Click to verify

While it is generally good manufacturing practice, neither the U.S. Food and Drug Administration (FDA) nor the European Commission require cosmetic manufacturers to conduct stability testing on products before commercially marketing them. Regardless, routine stability testing can provide cosmetic manufacturers critical data about their product’s safety and shelf life. While it is generally good manufacturing practice, neither the U.S. Food and Drug Administration (FDA) nor the European Commission require cosmetic manufacturers to conduct stability testing on products before commercially marketing them. Regardless, routine stability testing can provide cosmetic manufacturers critical data about their product’s safety and shelf life. Such information can prove useful to companies both externally and internally; externally in terms of creating successful products, and internally in terms of product development, material procurement and management, and lifecycle management. This paper provides an overview of the basics manufacturers should consider when developing a stability testing protocol for cosmetic products. Stability Testing: A Primer As is well-known, stability testing essentially is an experiment in which a batch of formula is created and placed into different environmental conditions for a set period of time. These conditions vary in temperature and humidity, and are meant to simulate what happens to the product during its life cycle. In the pharmaceuticals field, both the FDA and the European Medicines Agency require the stability testing of products before they can be sold to consumers. The main purpose is to measure and document the potency of medications up until a predicted expiration date. This data has proven important, especially considering the FDA has cited, within the past two years, stability-related issues as key factors in pharmaceutical recalls. And, as pharmaceutical and cosmetic manufacturers well understand, such product recalls are not only expensive and labor intensive, but they also can seriously damage one’s brand image. Similar to pharmaceuticals, cosmetics naturally degrade over time, and stability testing can reveal the extent to which they degrade by measuring factors such as: The natural degradation rate of key ingredients; A product’s ability to resist microbial intrusion; The product’s reactivity to packaging materials; Impurities exacerbated by the manufacturing process; and Product response to heat, humidity and light. One objective of stability testing is to ensure that a product maintains its intended physical, chemical and microbiological qualities—as well as functionality and aesthetics—when stored under appropriate conditions. Another is to glean data by foreseeing the stability of the cosmetic product over time within its useful life span, as well as compatibility between the formulation and the container material. Stability Test Protocols As stated, there currently are no existing enforceable or uniform protocols outlined by the FDA Code of Federal Regulations or European Commission Regulation No. 1223/2009 for the stability testing of cosmetics. The exception is for some OTC products, such as sunscreens, antiperspirants/deodorants and dandruff shampoos. As such, a well-designed internal stability protocol must test those product attributes that are susceptible to change during storage, and that can influence the quality, safety and performance of the product. Stability studies include the evaluation of product quality at specific time intervals of a storage period under controlled conditions. There are three basic forms of stability tests: Physical and chemical integrity: These evaluate the color, odor or fragrance, pH value, viscosity, texture, flow and emulsion stability, or signs of separation. Microbiological stability: These evaluate the degree of contamination with bacteria, mold and/or yeast. Packaging stability: These evaluate the effect of packaging on the contained product. Stability testing for cosmetics is typically performed when: A new product is developed; An existing on-market product has been reformulated; The production method has been modified, or production has moved to a new facility or vendor; and/or packaging has changed. Currently, little published research exists to support specific methods for predicting cosmetic shelf life. The reasons for this gap in information include: The wide variety and complexity of cosmetic formulas and packaging; The proprietary nature of most cosmetic products and their associated stability test methods; and The scope of potential changes to be examined, including physical, chemical, microbial, functional or aesthetic. Method Development For each formulation type, manufacturers should determine the qualities to be examined, then test them at one or more temperature and humidity conditions. Test parameters should be evaluated and a decision made for each criterion based on the company’s own internal procedures and experience. Evaluations should allow for the deduction of predicted or real stability of the product. Since time is such a crucial parameter in the development of a new cosmetic product, real-time stability testing is not always feasible. In such situations, accelerated stability testing represents a good alternative. In accelerated stability testing, samples are stored in different elevated temperature and humidity conditions, as determined by product type and market demands. Given the absence of official guidance from regulatory authorities concerning stability testing for cosmetic products, manufacturers should take into account these considerations: Conditions that might accelerate or predict the effects of stress on product consistency, including varying temperatures; Changes to a product’s aesthetic properties, such as color, fragrance or texture, under varying conditions; Variations in the manufacturing process that might affect a product; and Packaging and its effect on formulation, and vice versa. 7 Steps for Stability Testing Following is a basic format for conducting a cosmetic formula stability test: Step 1: Batch Production. Calculate how much to produce based on the number of samples being used for testing. Guidelines from the International Conference on Harmonization (ICH) state that three batches at a certain scale must be placed on stability; these batches should be representative of the quality of the material to be made on a production scale. Step 2: Product Container Filling. The product should be filled in proper intermediate and final packaging, as it is best practice to test both the container and final packaging during stability testing. Samples should be representative of the batch size as well as the range of shades, fragrances and formulations to properly test stability extremes of the product. The closure system should be the same as the packaging proposed for storage and distribution. Step 3: Initial Test (Time Point Zero). Once samples are filled, one should test for all characteristics to be evaluated later. Exact tests depend on the specific product, but minimally, one should record appearance, color, pH, viscosity readings and fragrance. For aerosol products, spray patterns should be tested. Step 4: Product Storage. Stability testing requires different temperature and humidity conditions. Some standard temperatures include: 40°C/75% RH; 30°C/65% RH; 25°C/60% RH; and 5°C/no RH. Step 5: Product Evaluation. For long-term studies, the frequency of testing should be sufficient to establish the stability profile for the formulation. The frequency of testing at long-term storage conditions normally is three months during the first year; every six months during the second year; and once annually thereafter through the proposed re-test period. At the accelerated storage condition, a minimum of three points, including the initial and final time points (e.g. 0, 3 and 6 months), from a six-month study is recommended. Where an expectation exists that data from accelerated studies is likely to approach significant change criteria, one should conduct increased testing, either by adding samples at the final time point or by including a fourth time point in the study design. When testing at the intermediate storage condition is called for, due to a significant change under accelerated storage conditions, a minimum of four time points, including the initial and final time points (e.g. 0, 6, 9 and 12 months), from a 12-month study is recommended. Step 6: Determine Stability. After the defined stability study period, one should have a high level of certainty whether the formula is stable or not. If test results yield unsatisfactory or questionable results, additional testing should be performed. Nearly all products will exhibit some change, so it will be up to the manufacturer to determine whether the product passes. Step 7: Conclusion Report. Once testing has been completed, a conclusion report on stability should be compiled, including: Identification of the lab conducting the testing (if a third-party contractor is used); Identification of the product; Samples of primary packaging material used in the test; Description of the methodology used to determine the product’s minimum durability, study conditions and results of the study; and The signature of the person responsible for the study. Conclusion It can benefit cosmetic manufacturers to incorporate routine stability testing into the lifecycle of their products. By obtaining this critical data about a product, manufacturers can create better products while improving efficiencies in terms of material management. Furthermore, while the largest global regulatory authorities do not currently require cosmetic stability testing, they do require such testing for pharmaceuticals. This indicates at least some potential that the same expectation could be levied on cosmetic manufacturers eventually. In that event, early-adopter cosmetic manufacturers with routine stability testing processes in place would be well positioned to respond. Stability test helps ensure that a cosmetics maintains its intended physical, chemical, and microbiological properties over time. This process verifies that factors like appearance, color, odor, viscosity, and pH remain consistent, and that the product’s efficacy and safety are not compromised under various storage conditions. Guidelines and Standards for Stability Testing The Cosmetic Guidelines on Stability Testing of Cosmetics developed by the EU, along with the ISO/EU 18811:2018 technical report, provide industry best practices for conducting stability tests. The guidelines recommend testing under various conditions to simulate real-life scenarios, such as temperature fluctuations, exposure to light, and humidity. Key Aspects of Stability Testing Stability testing typically involves two main types: Accelerated Stability Testing: This method subjects the product to elevated temperatures (e.g., 40°C ± 2°C) and humidity levels to predict its shelf life over a shorter period. These tests are usually conducted over 3 to 6 months and provide insights into how the product will perform over its intended lifespan. Real-Time Stability Testing: This long-term approach assesses the product under normal storage conditions (e.g., room temperature) for a period that reflects the product’s intended shelf life, usually 12 months or longer. Real-time stability testing is essential for confirming the results obtained from accelerated tests. Factors Assessed During Stability Testing Physical and Chemical Stability: Evaluates changes in the product’s appearance, color, fragrance, pH, viscosity, and other physical attributes over time. Microbiological Stability: Ensures that the product remains free from microbial contamination throughout its shelf life, especially for water-based formulations. Packaging Compatibility: Assesses the interaction between the product and its container to ensure that the packaging does not compromise the product’s stability. This includes checking for leaks, corrosion, or degradation of packaging materials. Importance of Stability Testing in the Cosmetic Product Safety Report (CPSR) Stability testing is a vital part of the Cosmetic Product Safety Report (CPSR), required by the EU Cosmetics Regulation before a product can be placed on the market. The CPSR includes: Part A: Cosmetic product safety information, where stability test results are documented to confirm the product’s durability. Part B: Cosmetic product safety assessment, which relies on the stability data to determine the product’s safety profile. If you need stability testing for your product, check out our Accelerated Stability and Compatibility Test product for the best prices and fast solutions. Accelerated Stability and Compatibility Test Cosmetic stability testing is an experiment to assess the physical, chemical and microbiological stability of a cosmetic under controlled storage conditions during its lifecycle. These tests are essential for cosmetics' safety, efficacy, and quality, especially in the product's shelf life after introduction. Stability testing will help determine if there is any potential for changes during storage, transport and use, and whether these are within safe range. Learn more about beauty products testing.Potential Consequences of Unstable Cosmetic ProductsChanges in Appearance and TextureColor change, seperation or texture variations may occur in makeup product when stored and applied. They don't only influence the product design but also the user experience.Performance DegradationCosmetics may be chemically or physically altered in storage and subsequently the product will lose its effectiveness. For example, actives might break down by oxidation, hydrolysis or some other reaction and so it may lose its cosmetic properties.Safety RisksStable cosmetics could irritate your skin, cause allergies or other illnesses. It also may be contaminated with microorganisms that may cause bacterial infection during usage.Legal and Reputational RisksIn case instability cause product recall or lawsuits, manufacturers can lose substantial sum of money and lose their brand.How Stability Testing Ensures Compliance and Consumer Confidence?Ensuring Product Quality and SafetyStability testing allows manufacturers to ensure that products are physically, chemically, and microbiologically quality through out the shelf life without recalls and legal actions due to quality issues.Meeting Regulatory RequirementsMany countries and territories are very strict on the stability of cosmetics. For instance, EU regulations require cosmetics to pass stability testing to be safe and effective. By carrying out such tests, companies can offer conformant products and circumvent sales restrictions if they fail.Extending Shelf LifeStability testing allows a manufacturer to measure the shelf life correctly so a product can be in the best state for the duration of its intended use. Not only does this reduce waste, but it also increases consumer happiness.Boosting Consumer TrustManufacturers can also show their product quality and safety with a well-tried and verified product, and hence gain more consumers trust and loyalty.The cosmetic industry doesn't go anywhere without stability testing. It increases product quality and safety, compliance for manufacturers, and consumer delight. Through scientific stability testing, producers can ensure that the quality of the product is properly managed, risks are limited and manufacturers are not losing out on the market.General Process of Stability TestingSample PreparationStability testing is done first with sample preparation. Usually it involves choosing a proper quantity and packaging type as per test requirements. A freeze-thaw cycle test, for example, might require three test samples and first measurements.Testing ConditionsStability conditions based on the product type and intended use. High temperatures, high humidity, light, mechanical noise are typical. For stability tests at rapid speed, for instance, samples can be placed in a 40°C ± 2°C condition for 60 days.The extreme temperature fluctuations experienced during transport and storage (flash freezing) must also be accommodated for some products.Evaluation ParametersTest conditions for stability are sensory qualities (such as shape, smell, color), physicochemical properties (such as viscosity, pH), microbiological data (such as bacteria, mold and yeast contamination), packaging performance (such as leakage rate).Lotion stability test ASometimes it also has to be determined how formulation components interact with packaging materials to protect the product.Stability testing is very important in cosmetic product development and testing. These tests make sure products on the market are safe and effective. Design the right stability testing procedure for their product to meet the characteristics and market requirements. They can modify formulae and packaging plans based on test findings to maximize shelf-life and market leadership.Regulatory Guidelines for Cosmetics Stability TestingCategoryRegulatory GuidelinesDescriptionInternational GuidelinesISO/TR 18811:2018International standard for cosmetics stability testing, offering manufacturers a method for testing cosmetics stability under market conditions. It provides a technical guide to choosing the right methods of stability testing but does not dictate test conditions or parameters.ISO 22716 and ISO 16128ISO 22716 (Good Manufacturing Practices for Cosmetics) and ISO 16128 (Technical Definitions and Criteria for Natural and Organic Cosmetics) provide guidelines on cosmetic manufacturing quality.Regional and National GuidelinesEuropean Union (EU)The EU Cosmetics Regulation (EC No. 1223/2009) requires stability testing prior to use to ensure product safety and effectiveness over its intended shelf life. However, it does not specify test procedures or criteria. Additionally, the EU publishes Guidelines on Cosmetic Product Safety Assessment, stressing the need to consider physical, chemical, and microbiological stability and apply accelerated aging tests for shelf life prediction.United States (US)The FDA does not require pre-market stability testing for cosmetics but considers it a part of Good Manufacturing Practices (GMP). Stability testing typically follows GMP standards to verify that products remain stable and safe during storage and use.Asia-Pacific RegionStability testing regulations in this region are nationalized. For example, China's Cosmetics Supervision and Administration Regulation mandates stability testing by manufacturers. Other countries like Japan and South Korea have their own regulations, often including minimum stability standards.There are similarities among the stability testing standards for cosmetics from different regions and countries, but also vast disparities. For that reason, manufacturers will need to adapt their stability testing strategy to the regulations of their target markets.Practical Considerations in Implementing Stability Testing GuidelinesAs you implement stability testing rules, here are the practical problems you should consider:Test Duration and FrequencyDetermining Appropriate Test DurationStability testing should be done as per product type, shelf life, and regulations, which should dictate the length of stability testing. For instance, stable product under suggested storage conditions are usually tested for a period of at least 12 months as a long-term stability test. Stability may require longer test times to confirm for some valuable/sensitive products.Establishing a Testing ScheduleThe usual testing schedules are first testing, periodic testing (3, 6, and 12 months), and last testing. These times must be chosen based on chemical and physical stability of the product and expected shelf life.Test Methods and TechniquesCommon Analytical MethodsVisible visual inspection, pH testing, viscosity measurement, HPLC testing of active components and microbiological analysis are the common stability testing analytical methods. The method should be adapted to the type of product and stability measures to be evaluated.Selecting Methods for Specific Product Types and Stability ParametersHPLC might be required for the degradation of actives in drugs, or accelerated stability testing for cosmetics to monitor temperature, humidity and so on effects on product performance.Data Interpretation and DocumentationStability testing results must be interpreted scientifically to see if the product stays in quality and safety during the agreed shelf life. For instance, if there is no quantifiable degradation during the recommended storage conditions, then the product is guaranteed to be stable.You need to keep accurate records of every testing step, test results and conclusion to satisfy regulations and for quality control. This is to not only make testing transparent and traceable, but also support future regulatory filings.Stability testing is a messy process. It is necessary to make a testing roadmap with the specific product details and market needs. The process should follow scientific processes for data capture and processing for the integrity of the product.Challenges and Limitations in Cosmetic Stability TestingChallengesVariability of Raw MaterialsLikewise, raw materials are likely to have different characteristics on cosmetics stability. For example, active ingredients, such as ferulic acid, dilvent under temperatures, light, and pH changes in water solutions. This results in lower product stability, or even oxidative yellowing. Moreover, raw materials quality could impact microbiological performance of the product.Complex Product FormulationsMany elements in a cosmetic are combined in the compositions and can also interact chemically or biologically which influences overall consistency. Examples of which include different elements of the formulation that may change in the event of oxidation, hydrolysis or isomerization reactions that results in lower performance for the product.The environment temperature, humidity, and light influence the stability of cosmetics. For example, high temperatures and low temperatures can cause the evaporation and degradation of some elements. Interactions between packaging material and the product can cause issues of stability.LimitationsLimitations of Accelerated TestingAccelerated stability testing is a useful way to collect stability information in a hurry but it doesn't always tell us about stability over the long term. Accelerated tests are typically run under severe conditions to test what will happen when the storage or transport is prolonged. But these are just assumed conditions, and might not reflect real use-cases.Lack of Standardized Testing MethodsFor some new substances or products, we do not have common standards for testing. For example, stability testing techniques for some natural extracts or new components haven't fully been codified, so it's difficult to test for stability over the long term.Insufficiency of Testing MethodsCurrent stability testing approaches typically involve a lot of sample preparation and advanced analysis that take a long time and cost money. Also, some approaches don't cover all stability problems completely. Degradation processes of certain ingredients in particular circumstances might not be well understood, for instance.The cosmetic stability testing problems are primarily related to the variability of raw materials, the complexity of formulations and environmental effects, the problems of the accelerated testing in that it is not completely reliable, there are no standardised testing methods for novel ingredients, and the testing methods are insufficient. These problems require further studies and technological fixes to get rid of them.Best Practices for Cosmetic Stability TestingTo ensure the best practices for cosmetic stability testing, the following points are crucial:Comprehensive and Systematic ApproachStability testing has to be comprehensive and systematic so that the product stays safe and quality all the way through the product's lifecycle. This involves evaluating the product performance under different environmental conditions like temperature, humidity, light to model its reliability under real-world storage and use conditions. Also, manufacturers need to adapt test methods in a flexible manner according to the needs and properties of the product, in response to new or strange technical issues.Use of Multiple Testing Conditions and ParametersThe ideal set of conditions and parameters for evaluating product stability is multiple to get the full picture. Physical and chemical characteristics (Color, Odor, Viscosity, pH, etc.), microbiological stability (like bacteria, mold, and yeast contamination), and packaging stability (like the effect of packaging on the product). From these multidimensional tests it is possible to have a more accurate view of the overall product stability and key influencers of product quality.Role of Quality Control and Quality Assurance SystemsStability test results should be guaranteed with a reliable and consistent quality control/QA systems. – Manufacturers need to implement strict quality control process to standardize and trace the testing process. These range from tight control of the conditions of experiments (temperature, humidity, light) to the reliability and precision of experimental records. The Quality Assurance team should also check test results periodically to be sure that they meet the quality standard and make the corrective steps to make testing more reliable.The best practices for cosmetic stability testing include, but are not limited to, applying multiple conditions and parameters to get a holistic view of product stability, as well as addressing the role of quality control and quality assurance processes to ensure test results are reliable. They will also take steps to make cosmetics in the market safe and effective.ReferenceZang, C. U., et al. "Application of desert date (balanites aegyptiaca) seed oil as potential raw material in the formulation of soap and lotion." American Journal of Analytical Chemistry 9.9 (2018): 423-437. It is crucial for cosmetics to be safe for use. Not only directly after opening a new product but also after a week, month or even a year. Just like in food, this is called the minimum durability, or expiration. It is required to test the durability of cosmetics before the product is allowed for sale, since the minimum durability must be indicated on the product packaging. The durability of a product is tested using various testing, such as stability testing, compatibility testing (= stability test in final packaging) and microbial challenge testing. Why are stability tests important for the minimum durability of cosmetics? Cosmetic products are substances or mixtures of substances that consumers can use for extended periods. During this entire time period, these products must remain stable. The last thing you want is that the product starts discolouring or deteriorating when it is still being consumed. Not just because such unstable products look weird and less attractive for users, but also because this can cause safety risks for the consumer. A sunscreen product that is unstable may have as a consequence that you apply less UV filter than you’d think, causing you to get sunburned much more quickly. Various types of stability tests Stability tests are done to test the product’s shelf life. The most ideal test would be to test the product at least as long as the expiration date indicates on the product labelling. This can be for example 2 years, and this type of testing is what we call real-time testing. With a 2-year test, you know that the product is indeed durable for 2 years. Sounds great and all, but that also means that the product is only allowed to be sold after the test is finished – in the example, this would be after 2 years (because: first the product must pass all testing and only then it may be sold). When you realize that the average product life cycle is 3 years (and then reformulated or replaced by a new variant), this would mean that you’d often be waiting almost for the same duration as you’d actually be selling the product. Stability tests are an essential part of cosmetics safety A better way to test cosmetics’ shelf-life To fix this problem, the cosmetics industry has adopted a much more efficient testing method. This is based on the work of the Swedish chemist Svante Arrhenius. He discovered that molecules (including the substances in cosmetic products) vibrate with a certain frequency. When he raised the temperature, the molecules would increase in vibration frequency. This insight showed that a higher temperature would result in more molecule vibrations in the same time period. With that, you can predict how often these molecules would vibrate at room temperature compared with a higher testing temperature. That sounds quite technical, but it’s a fantastic fix for the testing time of cosmetic products. By increasing the testing temperature, testing time can be reduced from years to months. A test done at a higher temperature is also called an accelerated stability test because the shelf-life of a product is simulated in an accelerated manner due to the elevated temperatures Stability testing at various temperatures Often various temperatures are used when doing stability testing. Because: the higher the temperature, the faster you have results, but the temperature can also get too high. Just like baking an egg, a cosmetic product can be irreversibly boiled due to the elevated temperature. That doesn’t say anything about the durability of the product, since this is only caused by the high temperature. Another example would be a deodorant stick, where a too-high temperature causes the product to melt. This also doesn’t provide a realistic view of the true product’s durability. So products are tested at various temperatures which ensures that you get fast, but also realistic results from the stability test. Naturally, it is also advisable to do a real-time test on the product so you can also get information from this scenario. Other methods for even faster testing Using various temperatures for an accelerated stability test is a great way to speed up the check of whether a product is stable. Besides this method, there are also other ways to pretty quickly get a sense of whether a product formula is unstable. These include tests that can be done even faster compared with accelerated stability testing. These tests often give a less accurate view of how long a product can be stable. But these tests do give a good answer to whether a product can withstand the most extreme stress. So you can see it more as a first check, if a product fails this step it doesn’t need to go through the 3-6 months of accelerated stability testing. Examples of these super-fast methods are Centrifuge testing for creams Temperatuur stress testing Mechanical stress testing Centrifuge testing for cosmetics, half an hour With centrifuge testing, creams are heated and centrifuged at 3000 rounds per minute. If cream is unstable, it will show this in the form of oil droplets on the surface of the cream. This is actually called ‘creaming’, and a stable cream shouldn’t be creaming. This test only takes half an hour to do which makes it a perfect first test for an emulsion formulation like a cream. Centrifuge tests for cosmetica only take half an hour Temperature stress testing or ‘cycle’ testing Temperature-based stress tests are also called ‘cycle’ tests because the temperature is changed every 24 hours between warm (25 degrees Celsius) and cold (-10 degrees Celsius). If you’ve ever visited a sauna you know that changing temperatures can be quite spicy, and that’s exactly the same for cosmetics. If a product passes this test with flying colours, then it is almost certain that the product is super stable. The added bonus of this test is that it also mimics product transport and shipping, during which products are also exposed to varying temperatures. Mechanical stress testing on roller or shaker machines Mechanical stress tests are tests during which products are shaken vigorously, to check whether they can withstand the physical aspects of shipping. No, that doesn’t mean that lab people are secretly throwing a cocktail-shaking competition in the lab (shaken, not stirred), this process is done on specialized equipment. Not recommended: do-it-yourself stability testing A lot of these methods are aimed at the first check for product stability. Especially in the past, many old-school product developers working at manufacturers also used some out-of-the-box tricks. Just by throwing a couple of product samples in the back of their car, driving them around and leaving them out in the burning sun, this was a perfect combination for testing new formulations. Nowadays testing is of course much more modern since the quality requirements have become much stricter. And the stakes have become higher, needing to produce results as soon as possible. This is how you shouldn’t do a stability test for cosmetics What does a professional stability test for cosmetics look like? Often stability tests are done in glass containers. This is because glass is inert, it reacts to (basically) nothing. If the product is unstable, then you know it’s really due to the formulation itself. In parallel, the product is also tested in its final packaging. Is the product stable in glass, but not in its final packaging, then you know the problem lies with the packaging (or the combination of product + packaging). It’s not a strict requirement to test in glass, but it can add a lot of information to your results, especially if you don’t have a lot of experience with the stability of a particular formulation or packaging. Testing in the final packaging: the compatibility test A stability test in its final packaging is also called a compatibility test because you look at how compatible the formulation and the packaging are. Because a product can leak out of its packaging, substances can migrate from the packaging into the product and vice versa, the product may discolour if the packaging isn’t airtight. You want to know that the product has a great shelf-life in its final packaging, before the product is sold on the market. Cosmetics with a long shelf-life are safe cosmetics Cosmetic products must have long minimum durabilities. Two of the most important tests to check product shelf-life are the stability of the product formulation and the compatibility between the formulation and its packaging. These can be studied using various methods, with the most common test being the accelerated 2-4 months stability test. Introduction Stability testing of cosmetics and personal care products is essential to ensure product safety, performance, and consumer satisfaction over the product’s intended shelf life. These products—ranging from creams and shampoos to serums and deodorants—undergo chemical, physical, and microbiological changes over time, which can impact their efficacy and safety. Unlike pharmaceuticals, cosmetics are typically non-sterile and are regulated differently across global jurisdictions, yet stability assurance remains a cornerstone of product integrity. This article offers a complete guide to stability testing for cosmetics and personal care formulations, covering test conditions, regulatory frameworks, physical and microbial stability parameters, ISO standards, packaging considerations, and case-based strategies for compliance and quality management. 1. Why Stability Testing Is Critical for Cosmetic Products Consumer Safety and Quality Ensures product does not degrade into harmful by-products Maintains expected texture, fragrance, color, and viscosity Prevents microbial contamination during prolonged use Business and Regulatory Risk Non-compliant products can lead to recalls, customer complaints, and reputational damage Label claims such as “12-month shelf life” or “preservative-free” must be scientifically supported 2. Key Regulatory Frameworks Governing Cosmetic Stability EU: Regulation (EC) No 1223/2009 Mandates Product Information File (PIF) containing stability data Labeling requires Period After Opening (PAO) or Best Before Date (BBD) US: FDA Cosmetic Requirements Stability testing is not mandatory but expected under GMPs Products must be safe under labeled storage conditions See also Regulatory Frameworks for Stability Testing Across IndustriesIndia and ASEAN Markets Follow Bureau of Indian Standards (BIS) IS 4011 and similar ASEAN Cosmetic Directives Require supporting stability data for new or reformulated products 3. Types of Stability Testing for Cosmetics Physical Stability Color, odor, viscosity, phase separation, precipitation pH and specific gravity changes Chemical Stability Fragrance integrity, oxidation (e.g., oils, essential actives) Degradation of active ingredients (e.g., retinoids, vitamins) Microbiological Stability Preservative efficacy (PET or Challenge Testing) Total aerobic count, yeast, mold testing 4. Accelerated and Real-Time Testing Protocols Accelerated Stability Testing Conditions: 40°C ± 2°C / 75% RH ± 5% for 3–6 months Simulates long-term storage to identify degradation risks Real-Time Stability Conditions: 25°C ± 2°C / 60% RH ± 5% or ambient Supports long-term shelf life labeling (e.g., 12–36 months) 5. Preservative Efficacy Testing (PET) ISO 11930 Standard Measures effectiveness of the antimicrobial preservation system Product inoculated with common challenge organisms and monitored over 28 days Common Organisms Staphylococcus aureus Pseudomonas aeruginosa Candida albicans Aspergillus brasiliensis Acceptance Criteria Log reduction requirements defined for each organism at 7, 14, and 28 days 6. Specialized Stability Testing Approaches Freeze–Thaw Cycling Typically 3 cycles of 24 h at –5°C to +40°C Detects phase instability and emulsion breakage Light Exposure and Photostability Especially for products containing essential oils, colorants, or vitamins Align with ICH Q1B conditions or natural sunlight simulation See also How Retest Dates Impact Pharmaceutical Product Stability7. Packaging Compatibility and Functional Testing Factors to Consider Material migration, leaching of colorants or plasticizers Dispensing consistency and pump/spray functionality Testing Techniques Headspace gas analysis Seal integrity and squeeze test for tubes 8. Shelf Life and Labeling Requirements EU Compliance PAO symbol (e.g., “12M”) for products lasting over 30 months BBD for those with US Labeling Trends No legal requirement for expiration dates, but common for natural and premium products Products labeled “preservative-free” require extra justification for microbial safety 9. Case Study: Stability Testing of a Natural Facial Serum Product Description Water-based serum with green tea extract, hyaluronic acid, and essential oils Testing Approach Accelerated stability: 40°C/75% RH for 6 months PET as per ISO 11930 using challenge organisms Freeze–thaw and light exposure cycles Findings Minor fragrance loss at 3 months; corrected with packaging upgrade Preservative system effective against all challenge organisms Shelf life set at 24 months with amber packaging and dry storage 10. Essential SOPs for Cosmetic Stability Testing SOP for Accelerated and Real-Time Stability Testing of Cosmetic Products SOP for Preservative Efficacy Testing as per ISO 11930 SOP for Physical Stability Assessment (Color, Odor, Phase Separation) SOP for Freeze–Thaw and PhotoStability Studies in Cosmetics SOP for Cosmetic Product Labeling and Regulatory Shelf Life Compliance Conclusion Stability testing is a vital aspect of cosmetic product development, regulatory compliance, and brand integrity. Whether it’s verifying the performance of a moisturizer under tropical conditions or ensuring the microbial safety of a preservative-free serum, stability data provides the foundation for consumer trust. By aligning testing with ISO guidelines, regional regulations, and scientific best practices, manufacturers can develop safe, high-quality personal care products with verifiable shelf lives. For validated test protocols, ISO compliance templates, and SOP documentation packs, visit Stability Studies. Stability Testing for Cosmetics and Personal Care Products, Stability Testing Regulations Across Industries Tags:cosmetic accelerated stability, cosmetic compatibility packaging, cosmetic freeze thaw protocol, cosmetic pH stability, cosmetic photostability testing, Cosmetic product shelf life, cosmetic regulatory compliance stability, cosmetic stability testing, cream lotion shelf life, EU cosmetic regulation 1223/2009, freeze thaw stability cosmetics, ISO 11930 preservative efficacy, ISO 29621 guidance, microbial limit cosmetics, microbial stability cosmetics, organoleptic testing cosmetics, personal care shelf life, physical stability lotions, preservative stability test ISO, stability SOP for cosmetics Routine stability testing provides cosmetic manufacturers with critical data about their products’ safety and shelf life and can help you align your products with the FDA’s cosmetic stability testing guidelines. Although the US food and Drug Administration (FDA) does not yet require cosmetic manufacturers to conduct stability testing on products before commercially marketing them, we consider it a good manufacturing practice. The information gained from stability testing can be useful to companies both externally and internally, creating successful ANDAs (abbreviated new drug applications) and informing product development, material procurement/management, and lifecycle management. This page provides an overview of the basics manufacturers should consider when developing a stability testing protocol for cosmetic products. About Product Stability Testing As is well-known, stability testing is essentially an experiment in which a batch of formula is created and placed into different environmental conditions for a set period of time. These conditions vary in temperature and humidity and are meant to simulate what happens to the product during its life cycle. The associated stability test protocol, then, should define test parameters that evaluate stability samples. In the pharmaceuticals field, both the FDA and the European Medicines Agency require the stability testing of products before they can be sold to consumers. The main purpose is to measure and document the potency of medications up until a predicted expiration date.This data has proven important, especially considering the FDA has cited, within the past two years, stability-related issues as key factors in pharmaceutical recalls. And, as pharmaceutical and cosmetic manufacturers well understand, such product recalls are not only expensive and labor intensive, but they also can seriously damage one’s brand image. Similar to pharmaceuticals, cosmetics naturally degrade over time, and stability testing via the manipulation of storage temperature and other factors can reveal the extent to which they degrade by measuring factors such as: The natural degradation rate of key ingredients A product’s ability to resist microbial intrusion The product’s reactivity to packaging materials Impurities exacerbated by the manufacturing process Product response to heat, humidity, and light One objective of stability testing is to ensure that a product maintains its intended physical, chemical and microbiological qualities—as well as functionality and aesthetics—when stored under appropriate (room temperature) conditions. Another is to glean data by foreseeing the stability of the cosmetic product over time within its useful life span, as well as compatibility between the formulation and the container material. Cosmetic Stability Testing Guidelines As stated, there currently are no existing enforceable or uniform protocols outlined by the FDA Code of Federal Regulations or European Commission Regulation No. 1223/2009 for the stability testing of cosmetics. The exception is for some OTC products, such as sunscreens, antiperspirants/deodorants, and dandruff shampoos. As such, a well-designed internal stability protocol must test those product attributes that are susceptible to change during storage, and that can influence the quality, safety, and performance of the product. Stability studies include the evaluation of product quality at specific time intervals of a storage period under controlled conditions. There are three basic forms of stability tests: Physical and chemical integrity: These evaluate the color, odor or fragrance, pH value, viscosity, texture, ow and emulsion stability, or signs of separation. Microbiological stability: These evaluate the degree of contamination with bacteria, mold and/or yeast. Packaging stability: These evaluate the effect of packaging on the contained product. Stability testing for cosmetics is typically performed when: A new product is developed; An existing on-market product has been reformulated; The production method has been modified, or production has moved to a new facility or vendor; and/orpackaging has changed. Currently, little published research exists to support specific methods for predicting cosmetic shelf life. Reasons for the gap in cosmetic shelf life information: The wide variety and complexity of cosmetic formulas and packaging; The proprietary nature of most cosmetic products and their associated stability test methods; and The scope of potential changes to be examined, including physical, chemical, microbial, functional or aesthetic. For each formulation type, manufacturers should determine the qualities to be examined, then test them at one or more temperature and humidity conditions. Test parameters should be evaluated and a decision made for each criterion based on the company’s own internal procedures and experience. Evaluations should allow for the deduction of predicted or real stability of the product. Since time is such a crucial parameter in the development of a new cosmetic product, real-time cosmetic stability testing is not always feasible. In such situations, accelerated stability testing represents a good alternative. In accelerated stability testing, samples are stored in different elevated temperature and humidity conditions, as determined by product type and market demands. Given the absence of official guidance from regulatory authorities concerning stability testing for cosmetic products, manufacturers should take into account these considerations: Conditions that might accelerate or predict the effects of stress on product consistency, including varying temperatures; Changes to a product’s aesthetic properties, such as color, fragrance or texture, under varying conditions; Variations in the manufacturing process that might affect a product; and Packaging and its effect on formulation, and vice versa. Steps for Cosmetic Shelf Life and Stability Testing Following is a basic format for conducting a cosmetic formula stability test: Calculate how much to produce based on the number of samples being used for testing. Stability guidelines from the International Conference onHarmonization (ICH) state that three batches at a certain scale must be placed on stability; these batches should be representative of the quality of the material to be made on a production scale. 2. Product Container Filling The product should be filled in proper intermediate and final packaging, as it is best practice to test both the container and final packaging during stability testing. Samples should be representative of the batch size as well as the range of shades, fragrances and formulations to properly test stability extremes of the product. The closure system should be the same as the packaging proposed for storage and distribution. 3. Initial Test (Time Point Zero) Once samples are filled, one should test for all characteristics to be evaluated later. Exact tests depend on the specific product, but minimally, one should record appearance, color, pH, viscosity readings and fragrance. For aerosol products, spray patterns should be tested. 4. Product Storage Stability testing cosmetics requires different temperature and humidity conditions. Some standard temperatures include: 40°C/75% RH; 30°C/65% RH; 25°C/60% RH; and 5°C/no RH. 5. Product Evaluation For long-term studies, the frequency of testing should be sufficient to establish the stability profile for the formulation. The frequency of testing at long-term storage conditions normally is three months during the first year; every six months during the second year; and once annually thereafter through the proposed re-test period. At the accelerated storage condition, a minimum of three points, including the initial and final time points (e.g. 0, 3 and 6 months), from a six-month study is recommended. Where an expectation exists that data from accelerated stability studies for cosmetics is likely to approach significant change criteria, one should conduct increased testing, either by adding samples at the final time point or by including a fourth-time point in the study design. When testing at the intermediate storage condition is called for, due to a significant change under accelerated storage conditions, a minimum of four time points, including the initial and final time points (e.g. 0, 6, 9 and 12 months), from a 12-month study is recommended. 6. Determine the Cosmetic’s Stability After the de ned stability study period, one should have a high level of certainty whether the formula is stable or not. If test results yield unsatisfactory or questionable results, additional testing should be performed. Nearly all products will exhibit some change, so it will be up to the manufacturer to determine whether the product passes. 7. Conclusion Report Once testing has been completed, a conclusion report on stability should be compiled, including: Identification of the lab conducting the testing (if a third-party contractor is used); Identification of the product; Samples of primary packaging material used in the test; Description of the methodology used to determine the product’s minimum durability, study conditions and results of the study; and The signature of the person responsible for the study. Conclusion It can benefit cosmetic manufacturers to incorporate routine stability testing into the lifecycle of their products. By obtaining this critical data about a product, manufacturers can create better products while improving efficiencies in terms of material management. Furthermore, while the largest global regulatory authorities do not currently require cosmetic stability testing, they do require such testing for pharmaceuticals. This indicates at least some potential that the same expectation could be levied on cosmetic manufacturers eventually. In that event, early-adopter cosmetic manufacturers with routine stability testing processes in place would be well positioned to respond.