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Original Research Article

Formulation and Evaluation of Preventive Gel Formulation Foe Metal Toxicity Produce by Cosmetics

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Abstract: The increasing use of cosmetic products has raised significant concerns regarding exposure to toxic heavy metals such as lead, cadmium, chromium, and nickel, which may be present as contaminants. Prolonged use of such products can lead to accumulation of these metals in the body, resulting in adverse health effects including skin disorders, systemic toxicity, and carcinogenic risks. The present study aims to develop and evaluate a preventive topical gel formulation to minimize heavy metal absorption through the skin. A hydrophilic gel containing disodium EDTA as a chelating agent was formulated using Carbopol 940, propylene glycol, triethanolamine, and rose water. EDTA binds with metal ions to form stable, water-soluble complexes, thereby preventing their penetration into the skin. The prepared gel was evaluated for physicochemical parameters such as pH, viscosity, spreadability, homogeneity, washability, and stability. Analytical studies including FTIR and microscopic evaluation confirmed the compatibility of ingredients and successful complex formation between EDTA and metal ions. The formulation exhibited desirable properties such as skin-friendly pH, good spreadability, and stability. The results indicate that the developed gel effectively reduces metal ion availability and minimizes the risk of toxicity. In conclusion, the formulated disodium EDTA gel represents a safe, economical, and effective preventive approach to protect against heavy metal exposure from daily cosmetic use, promoting improved skin safety and long-term health.

Key Words: Diasodium EDTA, Gel Formulation, Complex detection, FTIR analysis , metal toxicity.

1. Introduction

The use of cosmetics for personal care and beautification has been practiced since ancient times and continues to be an integral part of modern lifestyle. In recent years, the global cosmetic industry has experienced rapid growth due to increased awareness of personal grooming, rising living standards, and the influence of media and advertising. Cosmetic products are widely used by individuals of all age groups on a daily basis, making them an important component of routine body care. [1,2] Cosmetics are defined as substances or formulations intended for application to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. These include a wide range of products such as lipsticks, face powders, creams, lotions, shampoos, hair dyes, deodorants, and eye makeup. Although cosmetics are generally considered safe for topical use, increasing evidence suggests that many products may contain trace amounts of toxic heavy metals either as intentional ingredients (e.g., pigments, preservatives) or as contaminants introduced during manufacturing. [3,4]

Toxicity Causing Agents

Heavy metals such as lead (Pb), cadmium (Cd), chromium (Cr), nickel (Ni), arsenic (As), and mercury (Hg) are commonly detected in cosmetic products. These metals are characterized by high density and potential toxicity even at low concentrations. Continuous and prolonged use of such contaminated cosmetics can lead to gradual accumulation of metals in the body, posing serious health risks. Among these, lead exposure is particularly concerning, especially in women and children, as it can affect neurological development, reproductive health, and cause systemic toxicity. [7]

The primary route of exposure to these metals from cosmetics is through dermal absorption. Although the skin acts as a protective barrier, certain substances can penetrate through hair follicles, sweat glands, and intercellular pathways, eventually reaching systemic circulation. Long-term exposure enhances the risk of bioaccumulation, which may result in adverse effects such as skin irritation, allergic reactions, oxidative stress, DNA damage, and even carcinogenic outcomes. Additionally, heavy metals have the ability to interfere with essential biological processes by replacing vital elements in enzymes and proteins, thereby disrupting normal cellular functions. [9]

Another important concern is the vulnerability of specific populations such as pregnant women and infants. Heavy metals stored in bones can be mobilized during pregnancy, lactation, or menopause, leading to transfer through the placenta or breast milk. This may result in complications such as low birth weight, premature delivery, impaired fetal development, and increased risk of chronic diseases later in life.

Despite regulatory efforts to limit heavy metal content in cosmetic products, complete elimination remains challenging due to variability in raw materials and manufacturing processes. Therefore, there is a growing need for alternative preventive strategies that can minimize metal absorption at the site of application rather than relying solely on regulatory control[12].

Chelation therapy offers a promising approach in this context. Chelation is a chemical process in which a chelating agent binds to metal ions to form stable, water-soluble complexes that can be easily removed from the body. Disodium ethylenediaminetetraacetate (EDTA) is one of the most widely used chelating agents in pharmaceutical and medical applications. It has a strong affinity for metal ions such as lead, calcium, iron, and magnesium, forming non-toxic complexes that reduce their bioavailability and toxicity[13].

Based on this principle, the present research focuses on the development of a topical preventive gel formulation containing disodium EDTA. The gel is designed to act as a protective barrier on the skin, chelating metal ions present in cosmetic products before they can penetrate the skin. The formulation includes carbopol 940 as a gelling agent, propylene glycol as a humectant and solvent, triethanolamine as a pH-adjusting and neutralizing agent, and rose water as a soothing and antioxidant vehicle. This combination ensures appropriate consistency, stability, and skin compatibility of the formulation.

The proposed gel offers a novel and practical solution to reduce heavy metal exposure associated with daily cosmetic use. By preventing dermal absorption and promoting safe elimination of metal ions, this formulation aims to enhance consumer safety and provide longterm protection against metal-induced toxicity[14].

2. Materials and Methods

Sr no.	Name of material	Type	Purpose
1.	Diasodium EDTA	Active ingredient	Act as a chelating agent which form a complex with metal ion
2.	Propylene glycol	Preservative	To prevent the microbial growth
3.	Carbopol 940	Gelling agent	Gelling agent that act as a base and give structure to the formulation
4.	Triethanolamine	Active ingredient	Emulsifying agent
5.	Rose water	Vehicle	Solvent and base for gel formulation
6.	Rose extract	Perfumine	Antioxidant and soothing effect

1) Disodium EDTA

1) Category: Chelating agent / Preservative enhancer

2) Chemical Name : Disodium ethylenediaminetetraacetate

Molecular Formula: $C_{10}H_{14}N_2Na_2O_8$

Molecular Weight: 336.21 g/mol

3) Description :EDTA (Ethylenediaminetetraacetic acid) is commonly used in pharmaceutical and cosmetic gel formulations. It serves primarily as a chelating agent, which means it binds metal ions (such as Arsenic, Lead,CD,Hg, calcium, magnesium,iron, and others). EDTA helps to bind and remove heavy metal ions that may be present in cosmetics product 15White or almost white crystalline powder Slightly hygroscopic,Stable under normal conditions[21]

4) Odour : Odourless

5) Texture : Fine crystalline powder

6) Melting Point : approx. >250°C

7) Solubility : Freely soluble in water, Slightly soluble in alcohol, Practically insoluble in organic solvents

8) Pharmacological action : Forms stable complexes with metal ions (Ca^{2+}, Mg^{2+}, Fe^{3+}, etc.)

Uses: Enhances stability and shelf life of formulations 9) Incompatibility: Incompatible with strong oxidizing agents

2) Carbopol 940 gel

1) Category: Gelling agent/Thickening agent/Emulsifying agent

2) Chemical Name: Carbomer

High molecular weight cross-linked polymer of acrylic acid

3) Description: Carbopol is an acrylic polymer. Carbopol is non-toxic and non-irritating so that it is suitable for gel preparations. Carbopol 940 is often used as a gelling agent in gel preparations. Concentration of Carbopol 940 as

a gelling agent needs to be concerned to obtain a good gel preparation. The selection of carbopol 940 is due to its large viscosity range of 40,000- 60,000 cP. The concentration of carbopol 940 gelling agent directly affects the viscosity of the preparation which also affects the physical properties of the gel preparation[14]High molecular weight cross-linked polymer of acrylic acid White, fluffy powder (before gel formation) Forms clear, transparent gel after neutralization[9].

4) Odour: Odourless

5) Texture: Powder form-Fine, light, fluffy powder

Gel form-Smooth, clear, viscous gel

6) Melting Point: Does not have a sharp melting point

Softens and decomposes at high temperature (>200°C approx.)

7) Solubility: Insoluble in water (as powder), Swells in water

Forms gel after neutralization with triethanolamine or sodium hydroxide

Insoluble in organic solvents

8) Pharmacology: Pharmacologically inactive (excipient)

Used: As a gelling agent

9) Storage: Store in airtight container, Store in cool, dry place

10) Incompatibility: Incompatible with strong acids, Incompatible with strong oxidizing agents

3) Propylene glycol

a) Category: Humectant, Preservative vehicle

b) Chemical Name: IUPAC Name- Propane-1,2-diol

Molecular Formula- $C_3H_8O_2$

Molecular Weight-76.09 g/mol

c) Description: It is a colorless, odorless, and tasteless liquid that is hygroscopic (absorbs water) In gel formulations, propylene glycol plays multiple roles — acting as a humectant to retain moisture, a solvent to enhance the effectiveness of active ingredients, and a stabilizer to improve texture and shelf life. Although propylene glycol must be heated or briskly shaken to produce a vapor[18].Clear, colourless,Viscous liquid, Practically odourless, Slightly sweet taste, Hygroscopic in nature[24]

d) Odour: Odourless or faint characteristic odour

e) Texture: Thick, viscous, syrupy liquid

f) Melting Point: 59°C (approx.)

g) Solubility: Miscible with water, alcohol, acetone and chloroform

Soluble in ether

h) Pharmacology: Used as a vehicle and solvent in oral, topical, and injectable formulations Acts as a humectant (retains moisture) Enhances drug solubility Has mild antimicrobial properties

i) Used: as a preservative

j) Storage: Store in a well-closed container, protect from moisture,Keep at room temperature, Protect from strong light

k) Incompatibility: Incompatible with strong oxidizing agents May react with potassium permanganate, can degrade in presence of strong acids[11].

4) Triethanolamine

a) Category: PH adjusting agent, Neutralizing agent (used in gel formulations like carbopol gel)

b) Chemical Name: IUPAC Name: 2,2′,2″-Nitrilotriethanol

Molecular Formula: $C_6H_{15}NO_3$

Molecular Weight: 149.19 g/mol

c) Description: Use Cosmetic Triethanolamine is reported to function in cosmetics as a surfactant or pH adjuster, and it can be used in fragrances. Most of the other triethanolamine ingredients are reported to function in cosmetics as surfactants, skin conditioning agents, or hair conditioning agents. TEA- sorbate is reported to function only as a preservative. primarily acts as a pH adjuster and emulsifier, ensuring a stable and balanced gel consistency, while also helping to solubilize ingredients and improve texture[17] . Clear, colourless to pale yellow liquid, Slight ammonia-like odour, Hygroscopic in nature, Viscous liquid.

d) Odour: Faint ammoniacal odour

e) Texture: Thick, viscous liquid, slightly oily appearance

f) Melting Point: 20–21°C (approx.)

g) Solubility: Miscible with water and alcohol, slightly soluble in ether and chloroform

h) Pharmacology: Pharmacologically inactive (excipient)

Uses

- Adjust pH in pharmaceutical formulations
- Neutralize carbopol to form gel
- Act as emulsifying agent in creams and lotions
- Widely used in topical preparations and cosmetics

i) Storage: Store in airtight container,Protect from moisture,Store in cool, dry place, Protect from light.

j) Incompatibility: Incompatible with strong acids, Reacts with copper, zinc.

5) Rose water

a) Category: Flavoring agent, Perfuming agent, Mild astringent, Vehicl(aqueous base), Skin soothing agent, Cosmetic ingredient, pharmaceutical excipient

b) Chemical Name: Aqua Rosae, Rosa damascena distillate

c) Description: A clear, colorless liquid, obtained by steam distillation of fresh rose petals, contains small quantity of rose essential oil, slightly acidic in nature, Used in pharmaceutical, cosmetic and food preparations

d) Odour: Pleasant, Sweet, Characteristic rose-like fragrance Aromatic

e) Texture: Watery liquid, Non-viscous, Smooth, Light, Non-greasy

f) Melting Point: Rose water is a liquid, so melting point is not applicable.

g) But approximate freezing point-Around 0°C (similar to water)

h) Solubility: Completely miscible with water, Soluble in alcohol, Slightly soluble in glycerin and alcohol

i) Pharmacology: Rose water shows the following pharmacological actions-

j) Anti-inflammatory, Cooling effect, Antioxidant, Skin soothing, Anti-irritant, Mild antimicrobial, Eye soothing action

k) Used in: Eye drops (as soothing agent), Skin preparations, Gels, Creams, Lotions,

1)Aromatherapy.

Firstly All the containers need to be sterilized by hot air oven and disinfected by ethanol .

Carbopol 940 was gradually dissolved in demineralized water with continuousstirring for 1 hour to prevent agglomeration.

Separately, disodium EDTA, citric acid, and triethanolamine were dissolved in demineralized water and stirred for 10 minutes.

Propylene glycol and cinnamon oil were then mixed with demineralized water and stirred for 10 minutes.

The disodium EDTA and triethanolamine solution was added to the Carbopol solution, and the pH was adjusted to 7.4 by stirring for 10 minutes.

Finally, the propylene glycol and cinnamon oil solution was incorporated into the mixture, followed by stirring for 10 minutes until a clear and consistent gel base was obtained.

Then fill it in to a well closed glass container.

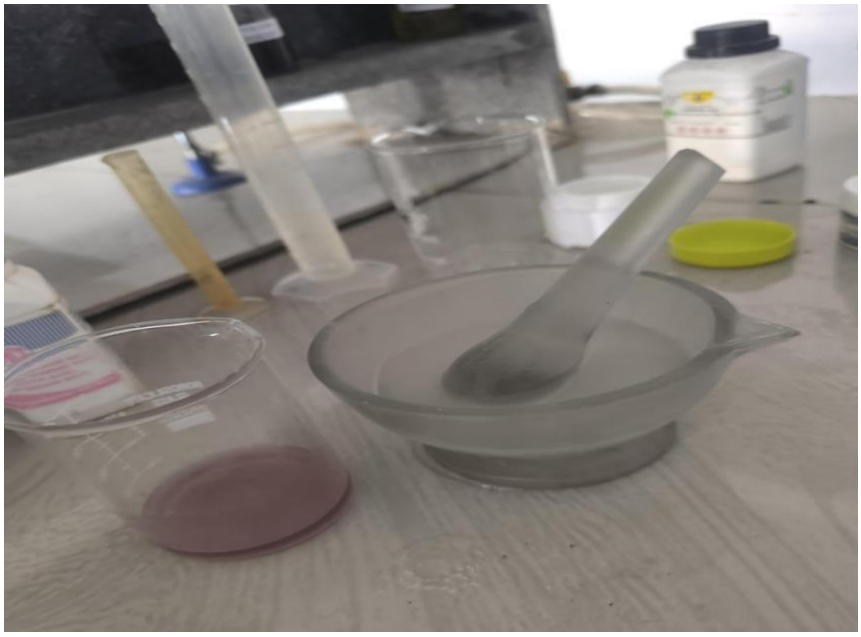


Fig.no.1: Gel Base Preparation

4.FORMULATION TABLE

Sr. No.	Ingredients	F1	F2	F3	Function
1.	Carbopol gel	5gm	5.2gm	4.8gm	Gelling agent
2.	EDTA	1gm	1.5gm	1gm	Complexing agent
3.	Triethanolamine	1ml	1ml	1ml	Humectant
4.	Propylene glycol	10.5ml	10.3ml	10.4ml	Preservative
5.	Rose water	QS	QS	QS	QS

Table No.2: Formulation Table

Fig. No. 2 : Gel

5.EVALUATION PARAMETERS

1)Organoleptic Character

Sr. no.	Test	Result
1.	Colour	Transparent
2.	Odour	Rose aroma
3.	Texture	Smooth
4.	Consistency	Semi solid

Table no.3: Organoleptic character

2)PH Measurement

The PH of gel formulation was measured by using calibrated PH meter and PH paper it found to be 4.5

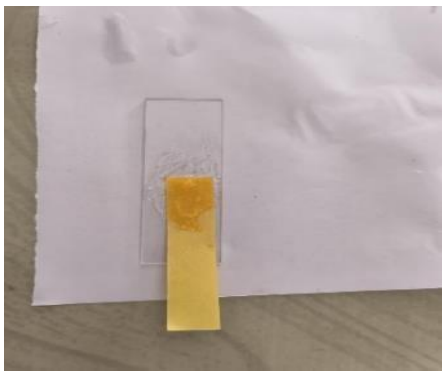


Fig.no.3: PH Test

3)Spreadability

The gel formulation has excellent spreadability that is 3.3gmcm/sec.

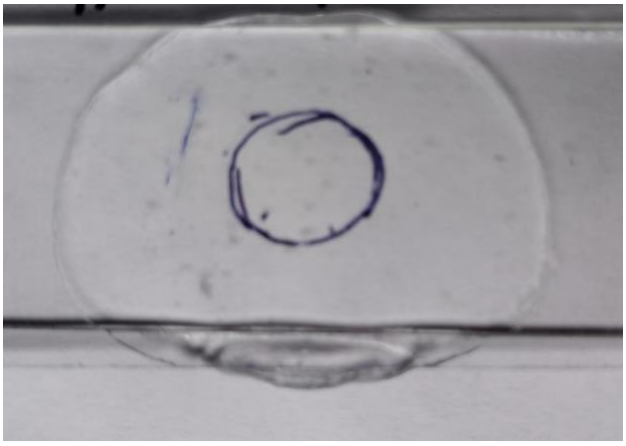


Fig.no.4: Spreadability Test

4)Homogeneity

All formulated gels were visually examined for homogeneity after being set in their containers. Their appearance and the presence of any accumulations were assessed.

5)Washability

Washability refers to how the gel can be removed from the skin using water. This is important for user convenience and hygiene especially for products used multiple times a day or over large skin areas.

6)Stability

The stability study results indicated that the developed gel formulation remained physically and chemically stable over a period of four months at room temperature conditions. Throughout the study, no significant changes were observed in key evaluation parameters such as color, odor, pH, viscosity, spreadability, and homogeneity. The formulation retained its uniform consistency without any signs of phase separation, precipitation, or microbial growth. These findings confirm that the formulation possesses good stability and is suitable for storage at room temperature for at least four months without compromising its quality, safety, or effectiveness.

7)complex formation: These was a complex seen under the microscope and in a FTIR analysis also show the presence of compound which we will use and the positive result will get.

Fig.no.5: Complex Detected

6.FTIR ANALYSIS

The FTIR spectrum of the formulated gel containing lipstick sample shows several characteristic absorption peaks indicating the presence of different functional groups. A broad absorption band observed around 3400–3200 cm^{-1} suggests the presence of O–H stretching vibrations, which can be attributed to alcohols and water content, likely originating from propylene glycol and carbopol gel base. The peak around 2920–2850 cm^{-1} indicates C–H stretching of aliphatic hydrocarbons, confirming the presence of organic compounds such as waxes and oils commonly found in lipstick.

A distinct peak near 1700–1730 cm^{-1} corresponds to C=O (carbonyl) stretching, which may arise from ester groups present in cosmetic ingredients. The absorption band around 1600– 1500 cm^{-1} indicates C=C stretching or aromatic ring vibrations, suggesting the presence of aromatic compounds or pigments in lipstick formulation. Peaks observed near 1450–1380 cm^{-1} are due to CH_2 bending vibrations, confirming aliphatic chains.

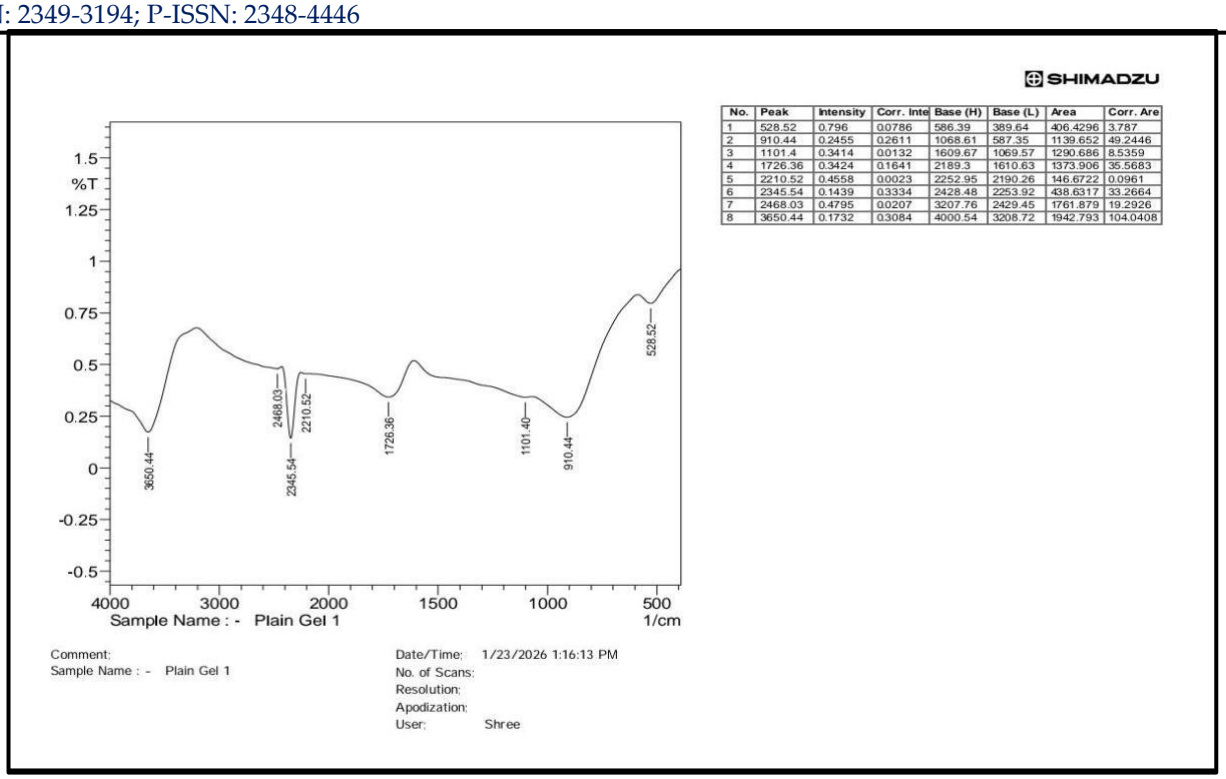
Further, strong peaks in the region of 1200–1000 cm^{-1} indicate C–O stretching vibrations, which are characteristic of alcohols, ethers, or esters, again supporting the presence of excipients like triethanolamine and propylene glycol. The region below 900 cm^{-1} shows fingerprint region peaks, confirming the complex mixture of compounds in the formulation.

The FTIR analysis confirms that the gel formulation containing lipstick exhibits characteristic functional groups such as hydroxyl (–OH), carbonyl (C=O), aliphatic C–H, and C–O groups, indicating the presence of both gel base components and cosmetic ingredients. No significant peak shifts or disappearance of major functional group peaks were observed, suggesting no chemical incompatibility or interaction between the gel excipients and lipstick components. Thus, the formulation is considered chemically stable and compatible.

Under the FTIR there is a analysis of gel formulation in with lipstick and analyse that the complex should be formed it show that the gel will work properly and prevent the metal toxicity.

a) Analysis of Graph1 Gel+Lipstick

The spectrum shows several characteristic peaks corresponding to functional groups present in the gel formulation (likely Carbopol, Propylene glycol, Triethanolamine, etc.).



No.	Peak	Intensity	Corr. Inte	Base (H)	Base (L)	Area	Corr. Are
1	528.52	0.796	0.0786	586.39	389.64	406.4296	3.787
2	910.44	0.2455	0.2611	1068.61	587.35	1139.652	49.2446
3	1101.4	0.3414	0.0132	1609.67	1069.57	1290.686	8.5359
4	1726.36	0.3424	0.1641	2189.3	1610.63	1373.906	35.5683
5	2210.52	0.4558	0.0023	2252.95	2190.26	146.6722	0.0961
6	2345.54	0.1439	0.3334	2428.48	2253.92	438.6317	33.2664
7	2468.03	0.4795	0.0207	3207.76	2429.45	1761.879	19.2926
8	3650.44	0.1732	0.3084	4000.54	3208.72	1942.793	104.0408

Graph1: Gel + Lipstick

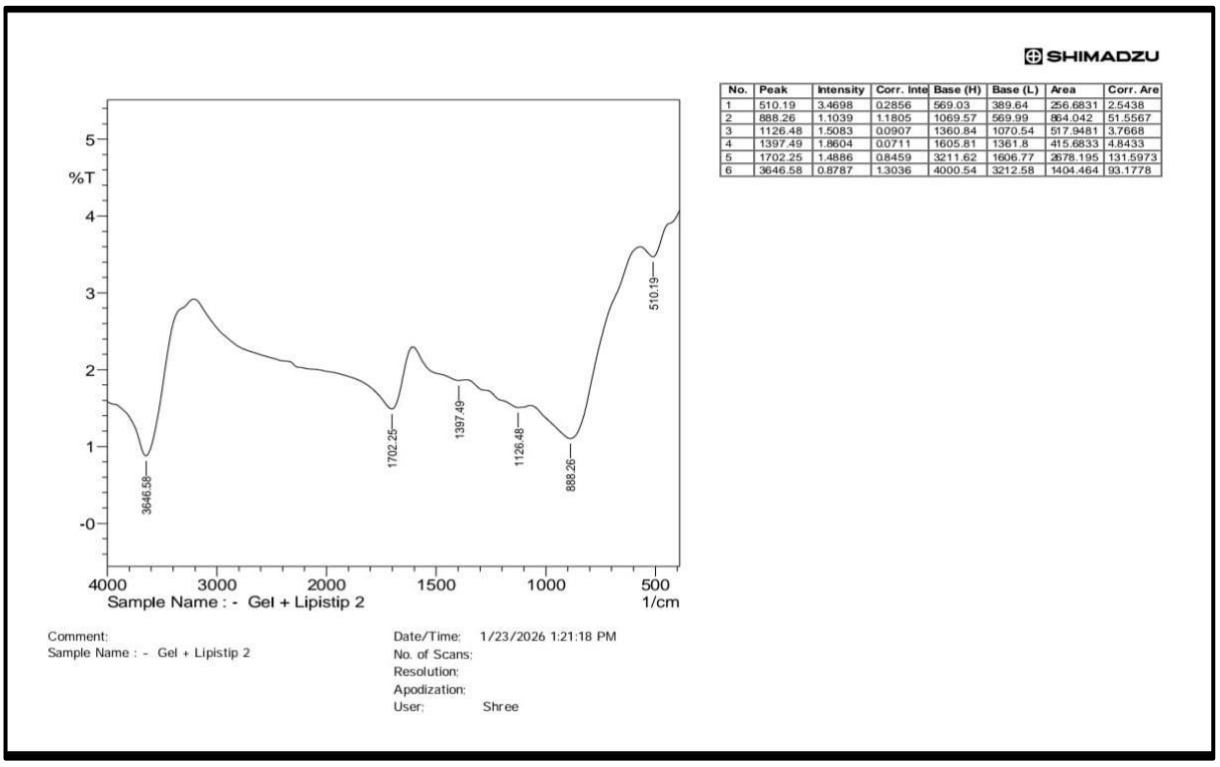
Table no.4: Analysis of Graph1 Gel+Lipstick

Sr. No.	Peak(cm)	Functional Group	Interpretation
1.	3650.44 cm^{-1}	O–H stretching	Broad peak indicating presence of alcohols / hydroxyl groups (Propylene glycol, water, Carbopol)
2.	2345.54 cm^{-1}	CO_2 stretching	Atmospheric carbon dioxide absorption
3.	2210.52 cm^{-1}	C≡N / C≡C stretching	Weak peak; may indicate trace impurities or instrumental artifact
4.	1726.36 cm^{-1}	C=O stretching	Strong peak of carboxylic acid
			groups (Carbopol polymer backbone)

5.	1101.40 cm^{-1}	C–O stretching	Indicates alcohols/ethers (Propylene glycol, triethanolamine)
6.	910.44 cm^{-1}	=C–H bending	May indicate alkene or polymer structure vibrations
7.	528.52 cm^{-1}	C–X (halogen) / skeletal vibration	low-frequency region, often due to polymer backbone vibrations

b)Analysis Of Graph2gel+Lipstick

The spectrum shows several characteristic peaks corresponding to functional groups present in the gel formulation (likely Carbopol, Propylene glycol, Triethanolamine, etc.).



No.	Peak	Intensity	Corr. Inte	Base (H)	Base (L)	Area	Corr. Are
1	510.19	3.4698	0.2856	569.03	389.64	256.6831	2.5438
2	888.26	1.1039	1.1805	1069.57	569.99	864.042	51.5567
3	1126.48	1.5083	0.0907	1360.84	1070.54	517.9481	3.7668
4	1397.49	1.8604	0.0711	1605.81	1361.8	415.6833	4.8433
5	1702.25	1.4886	0.8459	3211.62	1606.77	2678.195	131.5973
6	3646.58	0.8787	1.3036	4000.54	3212.58	1404.464	93.1778

Graph2: Gel + Lipstick

Table no.5: Analysis of Graph2gel+Lipstick

Sr. No.	(Peak cm)	Functional group	Interpretation
1.	3646.58	O–H stretching	Presence of alcohols, phenols, or water; indicates gel base components like carbopol, rose water, and propylene glycol
2.	1702.25	C=O stretching	Indicates carboxylic acids or esters; confirms presence of carbopol and esterbased lipstick ingredients
3.	1397.49	C–H bending / O–H bending	Represents aliphatic compounds; suggests organic backbone from waxes and lipids in lipstick
4.	1126.48	C–O stretching	Indicates alcohols, ethers, or esters; confirms presence of propylene glycol and cosmetic excipients
5.	888.26	C–H bending (aromatic/alkene)	Suggests unsaturated or aromatic compounds; likely from pigments or additives in lipstick
6.	510.19 Metal–O (M–O) vibration	Metal–O (M–O) vibration	Indicates presence of metal ions or complexes; suggests interaction of EDTA with metals in lipstick

7.RESULT AND DISCUSSION

The preventive gel formulation was develop evaluated for the metal toxicity the gel was form a compelx with the metal present in a cosmetics and prevent the penetration of heavy metal in a body from cosmetics and prevent metal toxicity.

Reaction

Disodium EDTA + Pb Acetate $\longrightarrow$ Pb EDTA + Disodium Acetate

8.SUMMARY AND CONCLUSION

The development and evaluation of a protective topical gel against metal toxicity from cosmetic products demonstrated promising physicochemical properties, stability, and effectiveness. The gel exhibited smooth texture, good homogeneity, and a faint whitish color with no visible foreign particles. The pH values(4.5) ensured skin compatibility, while the viscosity (18,230– 22,230 cps) provided an optimal gel consistency. Additionally, spreadability (3.3g·cm/s) was within an acceptable range, ensuring ease of application. The optimized formulation (G2) showed excellent stability after three months of accelerated storage (40 ± 2°C and 75 ± 5% RH), with no crystallization or degradation. Its pH (6.88) and viscosity (20,800 cps) remained consistent with initial values, confirming its long- term stability. The optimized formulation enhances metal chelation (Disodium EDTA), hydration and penetration (Propylene Glycol), pH stability (Triethanolamine). These properties make the gel a promising protective barrier against heavy metal exposure from cosmetics, ensuring skin safety and long-term effectiveness.

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