESTING REQUIRED?

- During the development of a new product
- When an existing on-market product has been re-formulated
- When the production method has changed
- When the production has moved to a new facility
- When the packaging material has changed

To ensure safety and quality of the cosmetic product



# MICROBIOLOGICAL STABILITY

- The formulation is challenged with typically 5 different microorganisms (e.g. 3 bacterial strains and 2 fungal strains)
- Samples are collected at different time points during the experiment and the number of CFU's are recorded
- Growth of microorganisms must be within acceptable limits
- In case of **unacceptable results**, the preservation system in the formulation needs to be improved
- Recommended test methods: [USP 51](#) (US Pharmacopeia, 2021) or [ISO 11930:2019](#)

# MICROBIOLOGICAL CONTAMINATION

- Most common sources:
  - Raw material
  - Production and filling process
  - Consumer use
- $\geq 2$  different preservative agents needed to combat the main potential pathogens in cosmetics (*P. aeruginosa*, *S. aureus*, *C. albicans*)
- Recommended to perform routine testing on new batches of the finished product
- **Screening tests:** There are various easy testing kits available (e.g. dip-slides) that can provide quick and semi-quantitative results whether a cosmetic product is significantly contaminated or not

# PHYSICAL AND CHEMICAL STABILITY

- Evaluation of colour, odour/fragrance, pH, viscosity, texture/flow and emulsion stability over a period of time
  - Accelerated conditions: Temperature (up to 37 - 45°C) w/wo. increased relative humidity (up to 80%)
  - Freeze/thaw testing
  - Mechanical testing
  - Photostability testing
- 
- No single stability testing procedure, as it will depend on product type, formulation, how the product is shipped etc.

Recommended reading: Kirkbride et al. Designing a Suitable Stability Protocol in the Face of a Changing Retail Landscape. *Cosmetics* 2021; 8, 64.

<https://doi.org/10.3390/cosmetics8030064>



# PHYSICAL AND CHEMICAL STABILITY – ACCELERATED CONDITIONS



Test Conditions	Time period of test
4°C (control sample)	
40°C	1 to 3 months
45°C	1 to 3 months

**As a general rule:**

3 months stability at 40 to 45°C represent a predictive 1 year stability at room temperature.

# PHYSICAL AND CHEMICAL STABILITY – ADDITIONAL TESTING

Test	Procedure	Indicated for:
Freeze/Thaw Testing	The sample is cycled between -30°C and RT for a minimum of 6 cycles.	<ul style="list-style-type: none"> <li>• Products that are planned to be shipped internationally</li> <li>• Formulations that are prone to instability, crystallization, sedimentation and clouding.</li> </ul>
Mechanical Testing	Vibration or centrifugation	<ul style="list-style-type: none"> <li>• Products that are planned to be shipped internationally</li> <li>• Good immediate indicator for emulsion stability.</li> </ul>
Photostability testing	The sample is placed on the window sill or in a UV chamber.	<ul style="list-style-type: none"> <li>• Products that are likely to be exposed to sunlight</li> </ul>

RT = room temperature





## PACKAGING COMPATIBILITY

- Compatibility between the formulation and the packaging material
- Evaluated during accelerated conditions (e.g. 3 months at 40°C) for physical and chemical integrity
- Recommended to use packaging material with a history of safe use in the cosmetic industry and (or) the food industry





# WHAT IS CONSIDERED A SIGNIFICANT CHANGE?

- Microbiological stability:
  - Growth of microorganisms above protocol acceptance criteria
- Physical and chemical integrity:
  - Degradation that is exceeding acceptance criteria
  - Failure to meet acceptance criteria for appearance and physical attributes. However, some changes in physical attributes e.g. melting of creams may be expected under accelerated conditions.
  - Failure to meet acceptance criteria for pH
  - Failure to meet acceptance criteria for functionality e.g. dose delivery volume per actuation

# SHELF LIFE

- The length of time you can expect a product to look and act as expected and to stay safe for use
- Predicted under accelerated conditions
  - 3 months stability at 40 to 45°C represent a predictive 1 year stability at RT
- Factors that can affect shelf life:
  - Dipping fingers into a product
  - Exposure to moisture
  - Changes in temperature and exposure to sunlight

# SUMMARY

- Stability testing is necessary to ensure safety and quality of the cosmetic product
- Stability testing should be well documented, with a rationale on how and why
- Stability testing should be run by trained professionals and be properly recorded
- There are several good references and guidelines on how to run and interpret results

1. International Federation of Societies of Cosmetic Chemists, IFSCC Monograph, Number 2: The Fundamentals of Stability Testing, Michelle Press, 1992.

2. “Guideline on Stability Testing of Cosmetics” (COLIPA/CTFA 2004) ...  
[https://www.cosmeticseurope.eu/files/5914/6407/8121/Guidelines\\_on\\_Stability\\_Testing\\_of\\_Cosmetics\\_CE-CTFA\\_-\\_2004.pdf](https://www.cosmeticseurope.eu/files/5914/6407/8121/Guidelines_on_Stability_Testing_of_Cosmetics_CE-CTFA_-_2004.pdf)

3. Kirkbride et al. Designing a Suitable Stability Protocol in the Face of a Changing Retail Landscape. *Cosmetics* 2021; 8, 64. <https://doi.org/10.3390/cosmetics8030064>





# Thank you!

## GPC-CHEMEXCIL COSMETIC PRODUCT SERIES

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