

# **SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES**

*Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai*

*Approved by Pharmacy Council of India, New Delhi.*

**Coimbatore -641035**

**COURSE NAME : COSMETIC SCIENCE- BP809ET**

**B.PHARM IV YEAR / VIII SEM**

**UNIT III**

**SUB TOPIC : BIS SPECIFICATION AND ANALYTICAL METHODS FOR  
SHAMPOO, SKIN CREAM AND TOOTHPASTE**

# Introduction to BIS



**Bureau of Indian Standards (BIS)**

- Established under BIS Act 2016;
- Sets quality standards for products in India.

## Role in Cosmetics



- Ensures Safety, Efficacy, and Quality
- Regulates under Drugs & Cosmetics Act 1940

## Key Principles



- Physical & Chemical Properties
- Microbial Limits
- Heavy Metals: Pb < 20 ppm, As < 2 ppm
- Analytical Test Methods

## Importance



- Protects Consumers from Harmful Substances
- Mandatory for Certification

# Analytical Cosmetics Overview

**Definition:** Analysis of cosmetic formulations for quality control, safety, and performance.

## Products Covered:



**Shampoo**  
(Surfactant-Based)



**Skin Cream**  
(Emulsion-Based)



**Toothpaste**  
(Dentifrice)

## Common Analytical Aspects:



**pH Testing**



**Viscosity Measurement**



**Microbial Enumeration**



**Heavy Metal Detection**  
(Atomic Absorption Spectroscopy)

## Regulatory Context:



- Aligned with BIS & International Standards (ISO)



- Focus on Surfactants, Preservatives, & Abrasives





# BIS for Shampoo - Introduction



## Scope:



Covers surfactant-based shampoos for hair cleansing;  
Excludes soap-based or medicated variants.

## Types:

- Clear, Opaque, Conditioning,
- Anti-Dandruff (Non-Medicated).



## Objectives:

- Ensure Cleansing Efficiency,
- Mildness on Scalp,
- Safety & Quality.



# Shampoo Specifications

Parameter	Requirement	Purpose
pH Value	5.5 – 7.5	Matches scalp pH; prevents irritation
Active Detergent	Min. 10–15% (w/w)	Ensures foaming and cleansing
Foaming Power	Min. 50 ml foam height	Measures cleaning efficacy
Microbial Limits	Total count <1000 CFU/g; No pathogens	Safety against infections
Heavy Metals	Pb < 20 ppm, As < 2 ppm	Prevents toxicity
Viscosity	2000–5000 cps (typical)	Ensures pourability

Free from rancidity; Stable at 37°C



## Analytical Methods for Shampoo – Part 1

### pH Determination

pH meter on 10% aqueous solution.



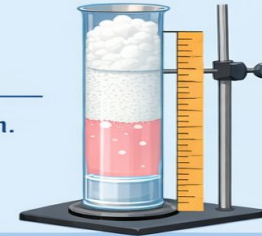
### Active Detergent Content

Titration with cetyltrimethyl ammonium bromide or benzethonium chloride.



### Foaming Power

Ross-Miles method — Measure foam height after agitation.



### Viscosity

Brookfield viscometer at specified RPM.



*Methods from IS 7884 Annexes; Accurate analysis in lab settings is essential.*

## Analytical Methods for Shampoo – Part 2

### Microbial Testing



- Plate count method (IS 5402)
- Absence of *E. coli*, *Staphylococcus*.

### Heavy Metals



- AAS or ICP-MS.

### Stability Test



- Incubate at 37°C for 7 days.
- Check for separation or odor.

### Other

- Total fatty matter by solvent extraction.
- Dirt dispersion test.



*Dispute resolution uses benzethonium chloride for surfactants.*

# BIS for Skin Cream – Introduction

**Standard:** IS 6608:2004 – Skin Creams

**Scope:** Covers emulsion or semisolid creams for skin moisturizing / protection.

**Types:**

- Vanishing Cream
- Cold Cream
- Moisturizing Cream
- Foundation Cream

**Objectives:**

- Ensure hydration, stability, and non-irritancy.
- Free from harmful dyes, if used.
- Complies with IS 4707 for dyes if pigmented.





# Specifications for Skin Cream

*Smooth, homogeneous texture; no grittiness.*

Parameter	Requirement	Purpose
pH Value	4.5 – 8.0	Skin compatibility
Total Fatty Substance	Min. 10–20% (type-dependent)	Moisturizing efficacy
Thermal Stability	No separation at 37°C / 7 days	Shelf-life assurance
Microbial Limits	Total count < 1000 CFU/g; No pathogens	Hygiene
Heavy Metals	Pb < 20 ppm, As < 2 ppm	Safety
Water Content	Max. 80%	Formulation balance



## Analytical Methods for Skin Cream

### pH



Potentiometric method  
on diluted sample.

### Total Fatty Substance



Solvent extraction  
and gravimetry.

### Thermal Stability



Visual inspection  
after incubation.

### Microbial



Pour plate method  
(IS 14648).

### Heavy Metals



Colorimetric or AAS.

### Other



Ash content, acid value for oils.

*Methods ensure compliance; Faster revisions recommended for outdated tests.*



BUREAU OF  
INDIAN STANDARDS

## TOOTHPASTE – INTRODUCTION

### STANDARD

- **IS 6356:2021** – Toothpaste Specification.






### SCOPE

- Covers abrasive-based dentifrices for oral hygiene.

### TYPES

- Fluoridated / Non-Fluoridated,
- Herbal, etc.

### OBJECTIVES

-  Cleaning & Oral Health
-  Fluoride Protection
-  Safety Assurance
-  Not for Whitening Claims Without Evidence 





## Specifications for Toothpaste

Parameter	Requirement	Purpose
✓ pH Value	5.5 – 10.5	Prevents enamel damage
✓ Fluoride Content	Max. 1000 ppm (as F)	Cavity prevention
✓ Abrasiveness	RDA < 250	Safe on enamel
✓ Microbial Limits	Total count < 1000 CFU/g	Oral safety
✓ Heavy Metals	Pb < 20 ppm, As < 2 ppm	Toxicity prevention
✓ Consistency	Extrudable paste	Usability

**No sharp particles; stable homogeneity.**

## Analytical Methods for Toothpaste

### pH



Electrode method on slurry.

### Fluoride



Ion-selective electrode or  
Colorimetric.

### Heavy Metals



AAS for Pb/As.

### Abrasiveness



Radioactive dentin abrasion  
(RDA) test.

### Microbial



Serial dilution and plating.

### Other



Lead by dithizone method;  
Extrusion test for consistency.

Methods from IS 6356 Annexes; Ensure low metal content.

# Conclusion

## Summary



**BIS standards (IS 7884, 6608, 6356) ensure safe, effective cosmetics through specs and methods.**

## Key Takeaways



**Focus on pH, microbes, metals; Analytical tests like titration, spectroscopy vital for QC.**



## Implications



**Compliance boosts consumer trust; Regular updates needed for innovation.**



## Future Outlook




**Alignment with global regulations like EU cosmetics standards.**





## The Confused Cosmetic

**Q1.** A shampoo has excellent foam, smells great, and looks premium—but its pH is **9.2**.  
The manufacturer says:  
"Foam matters more than pH."

**Critical Thinking:**  
Would this shampoo be acceptable?  
According to IS 7884:2023: **NO**

 **pH Too High!**  
Recommended pH: 4.5 - 6.5

**What Scalp Problems Could Arise?**

		
Irritated Scalp	Damaged Hair	Dandruff & Dryness

**What's More Important for Consumer Safety?**  
*Appearance or Analytical Compliance?*

**ANALYTICAL COMPLIANCE WINS!**

pH Balance is Essential for Hair & Scalp Health

“Our toothpaste is so strong it cleans enamel faster than competitors!”

Lab results show:  $RDA \equiv 310$

## Critical Thinking:

- ✓ Is this a Marketing Advantage or a Regulatory Disaster under IS 6356:2021?

**Regulatory Disaster!**

- ✓ Why does higher abrasiveness not always mean better cleaning?

**High abrasiveness can damage enamel and cause sensitivity!**

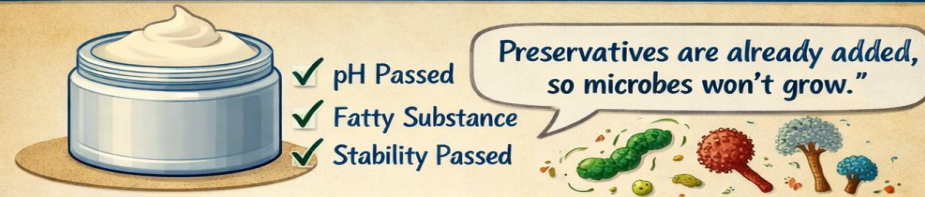
- ✓ If you were a BIS Inspector, what action would you take?

**Issue an Immediate Notice of Violation & Product Recall!**





### Questionnaire 3: "The Invisible Enemy"



**Why is this assumption scientifically incorrect under IS 6608:2004?**

Microbes can still survive or grow despite preservatives. Over time, bacteria, yeast and mold can develop.



**Which microbial test method would expose this mistake?**

**Challenge Test**  
(Preservative Efficacy Test)



**Can a product look perfect and still be unsafe?**

Yes! A cream can look, feel, and smell fine but be contaminated with harmful microbes.

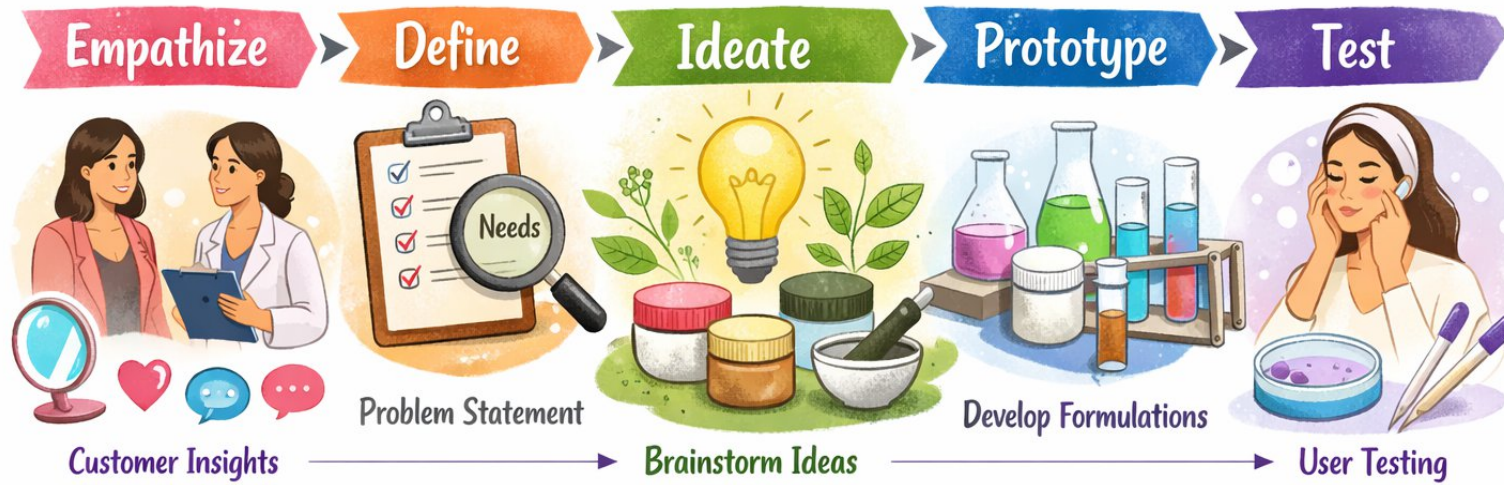
**Looks Good...**  
**BUT MAY HIDE DANGER!**





# Design Thinking

— for **Cosmetic Formulation** —



## REFERENCES :

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics- Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

