

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

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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)

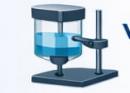


Toothpaste
(Dentifrice)

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

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.



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 ≈ 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"



✓ pH Passed
 ✓ Fatty Substance
 ✓ Stability Passed

Preservatives are already added, so microbes won't grow.

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 —



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- 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.

