Ind. J. Pharm. Edu. Res., 2026; 60(4s):s1474-s1485.
https://www.ijper.org

Original Article

# Evaluation of Commercial Lipstick Formulations for Compliance with BIS Standards: A Comparative Study

**Deepak Sharma, Dipanjan Koley, Khushbu Mehlawat, Kavita Attri, Vijay Bhalla*, Manvi Singh***

Department of Pharmaceutics, SGT College of Pharmacy, SGT University, Gurugram, Haryana, INDIA.

## ABSTRACT

**Background:** The Indian cosmetic industry is experiencing rapid growth, valued at USD 8.1 billion in 2023 and projected to reach USD 18.4 billion by 2032. Among cosmetic products, lipsticks are widely used and frequently applied, raising concerns regarding cumulative exposure to potentially harmful substances such as toxic heavy metals. Previous studies have reported contamination of cosmetics with elements like lead, cadmium, chromium, and arsenic, emphasizing the need for strict quality evaluation and regulatory compliance. Aim: The present study was conducted to evaluate the physicochemical quality characteristics and toxicological safety of commercially available lipstick formulations in accordance with Bureau of Indian Standards (BIS) guidelines. **Materials and Methods:** A total of 17 commercially available lipstick samples were collected and subjected to comprehensive physicochemical evaluation, including softening point, peroxide value (rancidity), breaking load, pay-off, and grittiness. Heavy metal analysis was performed using Atomic Absorption Spectrometry (AAS) for the detection and quantification of lead, cadmium, chromium, and arsenic. Toxicological risk assessment, including cancer risk estimation, was also carried out based on standard models. **Results:** All samples complied with BIS standards for physicochemical parameters, demonstrating adequate mechanical strength, thermal stability, low oxidative degradation, satisfactory application properties, and uniform texture. Cadmium and chromium were not detected in any sample. Lead was detected in one sample at an elevated level, indicating a reduced margin of safety and potential health risk. Arsenic was detected in all samples but remained within permissible regulatory limits. However, its consistent presence across all samples raises safety concerns. The calculated cancer risk values for all samples were within acceptable regulatory limits. **Conclusion:** Most lipstick formulations complied with established physicochemical and safety standards. However, the detection of heavy metals, particularly lead in one sample and arsenic across all samples, highlights the need for continuous monitoring, strict quality control, and strengthened regulatory oversight to ensure long-term consumer safety.

**Keywords:** BIS, Cosmetic Regulation, Lipstick, Oils, Waxes.

**Correspondence:**

**Dr. Vijay Bhalla**
Department of Pharmaceutics, SGT College of Pharmacy, SGT University, Gurugram-122001, Haryana, INDIA.
Email: vijay0434@gmail.com

**Dr. Manvi Singh**
Department of Pharmaceutics, SGT College of Pharmacy, SGT University, Gurugram-122001, Haryana, INDIA.
Email: manvi_pharmacy@sgtuniversity.org

**Received:** 03-05-2026;
**Revised:** 14-06-2026;
**Accepted:** 21-08-2026.

## INTRODUCTION

Cosmetics are a fundamental component of everyday personal care and are used by a wide range of people to cleanse, protect, as well as enhance their physical appearance. Even minimal amounts of potentially hazardous substances in skincare products might cause cumulative exposure and possible health hazards over time due to their frequent and prolonged consumption.[1] According to Heusèle *et al*., 2022[2] cosmetics are preparations that are applied to the skin, lips, hair, nails, and teeth in order to preserve or improve aesthetic appeal. Lipsticks, which are made with a complex blend of waxes, oils, pigments, and functional ingredients to produce color, texture, and stability, are among the most widely used color cosmetics among these products. While safety is defined by the lack of harmful health consequences under typical usage conditions, the quality of such items is assessed by their physicochemical stability, performance, and consumer acceptability during shelf life[3] however, have been reports of negative reactions such dermatitis, cheilitis, and irritation, which are frequently linked to allergies, dyes, preservatives, or pollutants like hazardous metals. A systematic assessment of product safety and compliance is required because the Indian cosmetic market, which is marked by the coexistence of international brands, domestic manufacturers, and unregulated products, shows substantial variations in formulation quality and manufacturing practices.[4] Lipstick safety assumes particular significance due to its unique route of exposure. In contrast to the majority of topical cosmetics, lipsticks come into direct contact with the lips and oral cavity, which increases the risk of accidental ingestion when speaking, eating, or drinking.[2] Chronic low-dose exposure to lipstick formulation elements may arise from

**DOI:** 10.5530/ijper.20265022

repeated daily application.[5] Adolescents, people with sensitive skin or dermatological disorders, and frequent cosmetic users are among the vulnerable groups that may be more susceptible to detrimental effects.[6] Product acceptability and safety may be further jeopardized by quality-related flaws such rancidity, instability, and grittiness in addition to local reactions like allergic cheilitis and irritation.[7]

These concerns underscore the importance of comprehensive quality and safety assessment of lipstick formulations. Physical instability, phase separation, microbiological contamination, and uneven performance are examples of quality-related problems in cosmetics.[1] In particular, lipsticks may have shortcomings such stick breakage, oil sweating, blooming, uneven color dispersion, and poor spreadability, which are frequently caused by imbalances in the composition of wax and oil or insufficient processing conditions.[2] Lipsticks are prone to oxidative decomposition due to their high lipid content, which might result in rancidity and the generation of potentially bothersome byproducts.[3] Additionally, improper pigment dispersion or wax crystallization can produce grittiness, which negatively impacts texture and user comfort. Microbiological safety also becomes a crucial factor in cosmetic evaluation because of their frequent handling and contact with oral flora.[1] Toxic heavy metal contamination is a major worldwide concern related to cosmetic items, especially in color cosmetics like lipsticks.[8] Lead (Pb), Cadmium (Cd), Chromium (Cr), Arsenic (As), Nickel (Ni), and Mercury (Hg) are among the metals that can be added as impurities in mineral pigments or during production processes. Long-term exposure and bioaccumulation may have substantial toxicological effects even if they are usually found in trace amounts.[5] Because of the neurotoxic, hematological, and nephrotoxic effects of lead, regulatory bodies including the U.S. FDA have recommended acceptable levels in cosmetic items. Exposure to arsenic is linked to systemic toxicity and the risk of cancer, whereas cadmium and chromium are linked to renal toxicity and allergic reactions.[5] Detectable levels of these metals have been found in cosmetics in many countries, according to numerous research, suggest that contamination is a prevalent issue. For instance, research conducted in Nigeria revealed Pb concentrations up to 0.19 mg/kg and Cd concentrations up to 1.67 mg/kg in lipstick samples, while[8] observed that Cd and Pb concentrations in European and Chinese lipsticks stayed within regulatory limits. According to Afridi *et al*, 2023.[6] Pb levels in cosmetic goods ranged from 50.5 to 120 μg/g, which correlated with higher biological levels in exposed people. In a similar vein, emphasized the possible health hazards linked to long-term exposure to Pb, Cd, and Cr because of bioaccumulation.[5] Advanced analytical techniques such as ICP-OES, GC-MS, ATR, MEKC, SEM-EDS, and Atomic Absorption Spectrometry (AAS) have been widely employed for the detection and characterization of such contaminants.[3,9]

Regulatory frameworks play a crucial role in ensuring the safety and quality of cosmetic products. The Drugs and Cosmetics Act, 1940 and Cosmetic Rules, 2020 control cosmetics in India, and the Bureau of Indian Standards (BIS) offers comprehensive guidelines and testing procedures for product assessment.[1] International regulatory organizations place a strong emphasis on strict stability and safety testing, control of heavy metal impurities, and adherence to Good Manufacturing Practices (GMP).[10,7] Softening point, breaking load, rancidity (peroxide value), pay-off, and absence of grittiness constitute the BIS guidelines for lipstick evaluation that conjointly influence product stability, performance, and customer acceptability.[2] The fast expansion of the cosmetics business and growing consumer exposure require ongoing monitoring and scientific assessment despite current rules. Growing disposable incomes, urbanization, and shifting lifestyles have all contributed to a sharp rise in the demand for cosmetics worldwide, especially in developing nations like India. The market for lipstick alone in India is expected to develop significantly because to rising consumer demand and a wider range of products. However, this growth is accompanied by concerns regarding the presence of toxic contaminants and variability in product quality. Waxes, oils, pigments, antioxidants, and fillers including mica, silica, and titanium dioxide are just a few of the many components included in lipsticks that could be causes of metal contamination.[11] Continuous application, often many times a day may cause the body to gradually accumulate harmful metals through eating, skin absorption, and inhalation. According to toxicological data, metals like Pb, Cd, and Cr have no biological function and can cause serious health problems such neurotoxicity, kidney damage, cancer, and poor reproductive results.[4] In this regard, the current study attempts to methodically assess, in compliance with BIS standards and regulatory guidelines, the physicochemical quality and toxicological safety of currently available lipstick formulations. By integrating conventional quality assessment with advanced heavy metal analysis, calculation of the heavy metal ion and cancer risk characterization, this work seeks to provide a comprehensive understanding of formulation performance, regulatory compliance, and potential health risks.

## MATERIALS AND METHODS

### Materials

All chemicals and reagents used in the present study were of analytical grade and utilized without further purification. Acetic acid, chloroform, and nitric acid (for sample digestion in heavy metal analysis) were procured from Merck Pvt. Ltd., Potassium iodide solution and sodium thiosulphate solution (0.01 N) were obtained from Loba Chemie Pvt. Ltd., Starch indicator was purchased from HiMedia Laboratories. Standard metal solutions of Lead (Pb), Cadmium (Cd), Chromium (Cr), and Arsenic (As) were obtained from Sigma-Aldrich. Distilled water used throughout the study was of laboratory grade and prepared in-house. All reagents were handled in accordance with standard laboratory protocols to ensure accuracy and reproducibility of experimental results.

## Sampling Strategy

A total of seventeen lipstick samples with each brand having 6 samples (17*6=102 samples), coded from A to Q, were procured from various local and branded cosmetic outlets to ensure representation across different price ranges and formulation types. The coding of samples was performed to maintain confidentiality of brand identity and to eliminate any potential analytical bias during the evaluation process. The various evaluation procedure in accordance to BIS are elaborated below.

## Inclusion Criteria

The study included only conventional wax-based lipstick formulations intended for cosmetic application on the lips. Both branded and locally manufactured lipstick products were included to represent a broad spectrum of products available in the Indian cosmetic market.

Lipstick samples were procured from authorized cosmetic stores, pharmacies, supermarkets, and local retail markets. Only products available in their original, unopened, and manufacturer-sealed packaging were considered for inclusion to minimize the possibility of contamination or product deterioration. Samples bearing complete product information, including the brand name, manufacturer details, batch number (where available), manufacturing date, expiry date, and ingredient declaration, were preferentially selected. Products with a valid shelf life at the time of purchase and representing different price categories (economy, mid-range, and premium) were included to provide a comprehensive assessment of commercially available formulations.

## Exclusion Criteria

Products that did not satisfy the inclusion criteria were excluded from the study. Liquid lipsticks, lip glosses, lip balms, lip crayons, lip tints, medicated lip preparations, and other non-wax-based formulations were excluded because of differences in composition and manufacturing processes that could influence physicochemical characteristics and analytical outcomes. Expired products, samples with damaged or previously opened packaging, visibly deteriorated or contaminated products, counterfeit or duplicate products, and products lacking adequate labelling or manufacturer information were also excluded. These exclusion criteria were adopted to ensure uniformity of the study samples and to enhance the reliability and reproducibility of the analytical findings.

## Softening point evaluation

Place the lipstick with protruded salve in the flat bottom tube. Fix the thermometer through cork in such way that bulb of thermometer just touches the lipstick salve. Insert this arrangement into a 1L beaker filled with water to level 1cm above the upper tip of lipstick salve. Slowly heat the temperature rises at a rate not exceeding 2°C/min. When the temperature reaches about 45°C, raise the temperature at the rate of 1°C/min. constantly watch the lipstick salve. Record the temperature when the salve starts bending & losing its shape.[12]

## Rancidity evaluation (Per-oxide number)

Weigh 5.0±0.05 g of lipstick sample in a 250 mL conical flask and dissolve in 30 mL of acetic acid - chloroform mixture (3:2). Heat if necessary to dissolve the sample. Add 0.5 mL of freshly made saturated potassium iodide solution. Shake and after 2 min add 30 mL of distilled water and then titrate with 0.01 N sodium thiosulphate solution using starch as an indicator 12.

Peroxide number = Milli equivalents peroxide per 1000 g sample

$$\frac{A \times N \times 1000}{\text{Mass of sample}}$$

A=volume in mL of sodium thiosulphate.

N=normality of sodium thiosulphate solution.

## Breaking load test evaluation

Fix firmly the lipstick container with protruded salve of diameter ranging 11 to 13 mm, into a screw type of chuck so that the assembly is perfectly horizontal. Adjust the burette just above the lipstick salve. Make a marking at a distance of 1.5cm from the base of the salve where lipstick salve sits in salve holder cup. Weigh the aluminium container along with hook & suspend it on this 1.5 cm mark slowly release water from the burette into the aluminium container till the salve breaks. Burette reading added with the mass of the suspended container gives the breaking load of the lipstick.[12]

## Pay-off test evaluation

Chop off the portion of lipstick salve 1cm from the tip using sharp blade. Rub remaining portion of the salve on piece of paper & make the end portion perfectly flat. Run the constant speed motor & determine the time required for pulling out 100cm of paper length. Weigh the lipstick with chopped off tip on a balance accurately. Insert this lipstick in the slot arrangement so that the flattened salve portion rests on the surface of the paper strip. Place a total load of 50 g including mass of the lipstick on top of the lipstick. Start the constant speed motor & with the help of stopwatch allow 100 cm length of piper to run. Reweigh the lipstick after the rub off & measure the length & width of the line drawn on the paper strip.[12]

## Freedom from grittiness

Collect approx. 0.5 g of lipstick paste & spread the paste on butter paper on a HMHD sheet. Test the paste by pressing it along the length by a finger for presence of any hard- & sharp-edged abrasive particles which will be distinguished readily. The material shall be free from hard- & sharp-edged particles.[12]

## Microbiological evaluation

Microbiological evaluation of the samples was performed in accordance with standard BIS guidelines using plate count methods[12] on microorganism such as *Staphylococcus aureus, Pseudomonas aeruginosa*, and *Escherichia coli*. Prior being used, nutritional agar and Sabouraud agar media were produced, sanitized, and kept at 48±2ºC. The sample was aseptically put into molten agar tubes in precisely weighed volumes (0.5 g each), carefully mixed, and then poured into sterile Petri dishes. For bacterial growth, the nutrient agar plates were incubated at 37±0.5ºC for 48 hr, and for fungal growth, the Sabouraud agar plates were incubated at 20-25ºC for 7 days. Following incubation, visible colonies were counted using a colony counter. The mean count from both counts was used to determine the average number of Colony-Forming Units (CFU) per gram of sample. Standards BIS parameters and acceptance criteria are mentioned in Table 1.

## Determination of Heavy Metals by Atomic Absorption Spectrophotometry (AAS)

The determination of heavy metals, namely Lead (Pb), Cadmium (Cd), Chromium (Cr), and Arsenic (As), in the lipstick samples was carried out using Atomic Absorption Spectrophotometry (AAS), a widely established technique for trace metal analysis in cosmetic matrices. Approximately 0.5 g of each homogenized lipstick sample was accurately weighed into a digestion flask. To each sample, 10 mL of concentrated nitric acid ($HNO_3$, 65%) was added and the mixture was allowed to stand for 30 min for predigestion at room temperature. The samples were then heated on a hot plate at 120-150ºC until the evolution of brown nitrogen dioxide fumes ceased. Subsequently, 2 mL of perchloric acid ($HClO_4$, 70%) was added to complete oxidation of the organic matrix, and digestion was continued until a clear, colourless solution was obtained. After cooling, the digest was filtered through Whatman No. 42 filter paper into a 50 mL volumetric flask and diluted to volume with deionized water. Calibration standards for Pb, Cd, Cr, and As were prepared from certified 1000 mg/L stock standard solutions by serial dilution. Calibration curves were constructed prior to sample analysis, and reagent blanks were analysed simultaneously to monitor contamination with calibration range 1.0 to 50.0ug/L and ultraviolet region of 193.7 nm.

Each sample was analysed in triplicate, and the concentrations were expressed as Mean±Standard Deviation (SD) in parts per million (ppm).[13] Additionally, studies have demonstrated that acid digestion using nitric acid or its combinations is essential for complete extraction of metals prior to spectrometric determination.[14,15]

## Cancer risk assessment procedure

The concentration of heavy metals, namely Arsenic (As), Cadmium (Cd), Chromium (Cr), and Lead (Pb), was obtained from analytical testing of lipstick samples and expressed in parts per million (ppm). Only the final reported values (ppm) were used for all calculations, as these represent the corrected concentrations after accounting for sample weight and dilution factors. All exposure-related parameters were adopted from standard regulatory guidelines (e.g., US EPA and cosmetic safety studies) and were kept constant for all samples to ensure uniformity in risk assessment. The measured concentration was converted from ppm to mg/kg, then mg/kg to mg/g. Exposure Assessment Parameters with standard values are presented in Table 2.

**Table 1: Various test parameter with their BIS Acceptance Criteria.**

| Sl. No. | Test Parameter | Purpose of Test | BIS Acceptance Criteria |
|---|---|---|---|
| 1. | Softening Point | Determines thermal stability of lipstick formulation | Not less than 55ºC |
| 2. | Rancidity (Peroxide Value) | Evaluates oxidation of oils and fats present in lipstick | Not more than 10 |
| 3. | Breaking Load Test | Determines mechanical strength of lipstick stick | Not less than 200 g |
| 4. | Pay-off Test | Measures amount of lipstick transferred during application | 0.01-0.25 g/cm$^2$ |
| 5. | Freedom from Grittiness | Detects presence of abrasive pigment particles | Lipstick should be free from gritty particles |
| 6. | Microbiological Limits (if evaluated) | Determines microbial contamination in cosmetics | Should comply with cosmetic microbiological safety guidelines |

**Table 2: Exposure Assessment Parameters Used for Cancer Risk Evaluation.**

| Parameter | Description | Value |
|---|---|---|
| IR | Ingestion rate | 0.024 g/day |
| BW | Body weight | 60 kg |
| EF | Exposure frequency | 350 days/year |
| ED | Exposure duration | 30 years |
| AT | Averaging time | 25,550 days |
| Fret | Retention factor | 1 |

## Stepwise Calculation Procedure

### *Calculation of Exposure (EX)*

$$EX = C \times q \times F_{ret}$$

Where:

C=concentration of metal (mg/g),

q=ingestion rate (0.024 g/day),

Fret=retention factor (1),

This step estimates the daily intake of the metal.

## Calculation of Systemic Exposure Dose (SED)

$$SED = EX \times OA$$

Where:

OA (Oral Absorption factor),

Pb=0.6,

Cd=0.05.

This represents the fraction of the metal that is absorbed into systemic circulation.

## Calculation of Margin of Safety (MoS)

$$MoS = \frac{NOAEL}{SED}$$

Where:

NOAEL (No Observed Adverse Effect Level),

Pb=0.00343 mg/kg/day,

Cd=0.0228 mg/kg/day.

## Interpretation

MoS ≥ 100 → Safe,

MoS < 100 → Potential risk.

## Calculation of Chronic Daily Intake (CDI)

$$CDI = \frac{C \times IR \times EF \times ED}{BW \times AT}$$

Where:

C=concentration (mg/g),

IR=ingestion rate,

EF=exposure frequency,

ED=exposure duration,

BW=body weight,

AT=averaging time,

This represents long-term daily exposure to the contaminant.

## Calculation of Cancer Risk

$$\text{Cancer Risk} = CDI \times SF$$

Where:

## SF (Slope Factor),

Pb=0.0085,

Cd=1.5,

As=1.5.

## Interpretation

Acceptable range: $10^{-6}$ to $10^{-4}$.

## Special Consideration for Arsenic

For Arsenic, the Margin of Safety (MoS) was not calculated due to its non-threshold carcinogenic nature and the absence of a reliable NOAEL value. Therefore, risk characterization for arsenic was performed using CDI and cancer risk assessment only.

## Statistical Analysis

All physicochemical determinations were performed in triplicate ($n$=3). Data are expressed as Mean±Standard Deviation (SD). Differences among lipstick brands were analysed using one-way Analysis of Variance (ANOVA) followed by Tukey's multiple comparison test. Statistical significance was considered at $p$<0.05.

# RESULTS

The experimental evaluation of the lipstick samples was carried out in accordance with the guidelines prescribed by the Bureau of Indian Standards (BIS) for cosmetic products, along with reference to relevant provisions under the Drugs and Cosmetics Act, 1940 and Cosmetic Rules, 2020. These regulatory frameworks provide standardized criteria for assessing the quality, stability, and safety of cosmetic formulations. The study focused on the assessment of key physicochemical parameters that directly influence the performance, stability, and consumer acceptability of lipsticks, including, Softening point, Rancidity (peroxide value), Breaking load, Pay-off value, Freedom from grittiness and heavy metal contaminations detection. These parameters were selected based on their relevance to product quality assurance and compliance with BIS specifications, and they collectively provide a comprehensive understanding of the formulation characteristics.

## Softening point evaluation

The softening point values of the seventeen lipstick samples (A-Q) were determined in accordance with BIS guidelines. As per the Bureau of Indian Standards (BIS), the acceptable limit for softening point is not less than 55ºC, as seen in Tables 3 and 3.1, and all samples were found to meet this specified criterion (Figure 1A).

**Table 3: Softening point evaluation results of 17 samples with standard BIS limits.**

| Samples | Result (Mean±SD) | Limits (According to BIS Standard) |
|---|---|---|
| A | 59.100±0.100 | All the samples should be NLT 55ºC. |
| B | 58.133±0.115 | |
| C | 59.100±0.100 | |
| D | 60.167±0.153 | |
| E | 58.100±0.100 | |
| F | 58.967±0.153 | |
| G | 59.000±0.100 | |
| H | 57.933±0.058 | |
| I | 58.467±0.115 | |
| J | 59.900±0.100 | |
| K | 56.800±0.100 | |
| L | 59.467±0.115 | |
| M | 57.700±0.100 | |
| N | 59.400±0.608 | |
| O | 58.467±0.153 | |
| P | 60.267±0.208 | |
| Q | 57.867±0.058 | |

## Rancidity evaluation (Peroxide number)

The rancidity of the lipstick samples (A-Q) was evaluated in terms of peroxide value in accordance with BIS guidelines. The observed values ranged from 0.17 to 0.35. As per BIS specifications, the peroxide value should not exceed 10, and all samples were found to comply with this requirement. The detailed results for all samples are presented in Tables 4 and 4.1 (Figure 1B).

## Breaking load test

The mechanical strength of the lipstick samples (A-Q) was evaluated using the breaking load test as per BIS guidelines. The observed values ranged from 206 g to 216 g. According to BIS specifications, the breaking load should not be less than 200 g, and all samples were found to comply with this requirement. The detailed results for all samples are presented in Tables 5 and 5.1 (Figure 1C).

## Pay-off test evaluation

The pay-off values of the lipstick samples (A-Q) were determined to assess the transfer efficiency during application as per BIS guidelines. The observed values ranged from 0.033 to 0.062 g/cm$^2$. The detailed results for all samples are presented in Tables 6 and 6.1 (Figure 1D). Show the graphical representation if all the BIS evaluation procedure.

## Freedom from grittiness evaluation

The freedom from grittiness test determines whether lipstick formulations contain coarse pigment particles or abrasive materials that may affect consumer comfort. During the evaluation, all lipstick samples passed the test, indicating the absence of hard or sharp particles. This observation suggests that the pigments used in the formulations were properly micronized and uniformly dispersed, ensuring a smooth texture and comfortable application. Table 7 elaborates the Freedom from grittiness evaluation results of 17 samples with standard BIS limits.

## Microbiological evaluation

The microbiological evaluation of all lipstick samples (A-Q) was carried out as per BIS guidelines using nutrient agar and Sabouraud agar media. The results indicated that all samples complied with the prescribed microbiological limits, with no significant microbial contamination observed. All samples were

**Table 3.1: One-way ANOVA of softening point values of commercial lipstick formulations. Data were obtained from triplicate determinations for each lipstick brand (A-Q). The analysis compares the mean softening point values among the 17 commercial lipstick brands. A one-way analysis of variance (ANOVA) was performed to determine whether significant differences existed between groups. A *p*-value <0.05 was considered statistically significant.**

| Source of Variation | SS (Sum of Squares) | $D_f$ (Degree of Freedom) | MS (Mean of Squares) | *F* | *p*-value |
|---|---|---|---|---|---|
| Between Groups | 42.706 | 16 | 2.669 | 75.626 | $7.64 \times 10^{-22}$ |
| Within Groups | 1.2 | 34 | 0.0353 | | |
| Total | 43.906 | 50 | | | |

**Table 4: Rancidity evaluation results of 17 samples with standard BIS limits.**

| Samples | Result (Mean±SD) | Limits (According to BIS Standard) |
|---|---|---|
| A | 0.257±0.006 | Peroxide number for all the samples should be Max.10 |
| B | 0.217±0.006 | |
| C | 0.340±0.010 | |
| D | 0.317±0.015 | |
| E | 0.190±0.010 | |
| F | 0.190±0.000 | |
| G | 0.340±0.010 | |
| H | 0.333±0.006 | |
| I | 0.210±0.000 | |
| J | 0.177±0.006 | |
| K | 0.170±0.010 | |
| L | 0.277±0.006 | |
| M | 0.210±0.010 | |
| N | 0.320±0.000 | |
| O | 0.353±0.006 | |
| P | 0.180±0.010 | |
| Q | 0.210±0.010 | |

found to be within acceptable limits for total bacterial and fungal counts. The detailed results are presented in Table 8.

## Heavy metal contamination evaluation

The concentration of heavy metals, namely Lead (Pb), Cadmium (Cd), Chromium (Cr), and Arsenic (As), in the lipstick samples (A-Q) was determined using Atomic Absorption Spectrophotometry (AAS). Cadmium (Cd) and Chromium (Cr) were not detected in any of the analyzed samples. Lead (Pb) was found to be Below Detectable Limits (BDL) in the majority of samples (A-E and G-Q), whereas Sample F exhibited a significantly higher concentration of 101.55 ppm. Arsenic (As) was detected in all samples, with concentrations ranging from 33.65 ppm to 44.58 ppm across the dataset. The detailed concentrations of each heavy metal in individual samples are presented in Table 9. For Arsenic the heavy metal concentrations were determined using an Atomic Absorption Spectrophotometer under the manufacturer's recommended instrumental conditions for each element with Method Detection Limit of 0.01 to 0.1 mg/kg (ppm) and Limit of Quantification (LOQ) of 0.03 to 0.33 mg/kg (ppm) and recovery rate between 90 to 105%.

**Table 4.1: One-way ANOVA of peroxide number values of commercial lipstick formulations. Data were obtained from triplicate determinations for each lipstick brand (A-Q). The analysis compares the mean peroxide number values among the 17 commercial lipstick brands. A one-way Analysis of Variance (ANOVA) was performed to determine whether significant differences existed between groups. A *p*-value <0.05 was considered statistically significant.**

| Source of Variation | SS | $d_f$ | MS | *F* | *p*-value |
|---|---|---|---|---|---|
| Between Groups | 0.220851 | 16 | 0.013803 | 207.048 | $4.23 \times 10^{-29}$ |
| Within Groups | 0.002267 | 34 | 6.67E-05 | | |
| Total | 0.223118 | 50 | | | |

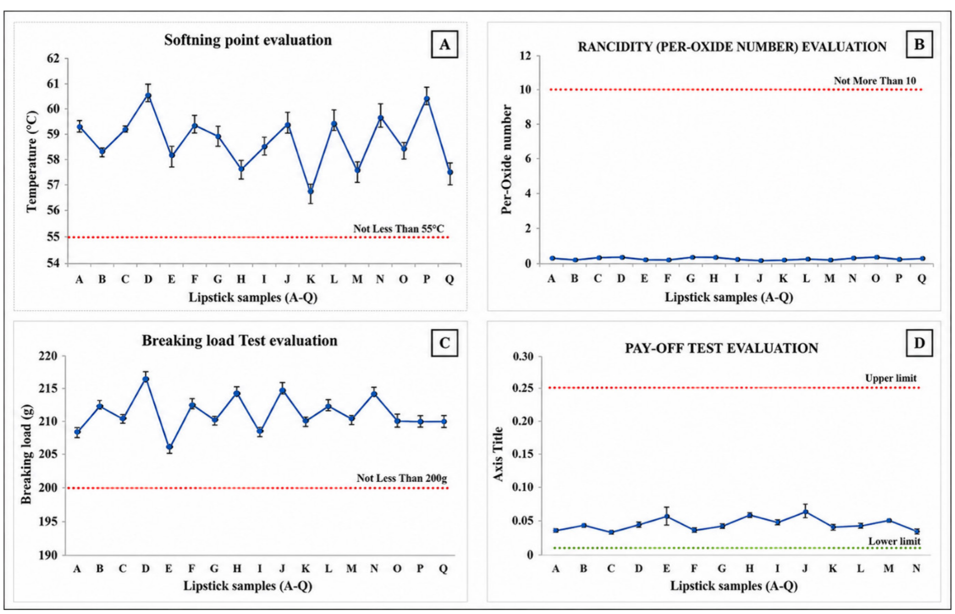


**Figure 1:** Various method for evaluation of lipstick according to the BIS standard. A. Softening point evaluation. B. Rancidity evaluation (Per-oxide number). C. Breaking load test. D. Pay-off test evaluation.

## Cancer Risk assessment

The cancer risk assessment of heavy metals in lipstick samples (A-Q) was performed using standard toxicological parameters including Exposure (EX), Systemic Exposure Dose (SED), Margin of Safety (MoS), Chronic Daily Intake (CDI), and lifetime cancer risk. Cadmium (Cd) was not detected in any of the samples, resulting in zero Exposure (EX=0), zero SED, infinite Margin of Safety (MoS=∞), and no associated cancer risk across all samples. For Lead (Pb), sixteen samples (A-E and G-Q) showed non-detectable levels with zero exposure and infinite MoS, whereas Sample F exhibited a markedly higher concentration (101.55 ppm), with calculated EX (0.002437), SED (0.001462), MoS (2.34), CDI ($1.67 \times 10^{-5}$), and cancer risk ($1.42 \times 10^{-7}$). Arsenic (As) was detected in all samples, with concentrations ranging from 33.65 to 44.58 ppm. The corresponding CDI values ranged from $5.53 \times 10^{-6}$ to $7.33 \times 10^{-6}$, while the calculated lifetime cancer risk ranged from $8.30 \times 10^{-6}$ to $10.99 \times 10^{-6}$. The detailed results for Cd, Pb, and As risk assessment are presented in Tables 10-12. Cancer risk assessment for various heavy metals is illustrated in Figure 2.

**Table 5: Breaking load test evaluation results of 17 samples with standard BIS limits.**

| Samples | Result (Mean±SD) | Limits (According to BIS Standard) |
|---|---|---|
| A | 209.000±1.000 | All samples should be NLT 200 g. |
| B | 211.333±1.155 | |
| C | 211.000±1.000 | |
| D | 216.000±1.000 | |
| E | 207.000±1.000 | |
| F | 211.667±1.528 | |
| G | 210.000±0.000 | |
| H | 212.667±1.528 | |
| I | 208.333±0.577 | |
| J | 214.000±1.000 | |
| K | 210.333±0.577 | |
| L | 211.667±0.577 | |
| M | 210.333±0.577 | |
| N | 213.000±1.000 | |
| O | 209.667±0.577 | |
| P | 209.000±1.000 | |
| Q | 209.000±1.000 | |

## DISCUSSION

The current study offers an extensive evaluation of the toxicological risk, microbiological safety, and physicochemical quality of lipstick formulations which are marketed commercially. The results of the softening point analysis showed that all formulations had sufficient thermal stability, with values ranging from 56.9°C to 60.3°C, surpassing the minimal criterion of 55°C. High-melting waxes like carnauba and candelilla wax, which are known to improve structural stiffness and resistance to deformation under high temperatures, may be present in samples with higher softening points. As previously highlighted in cosmetic formulation, research emphasizing the relevance of wax-oil ratios in determining mechanical stability, such compositional balance is crucial for maintaining product integrity during storage and application.[16]

The evaluation of oxidative stability via peroxide value measurement revealed exceptionally low values (0.17-0.35) in all samples, substantially beneath the BIS threshold of 10. These results show minimal amounts of lipid peroxidation and indicating that antioxidants were successfully incorporated into the formulations. The obtained low peroxide values are indicative of appropriate manufacturing procedures and formulation optimization, as oxidative breakdown of lipids is a major factor impacting the product's durability and consumer acceptability. Antioxidants including tocopherols and butylated hydroxytoluene significantly prevent oxidative degradation in cosmetic matrices, improving stability and safety, according to earlier research.[16,17]

The minimal requirement of 200 g was exceeded by mechanical strength evaluation using breaking load testing, which revealed values between 206 and 216 g. This narrow range of values shows that the formulation design is consistent and that the lipstick sticks have sufficient hardness and endurance. Similar results have been documented in the literature, where the ideal wax composition states to increased structural strength without sacrificing application qualities. Mechanical integrity is a crucial factor affecting consumer handling and product performance.[16]

The pay-off test results (0.033-0.062 g/cm²) confirmed satisfactory transfer efficiency across all samples, falling within the acceptable

**Table 5.1: One-way ANOVA of breaking load test values of commercial lipstick formulations. Data were obtained from triplicate determinations for each lipstick brand (A-Q). The analysis compares the mean breaking load test values among the 17 commercial lipstick brands. A one-way analysis of variance (ANOVA) was performed to determine whether significant differences existed between groups. A *p*-value <0.05 was considered statistically significant.**

| Source of Variation | SS | $d_f$ | MS | *F* | *p*-value |
|---|---|---|---|---|---|
| Between Groups | 240.078 | 16 | 15.005 | 16.282 | $1.77 \times 10^{-11}$ |
| Within Groups | 31.333 | 34 | 0.922 | | |
| Total | 271.412 | 50 | | | |

BIS range (0.01-0.25 g/cm²). This parameter is closely associated with formulation balance between waxes and emollients, influencing both color intensity and spreadability.[16] The observed values indicate that all formulations achieved an optimal balance, ensuring uniform application and consumer acceptability. Additionally, the absence of grittiness in all samples confirms proper pigment micronization and uniform dispersion, which are critical for achieving smooth texture and preventing irritation during application. All samples achieved permissible limits for bacterial and fungal contamination, according to microbiological examination, demonstrating efficient preservation methods and adherence to ethical manufacturing practices. Considering lip cosmetics are frequently used and may be consumed, the lack of significant microbial contamination is very crucial. This stands in accordance with established cosmetic microbiological guidelines that highlight the significance of microbial safety in consumer goods.[10]

**Table 6:** Pay-off test evaluation results of 17 samples with standard BIS limits.

| Samples | Result (Mean±SD) | Limits (According to BIS Standard) |
|---|---|---|
| A | 0.0387±0.001 | All samples should lie in range of 0.01 to 0.25 g/cm² |
| B | 0.044±0.001 | |
| C | 0.035±0.001 | |
| D | 0.043±0.000 | |
| E | 0.077±0.012 | |
| F | 0.036±0.001 | |
| G | 0.045±0.001 | |
| H | 0.061±0.000 | |
| I | 0.045±0.001 | |
| J | 0.067±0.001 | |
| K | 0.044±0.001 | |
| L | 0.041±0.002 | |
| M | 0.050±0.001 | |
| N | 0.035±0.001 | |
| O | 0.038±0.001 | |
| P | 0.045±0.001 | |
| Q | 0.034±0.001 | |

The heavy metal analysis produced noteworthy results in contrast to the good physicochemical and microbiological quality. Cadmium (Cd) and Chromium (Cr) were not detected in any samples, whereas Lead (Pb) was absent in most samples but detected at a significantly elevated concentration in one sample (Sample F: 101.55 ppm). All samples had quantities of arsenic (As) between 33.65 and 44.58 parts per million. Most lipstick samples complied with BIS physicochemical quality requirements; however, one sample exhibited lead concentration substantially exceeding internationally recommended limits, indicating the necessity for continued market surveillance and strengthened regulatory monitoring. Recent literature has extensively shown the occurrence of heavy metals in cosmetics, which are mostly linked to contamination of raw materials such mineral pigments and impurities added during manufacturing processes. In order of safeguarding consumers, oversight organizations like the FDA have also emphasized that heavy metals may be present as inevitable contaminants and need close observation. Previous studies have similarly indicated that while individual exposure levels may fall within acceptable thresholds, chronic use of contaminated cosmetics can lead to cumulative toxicity and potential systemic effects.[18]

Although calculated lifetime cancer risk values remained within internationally accepted risk ranges, the consistent detection of arsenic across all lipstick samples indicates possible contamination of pigments or mineral-derived raw materials. Continuous regulatory surveillance and stricter raw-material quality control are therefore recommended to minimize cumulative long-term exposure.[19-23]

**Table 6.1:** One-way ANOVA of pay-off test values of commercial lipstick formulations. Data were obtained from triplicate determinations for each lipstick brand (A-Q). The analysis compares the mean pay-off test values among the 17 commercial lipstick brands. A one-way analysis of variance (ANOVA) was performed to determine whether significant differences existed between groups. A *p*-value <0.05 was considered statistically significant.

| Source of Variation | SS | $d_f$ | MS | *F* | *p*-value |
|---|---|---|---|---|---|
| Between Groups | 0.006811 | 16 | 0.000426 | 49.568 | $7.17 \times 10^{-19}$ |
| Within Groups | 0.000292 | 34 | 8.59E-06 | | |
| Total | 0.007103 | 50 | | | |

**Table 7:** Freedom from grittiness evaluation results of 17 samples with standard BIS limits.

| Samples | Results | Limits (According to BIS Standard) |
|---|---|---|
| A to Q | All the samples pass the test. | Passes the test |

**Table 8:** Microbiological evaluation results of 17 samples with standard BIS limits.

| Samples | Results | Limits (According to BIS Standard) |
|---|---|---|
| A to Q | All the samples pass the test. | According to BIS Standards |

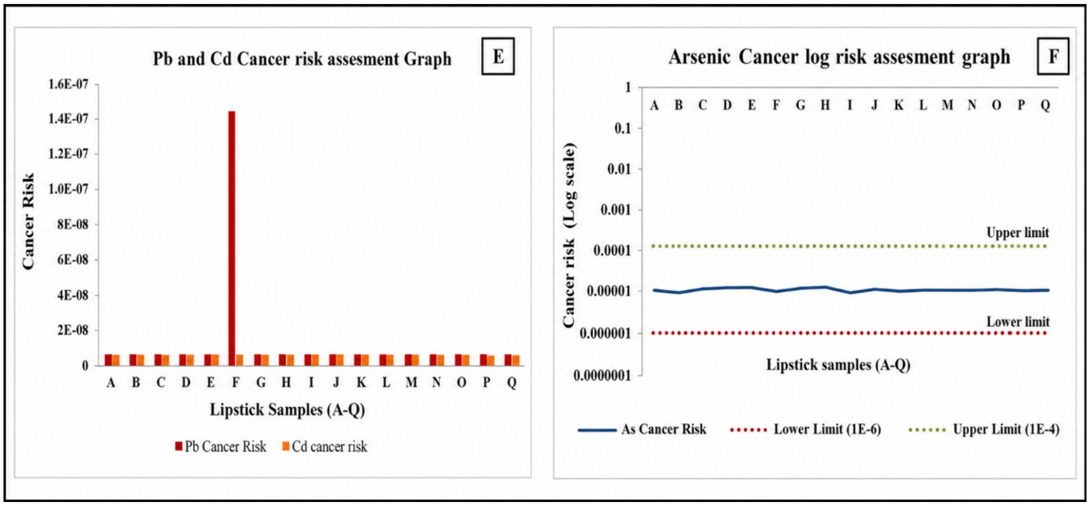


**Figure 2:** Cancer risk assessment for various heavy metals. E. Pb and Cd cancer risk assessment graph F. Arsenic cancer log risk assessment graph.

**Table 9: Heavy metal contamination evaluation results of 17 samples with standard BIS limits.**

| Sample | Lead (Pb) (ppm) | Cadmium (Cd) (ppm) | Chromium (Cr) (ppm) | Arsenic (As) (ppm) |
|---|---|---|---|---|
| A | BDL | BDL | BDL | 36.78±0.02 |
| B | BDL | BDL | BDL | 33.66±0.01 |
| C | BDL | BDL | BDL | 41.23±0.01 |
| D | BDL | BDL | BDL | 43.73±0.01 |
| E | BDL | BDL | BDL | 43.26±0.06 |
| F | 101.55 | BDL | BDL | 37.99±0.01 |
| G | BDL | BDL | BDL | 43.23±0.01 |
| H | BDL | BDL | BDL | 37.25±12.69 |
| I | BDL | BDL | BDL | 33.67±0.03 |
| J | BDL | BDL | BDL | 41.01±0.00 |
| K | BDL | BDL | BDL | 36.89±0.01 |
| L | BDL | BDL | BDL | 39.39±0.01 |
| M | BDL | BDL | BDL | 38.88±0.02 |
| N | BDL | BDL | BDL | 38.77±0.02 |
| O | BDL | BDL | BDL | 42.37±0.03 |
| P | BDL | BDL | BDL | 40.49±0.44 |
| Q | BDL | BDL | BDL | 40.49±0.44 |

**Table 10: Cd Risk Assessment- Risk Characterization of Cadmium (Cd) in Lipstick Samples.**

| Samples | A to Q |
|---|---|
| Heavy metal (ppm) | 0.00 |
| EX | 0 |
| SED | 0 |
| MoS | ∞ |
| CDI | 0 |
| Cancer Risk | 0 |
| Safety level | Acceptable (Safe) |

**Table 11: Pb Risk Assessment- Risk Characterization of Lead (Pb) in Lipstick Samples.**

| Samples | A to E, G to Q | F |
|---|---|---|
| Heavy metal (ppm) | 0.00 | 101.55 |
| EX | 0 | 0.002437 |
| SED | 0 | 0.001462 |
| MoS | ∞ | 2.34 |
| CDI | 0 | $1.67\times10^{-5}$ |
| Cancer Risk | 0 | $1.42\times10^{-7}$ |
| Safety level | Acceptable (Safe) | Unsafe |

For Pb & Cd: MoS ≥ 100 - Safe, MoS <100 - Unsafe.

**Table 12: Assessment of Chronic daily intake (CDI) and Lifetime Cancer Risk Associated with Arsenic in Lipstick Samples.**

| Sample | As (ppm) | CDI ($\times10^{-6}$) | Cancer Risk ($\times10^{-6}$) | Safety |
|---|---|---|---|---|
| A | 36.76 | 6.04 | 9.06 | Acceptable |
| B | 33.65 | 5.53 | 8.30 | Acceptable |
| C | 41.23 | 6.78 | 10.17 | Acceptable |
| D | 43.72 | 7.19 | 10.78 | Acceptable |
| E | 43.23 | 7.11 | 10.66 | Acceptable |
| F | 37.99 | 6.24 | 9.36 | Acceptable |
| G | 43.23 | 7.11 | 10.66 | Acceptable |
| H | 44.58 | 7.33 | 10.99 | Acceptable |
| I | 33.65 | 5.53 | 8.30 | Acceptable |
| J | 41.01 | 6.74 | 10.11 | Acceptable |
| K | 36.88 | 6.06 | 9.09 | Acceptable |
| L | 39.39 | 6.47 | 9.71 | Acceptable |
| M | 38.87 | 6.38 | 9.57 | Acceptable |
| N | 38.76 | 6.37 | 9.55 | Acceptable |
| O | 42.35 | 6.96 | 10.44 | Acceptable |
| P | 40.24 | 6.61 | 9.91 | Acceptable |
| Q | 40.24 | 6.61 | 9.91 | Acceptable |

Abbreviations: Pb-Lead, Cd-Cadmium, EX-Exposure (mg/day), SED-Systemic Exposure Dose (mg/kg/day), MoS-Margin of Safety, CDI-Chronic Daily Intake (mg/kg/day).

## CONCLUSION

In conclusion, the evaluated lipstick samples show satisfactory formulation performance and compliance with BIS quality standards, underscoring the efficacy of present manufacturing techniques. However, the presence of heavy metals highlights the significance of thorough safety investigation, especially the higher level of lead in one sample and the consistent finding of arsenic across all samples. The results highlight the necessity for ongoing monitoring, strict quality control, and regulatory oversight to guarantee long-term consumer safety even though the estimated carcinogenic risks are still within tolerable bounds. Overall, the results show that although the assessed lipstick samples have acceptable physicochemical quality and microbiological safety, the presence of hazardous metals, especially lead and arsenic, highlights the necessity of strict quality control, raw material screening, and regulatory monitoring. The results emphasize the importance of continuous surveillance and risk assessment to ensure consumer safety, especially considering the frequent application and potential ingestion of lip products. These observations align with recent global studies advocating for stricter regulatory frameworks and improved manufacturing practices to minimize heavy metal contamination in cosmetic products.

## ABBREVIATIONS

**BIS:** Bureau of Indian Standards; **AAS:** Atomic Absorption Spectrophotometry; **Pb:** Lead; **Cd:** Cadmium; **Cr:** Chromium; **As:** Arsenic; **Ni:** Nickel; **Hg:** Mercury; **GMP:** Good Manufacturing Practices; **ICP-OES:** Inductively Coupled Plasma–Optical Emission Spectrometry; **GC-MS:** Gas Chromatography–Mass Spectrometry; **ATR:** Attenuated Total Reflectance; **MEKC:** Micellar Electrokinetic Chromatography; **SEM-EDS:** Scanning Electron Microscopy–Energy Dispersive Spectroscopy; **BDL:** Below Detectable Limit; **LOQ:** Limit of Quantification; **SD:** Standard Deviation; **ANOVA:** Analysis of Variance; **IR:** Ingestion Rate; **BW:** Body Weight; **EF:** Exposure Frequency; **ED:** Exposure Duration; **AT:** Averaging Time; **Fret:** Retention Factor; **EX:** Exposure; **SED:** Systemic Exposure Dose; **MoS:** Margin of Safety; **NOAEL:** No Observed Adverse Effect Level; **CDI:** Chronic Daily Intake; **SF:** Slope Factor; **FDA:** Food and Drug Administration; **ppm:** Parts Per Million.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## REFERENCES


1. Khan S, Alam M. Cosmetics and their associated adverse effects: A review. Journal of Applied Pharmaceutical Science. 2019;9(03):122-31.
2. Heusèle C, Vial G, Ficheux AS. Composition and safety considerations of decorative cosmetics. Cosmetics. 2022;9(2):45.
3. Gładysz M, Król M, Chudecka A, Kościelniak P. Application of spectroscopic and separation techniques to examine the chemical composition stability of lipsticks. Forensic Science International. 2020;309:110230.

4. Sani A, Gaya M, Abubakar F. Determination of heavy metals in selected cosmetic products sold in developing markets. Journal of Toxicology and Environmental Health Sciences. 2016;8(5):45-52.
5. Tunde O, Akinyemi A, Adeyemi O. Evaluation of heavy metal contamination in cosmetic products and associated health risks. Environmental Monitoring and Assessment. 2024;196:112.
6. Afridi HI, Ali A, Bhatti M, *et al.* Effect of lead on the skin and health of female dermatitis patients through cosmetics. Journal of Ayub Medical College Abbottabad. 2023; 35(1)88-94.
7. Gładysz M, Krzyściak W, Gola J. Quality and safety evaluation of cosmetic products: Current challenges and perspectives. International Journal of Environmental Research and Public Health. 2020;17(11):3958.
8. Lara-Torres S, Figueiredo D, Paz S, Gutiérrez AJ, Rubio C, González-Weller D, *et al.* Determination and risk assessment of toxic metals in lipsticks from Europe and China. *J Trace Elem Med Biol*. 2021;67:126792.
9. U.S. Food and Drug Administration (FDA). Cosmetics safety and regulatory guidelines. Silver Spring, MD: FDA.
10. Lundov MD, Moesby L, Zachariae C, Johansen JD. Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy. Contact dermatitis. 2009;60(2):70-8.
11. Bureau of Indian Standards. IS 9875:1990. *Specification for lipsticks*. New Delhi: Bureau of Indian Standards; 1990.
12. Epa US. Method 3050B: acid digestion of sediments, sludges, and soils. Environ. Prot. Agency. 1996;2:3-5.
13. Maharaj D, Mohammed T, Mohammed A, Addison L. Enhanced digestion of complex cosmetic matrices for analysis of As, Hg, Cd, Cr, Ni, and Pb using triton X-100. MethodsX. 2021;8:101241.
14. Wongkalasin S, Ruengsitagoon W. Determination of lead in cosmetics using atomic absorption spectrophotometry. *Isan J Pharm Sci*. 2017;13(1 Suppl).
15. Jităreanu A, Trifan A, Caba IC, Mârțu I, Agoroaei L. An overview of heavy metals in cosmetic products and their toxicological impact. *Appl Sci*. 2025;15(24):12883.
16. Kilic S, Kilic M, Soylak M. Determination of toxic metals in traditional cosmetic products and health risk assessment. *Biol Trace Elem Res*. 2021;199(6):2272-7.
17. Saah SA, Boadi NO, Sakyi PO, Smith EQ. Human health risks of lead, cadmium, and other heavy metals in lipsticks. *Heliyon*. 2024;10(23):e40576.
18. Abrar S, Javed S, Kiran S, Awan H. Analysis of lead, cadmium, and arsenic in colored cosmetics marketed in Pakistan. *J Public Health Policy*. 2022;43:1-12.
19. Al-Saleh I, Al-Enazi S, Shinwari N. Assessment of lead in cosmetic products. Regulatory Toxicology and Pharmacology. 2009;54(2):105-13.
20. Tunde OL, Oluwagbemiga AP, Felix OO. Concentrations and probable health risks of potentially toxic metals (Pb, Cd and Cr) in Nigerian lipstick products. Journal of Trace Elements and Minerals. 2024;8:100142.
21. Sani A, Gaya MB, Abubakar FA. Determination of some heavy metals in selected cosmetic products sold in Kano metropolis, Nigeria. Toxicol Rep. 2016;3:866-9.
22. U.S. Food and Drug Administration. FDA's testing of cosmetics for arsenic, cadmium, chromium, cobalt, lead, mercury, and nickel content [Internet]. Silver Spring (MD): FDA; [cited 2026 Mar 26]. Available from: https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/fdas-testing-cosmetics-arsenic-cadmium-chromium-cobalt-lead-mercury-and-nickel-content.
23. U.S. Food and Drug Administration. Lead in cosmetics [Internet]. Silver Spring (MD): FDA; [cited 2026 Mar 26]. https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/lead-cosmetics.


**Cite this article:** Sharma D, Koley D, Mehlawat K, Attri K, Bhalla V, Singh M. Evaluation of Commercial Lipstick Formulations for Compliance with BIS Standards: A Comparative Study. Indian J of Pharmaceutical Education and Research. 2026;60(4s):s1474-s1485.