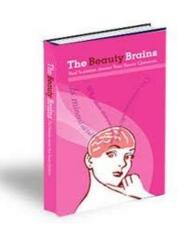
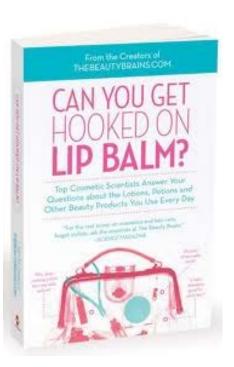
Cosmetic Chemist's Guide to Stability Testing

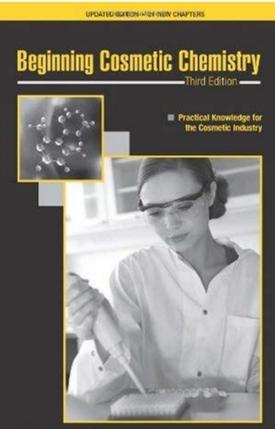
Perry Romanowski Element 44 Inc. chemistscorner.com

Instructor

- Perry Romanowski
- Vice President Element 44 Inc
- Cosmetic Scientist
- Author
- Online Training







Randy Schueller & Perry Romanowski





Announcement 70 comments Most recent by PerryR October 2 General	☆
	☆
Supposedly "better" emulsions Supposedly "better" emulsions S	☆
What paraben-free and formaldehide releaser-free conservative to use? 3 comments Most recent by Duncan 3:24AM Skin Care products	☆
Substitution of SLES and SLS Cosmetic Science talk 10 comments Most recent by Duncan 3:16AM Cosmetic Science talk	☆
Tanning beds increase melanoma in young women Second S	☆
Water based hair/scalp tonic - still need an emulsifier 3 comments Most recent by dess October 11 Hair Care products	☆
Formulate Differently 4 4 comments Most recent by Eliza October 11 Innovation	☆
Natural? Organic? Weigh-in please. 9 3 comments Most recent by Eliza October 11 Cosmetic Science talk	☆
Natural/Organic Preservative for toothpaste S 5 comments Most recent by Yulya October 10 Cosmetic Science talk	☆

Material/Actives for Formulators

1 comment Started by FormulatorSamples October 10 Skin Care products

Start a New Discussion

Categories					
All Discussions	313				
Career	15				
Cosmetic Industry	44				
Chemists Corner Podcast	8				
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General	42				
Hair Care products	24				
Innovation	9				
Makeup products	11				
Member-to-Member Joint Ventures					
	2				
Questions for Mentors	26				
Resources	24				
Skin Care products	37				

BOOKINAI KEU DISCUSSIONS
Water based hair/scalp tonic - still
need an emulsifier
3 October 11 dess
Testing of handmade soaps, anhydrous products and products

containing more than 35% ethanol

Deel/marked Discussions

☆



Modules

Course Description

Practical Cosmetic Formulation is designed to introduce the student to the principles of cosmetic science and formulation, including: understanding cosmetic form and function, the basics of cosmetic chemistry, cosmetic terminology and techniques, the product development process, formulation of specific cosmetics, an understanding of raw materials and their use, cosmetic product testing, product scale-up and government regulations affecting cosmetics and the consumer.

Course Frequency

New lessons will be published every other week. A Q&A session will be held monthly.

Modules

http://chemistscorner.com/members

If you want to download your

free bonuses, just click here.

NAVIGATION

<u>Resources</u> <u>Pre-lessons</u> <u>Career</u> Forum

Agenda

- Define stability testing
- When and why to test
- Basics of conducting a stability test

Objectives

- Know basic philosophy of stability testing
- Be aware of relevant regulations
- Know why & when to conduct a stability test
- Know how to conduct a cosmetic stability test
- Focus on US "rules"

What is stability testing?

- Predictive test
- Determine product longevity
 - Aesthetics
 - Functional
 - Microbial quality
 - Package compatibility
- Subjective decision

Regulations

- For OTC products follow Pharmaceutical Testing standard
 - 21 CFR part 211
 - 1.usa.gov/1BW8M2R
- In US cosmetic type products such as...
 - Anti-dandruff
 - Sunscreens
 - Antiperspirants

Cosmetic Standards

- <u>No specific</u> requirements
- Defined by manufacturer
 - Reasonable
 - Efficient
- Must document what is done
- PCPC has recommended guidelines



When to test

- New prototypes
- New raw material supplier
- New production equipment / procedure
- New Packaging
- Scale-up
- Ongoing QC / QA
- Regulations

General Guidelines







Type of Packaging Storage Conditions Testing Schedule

Basics of a stability test



Making Batches Testing Samples Making Decisions

Batch creation

- Calculate amount needed
 - Container size
 - Conditions tested
 - Available raw materials
- Test & Control batches
 - Take initial readings
 - Temp & light controls
- Packaging
 - Glass
 - Final packaging



Sample storage

- Various temperatures
 - 50C, 45C, 35C
 - RT, 4C
- Various lighting
 - Sunlight
 - UV light



Actual stability storage



Sample Evaluation Schedule

- Standard time checks
 - 2 weeks
 - 4 weeks
 - 8 weeks / Decision
 - 12wk, 26wk,
 52wk, & beyond



Standard cosmetic tests

- Appearance
- Odor evaluations
- pH testing
 - Indicates chemical changess
 - Unreacted residuals
 - Product functionality
- Viscosity
 - Consistency
 - Indicates possible separation





Other types of evaluations

- Weight Loss
- Specialty
 - Aerosol cans
- Performance tests
- Panel testing
- Clinical testing



Microbial Tests

- Contamination test
 - 2-5 days
 - Plate count should be zero



- Micro-Challenge test
 - Ensure preservation system works
 - Tested against 5 problematic microbes
 - Should effectively kill them all

Freeze Thaw Testing

- Freeze formula / thaw it
- Shows performance under variable conditions
- How
 - Freeze 3 samples overnight
 - Thaw and test
 - Repeat 3 times
- Observe changes
 - Separation
 - Color change



Additional Stability Tests

- Accelerated tests
- Centrifuge
- Package testing
 - Weight loss
 - Drop tests
 - Compatibility tests



Decisions

- Cosmetics stable for at least 1 year
 - 3 years for some products
- 8wk at 45C = 1 year stability
- 4 week = fragrance
- 8 week = provisional
- 12wk = higher confidence
- 52wk = verification
 - Requirement for OTC



Decisions

- Pass or Fail?
- Out of spec
- Color change
- Texture change
- Odor change
- Etc.



Should you outsource stability testing?

- Makes sense to do your own
 - Prototypes
 - Secondary source
 - Fragrance stability tests
- Makes sense to outsource
 - First production runs
 - Space issues
 - Equipment issues
- UL services bit.ly/1HmoWIP



Stability testing made simple

- Step 1 Make batches
- Step 2 Take initial readings
- Step 3 Fill containers
- Step 4 Put samples in accelerated conditions
- Step 5 Evaluate formula at checkpoints
- Step 6 Decide if formula is stable

Stability test example

- New fragrance skin lotion sold in 8 ounce bottle
- Samples:
 - 33 glass 4oz (120 g)
 - 33 package 8oz (240 g)
- Control / Test batches
- Initial readings
 - pH, Viscosity, odor, color, bottle mass, micro



Example stability test

	2wk	4wk	8wk	12wk	26wk	52wk
	LUIK		UNK	12.00	2000	52.00
45C						
37C						
510						
RT						
4C						
Light						
Freeze / thaw						
1.00207 414W						
Micro RT						
Micro 45C						
W/L RT						
W/L 45C						

Cosmetic Stability testing summary

- Predictive of product shelf life (1 year min)
- Not an exact science
- For cosmetics no specific regulation
- Test design depends on product type / package
- Numerous factors involved in deciding when and what to test

