Formulation And Evaluation of Herbal Cream-O-Gel Containing Bougainvillea Spectabilis Leaf Extract

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***Abstract*—The main aim of our research was to develop herbal cream-O-gel formulations consisting Bougainvillea spectabilis for the treatment of Anti-Acne. The herbal cream-O-gel formulation was designed by using the extract of Bougainvillea spectabilis. Formulated herbal is helpful for Anti-Acne It has good spredability. Formulated cream has no signs of instability such Cracking, Creaming or Phase separation. Herbal Cream-O-gel showed satisfactory organoleptic characteristics.**

Delicate paper-like bracts of *B. spectabilis'* have earned it the nickname "Paper Flower." Bougainvilleas typically come in purple or magenta, with different colors ranging from white to orange. Each part of this medicinal plant is used for some medicinal values and is used for various pharmacological actions such as Anti-Inflammatory activity, Antidiabetic activity, Antioxidant activity, Anti-ulcer activity and Anti-Acne activity. Key phytochemical constituents present in different parts of the plant such as Stem, flowers, and leaves of *B. spectabilis* can be used to extract a variety of phytochemical compounds, including alkaloids, flavonoids, furanoids, glycosides, phenols, phlobotannins, quinones, saponins, steroids, tannins, and terpenoids. Bougainvinonespeltogynoids, essential oils containing methyl salicylate, terpinolene, a-(E)-ionone, pinitol, -sitosterol, quercetin, and quercetin-3-O-rutinoside, are the additional active components.

***Index Terms*—Bougainvillea spectabilis, leaf extract, cream-O-gel, Anti-Acne.**

I. INTRODUCTION

When creams and gels are used in combined from the dosage forms are referred as Cream-O-Gel. Medicinal plants are an important resource to traditional health care systems. It is estimated that 70-80% of the rural population in developing Asian nations depends on traditional medicine for primary health care today. According to the World Health Organization (WHO), more than 80% of the World's population relies on traditional herbal medicine for their primary health care needs. These valuable herbal traditions found in developing countries have always been considered an important component of the cultural heritage of the world and traditional use and management of medicinal plants. B. spectabilis, also known as "paper flower," has long been recognized for its medicinal benefits. The plant contains a variety of phytochemicals, such as flavonoids, alkaloids, tannins, and terpenoids, which contribute to its pharmacological properties. Additionally, the presence of peltogynoids and betalains further enhances its therapeutic effects. This research aims to develop gel formulations using Bougainvillea spectabilis extracts. The gel undergoes thorough evaluation process, including assessments of physical properties, washability, skin irritation, spreadability, pH, viscosity, extrudability, swelling index, and accelerated stability. The goal is to create a stable, effective, and safe topical gel that leverages the bioactive compounds of Bougainvillea spectabilis for potential applications in skincare and pharmaceuticals. The results of this study could contribute to the expanding field of herbal-based topical products, offering a natural alternative to synthetic treatments while ensuring both safety and efficacy.

1.1. Topical Drug Delivery System:

Over the last decades, the treatment of illness has been accomplished by administrating drug to human body via various roots namely oral, sublingual, rectal, parentral, topical, inhalation, etc. The Topical drug delivery system can be defined as direct effects of formulation or drug containing medication to the skin to get localizing effect of drug or directly cure cutaneous disorders or the cutaneous manifestations of general diseases(eg psoriasis)with the intent of containing the pharmacological or the effect of drug

to the surface of skin or within the skin semisolid formulations in all their diversity dominate the system for topical delivery, but foams, sprays, medicated powder, solutions and even medicated adhesive system are in use. Dermatological products applied to skin are diverse in formulation and range in consistency from liquid to powder but the most popular products are semisolid preparation.

Advantages of topical drug delivery system:

- Avoidance of first pass metabolism.
- Avoidance of Gastro-intestinal incompatibility
- Avoid of risk.
- Convenient and easy to apply.
- Easy termination of medication, when needed.

1.2. Cream-O-Gel:

Cream-O-Gel is the topical preparations which can be applied on the skin. Creams-O-Gelis defined as "viscous liquid or semi-solid emulsions of either the oil-in-water or water-in-oil type" dosage forms which consistency varies by oil and water.

Cream-O-Gel can be Ayurveda, herbal or allopathic which are used by people according to their needs for their skin conditions. They contain one or more drugs substances dissolved or dispersed in a suitable base. Cream-O-Gelis used for cosmetic purposes such as cleansing, beautifying, improving appearances, protective or for therapeutic function. These topical formulations are used for the localized effect for the delivery of the drug into the underlying layer of the skin or the mucous membrane. These products are designed to be used topically for the better site-specific delivery of the drug into the skin for skin disorders. Cream-O-Gel are considered as a pharmaceutical product as they are prepared based on techniques developed in the pharmaceutical industry; unmedicated and medicated Cream-O-Gel are highly used for the treatment of various skin conditions or dermatoses. They contain one or more drugs substances dissolved or dispersed in a suitable base. Creams may be classified as o/w or w/o type of emulsion on the basis of phases. The term 'cream' and 'Gel' has been traditionally applied to semisolid formulated as either water-in-oil or oil-in-water.

1.3. TYPES OF SKIN CREAM-O-Gel:

They are divided into two types:

a. Oil-in-Water (O/W)

Cream-O-Gel which is composed of small droplets of oil dispersed in a continuous phase, and an emulsion in which the oil is dispersed as droplets throughout the aqueous phase is termed an oil-in-water (O/W) emulsion.

b. Water-in-Oil (W/O)

Cream-O-Gel which is composed of small droplets of water dispersed in a continuous oily phase. When water is the dispersed phase and oils the dispersion medium, the emulsion is of the water-in-oil (W/O) type.

1.4. ADVANTAGES:

1) They gives prolong contact in their site of application than any other pharmaceutical semi-solid dosage forms.
2) Injured area can be dried quickly by creams than other semi-solid preparations.
3) Non-irritating when applied to the skin. Easily water washable. Easy to wipe away.
4) Less greasy compared to ointment.
5) Easy to spread on the skin's surface.

1.5. DISADVANTAGES:

1. Stability is not as good as ointment.
2. They are less hydrophobic than other semi-solid preparation, so risk of contamination is high than the others.

1.6. IDEAL CHARACTERSTICS:

1) It should liquefy at body temperature.
2) It should penetrate the epidermis (via natural opening).
3) Its viscosity should be low enough to permit easy spreading.
4) It should be non-toxic.
5) It should be non-irritant.
6) It should be non-inflammatory.

1.7. EVALUTION TESTS:

1. pH of the cream
2. Viscosity
3. Rheological behavioral of the cream-o-gel
4. Determination of Type of cream-o-gel

a. Dilution Test

b. Dye Solubility Test

II. INTRODUCTION OF PLANT

Bougainvillea (Bougainvillea Commers.) is a popular ornamental shrub grown for its colourful and attractive bracts belongs to the family Nyctaginaceae. It is a native of tropical region of South America. It was introduced in India from Europein1860.Its wide adaptability into different agro climatic conditions. Blended with broad spectrum of recurring blooming habit has made bougainvillea commercially important plant in the nursery trade. The plant contains about 16 species. Out of 16 species, 4 have ornamental importance. There are around 1000 cultivars under different species available all over the world. Out of those, only three species namely B. spectabilis, Wild B Glabra Choicy and B. peruviana Humb & Bom possess color fullbacks for the ornamental values. These have a short history of domestication and have been cultivated about 150 years outside their natural habitats. Due to its high demand in nursery trade and landscape use, the demand for new and novel cultivars is growing steadily. Breeders all over the world, especially from tropical countries, are putting hard efforts to develop new cultivars with special traits, mainly dwarf and thorn less varieties, to match the changing taste and lifestyle. With the changing lifestyle, housing pattern and new landscape usages, the demand for new and novel varieties is growing day by day.

Medicinal plants are an important resource to traditional health care systems. It is estimated that 70-80% of the rural population in developing Asian nations depends on traditional medicine for primary healthcare today. According to the World Health Organization (WHO), more than 80% of the World's population relies on traditional herbal medicine for their primary health care needs. These valuable herbal traditions found in developing countries have always been considered an important component of the cultural heritage of the world and traditional use and management of medicinal plants.

Fig.no.1 *Bougainiville aspectabilis*

2.1. PLANT PROFILE:
Kingdom: Plantae
Subkingdom: Tracheobionta
Super division: Spermatophyta
Division: Magnoliophyta
Class: Magnoliopsida
Subclass: Caryophyllidae
Order: Caryophyllales
Family: Nyctaginaceae
Genus: Bougainivillea (Abarca-Vargas and Petricevich 2018)

2.2. SYNONYMS:
English: Great Bougainvillea, paper flower; Bengali; Bagan Bilash; Chinese: mao bao jin, jiuchongge, san jiaohua, ye zihua; French: bougainvillier, Hindi: booganbel; Italian: buganvillea; Indonesian: buganvil, kembangkertas, bungakertas; Japanese: felila; Konkani: bougainvillea; Malay: buganvil, buginvila, pokokbungakertas; Manipuri: Cherei; Spanish: buganvilla, veranera; Telugu: kagithalapuvvu
Botanical Characterization and Distribution:
The genus *Bougainvillea* is endemic to South America and was firstly reported in Brazil in 1778 before being introduced to Europe, by French military commander Louis Antoine de Bougainville. They are bushes spread in vines or small trees. They also possess stems with internodes and with straight or slightly curved thorns. The leaves are petiolate, elliptical, or wider towards the base. The bracts and flowers are presented in different colours, depending on the species, cultivars, or hybrid. They bloom throughout the year.
Botanical textbooks say that some species of the genus *Bougainvillea* are distributed worldwide and without being specific to any single place, species,

cultivars, or hybrids. Based on these results, a more exhaustive analysis was performed in the scientific literature.

III. MATERIALS AND METHODS

3.1. Drug:

Table No.1 Drug

1.	Bougainvillea spectabilis	Collected from Farmlands of Latur region.

3.2. Chemicals:

Table No.2 Chemicals

Sr. No.	Excipients/Solvents	Suppliers
01	Soya Lecithin	MCP Nilanga Pharmaceutical Lab
02	Ethanol	MCP Nilanga Pharmaceutical Lab
03	Cholesterol	MCP Nilanga Pharmaceutical Lab
04	Propylene Glycol	MCP Nilanga Pharmaceutical Lab
05	Glycerin	MCP Nilanga Pharmaceutical Lab
06	Propyl Paraben	MCP Nilanga Pharmaceutical Lab
07	Xanthan Gum	MCP Nilanga Pharmaceutical Lab
08	Rose oil	MCP Nilanga Pharmaceutical Lab
09	Distilled water	MCP Nilanga Pharmaceutical Lab

3.3. Equipment's:

Table.3. List of Equipment's

Sr. No	Equipment	Company
1	Magnetic Stirrer	LABGO Magnetic Stirrer
2	UV Spectrophotometer	Shimadzu (1800)
3	FT-IR Spectrometer	Perkin Elmer UARI Two.
4	pH Meter	Hanna Instruments Italy.
5	Mechanical Stirrer	Remi Mechanical stirrers
6	Thermometer	Lab world mercury thermometer
7	Electronic Balance	Citizen CTG -302
8	Brookfield Viscometer	AMETEK Brookfield DV2T Viscometer
9	Petri dishes	AGLO microscopes
10	Water Bath Apparatus etc.	Hanna Instruments Italy.

IV. EXPERIMENTAL WORK:

4.1. Collection of Bougainvillea Spectabilis Leaves: -

Leaves of Bougainvillea spectabilis are collected from the region of Nilanga.

4.2. EXTRACTION:

Leaves of B. spectabilis were collected and washed with distilled water and dried in hot air oven. Then after proper drying, the leaves were powdered in the mixture. Then 200g Powder of B. spectabilis+400ml distilled water was taken in a volumetric flask and then stirs for 2min then placed for 72hrs.

Then the solution was taken and stirred well then solution was filtered properly with filter paper, then filtered solution was placed on water bath at 80 to 100 degrees Celsius. For 48 hours, Then the filtrate or the filter product in which a clear solution or clear extract of B. spectabilis was used in the preparation.

Fig.no.2 Sample Of Extraction

4.3. FORMULATION TRIALS:

Table.4 Formulations table for Herbal Cream-O-Gel

Sr.no.	Ingredients	F1H	F2H	F3H	F4H	F5H	F6H
01	Extract	2	2	2	2	2	2
02	Soya Lecithin (gm)	1	2	3	1	2	3
03	Ethanol (ml)	20	20	20	30	30	30
04	Cholesterol (gm)	0.2	0.2	0.2	0.2	0.2	0.2
05	Propylene Glycol (ml)	10	10	10	10	10	10
06	Glycerin (ml)	3	3	3	3	3	3
07	Propyl Paraben (gm)	0.2	0.2	0.2	0.2	0.2	0.2
08	Xanthan Gum (gm)	1	1.5	2	2.5	3	3.5
08	Distilled water	q. s	q.s	q.s	q. s	q. s	q. s
09	Rose Oil	q. s	q.s	q.s	q. s	q. s	q. s

4.4. Procedure:

1. In this method, accurately weighed 200 mg of extract was dissolved in ethanol and propylene glycol was added to it and heated to 40^0C.
2. In a separate vessel, Soya Lecithin and Cholesterol were dispersed in distilled water by heating on a water bath at 40^0C until a colloidal solution was obtained.
3. Once both the mixtures reached at 40^0C, the drug solution was added to the soya lecithin dispersion of water in a closed vessel under stirring at 3000 rpm.
4. After adding, mixing was continued for another 10 minutes to get microparticulate dispersion.
5. The optimized ethasomal suspension was incorporated into Cream-O-Gel.
6. To the mixture of specified amount add Xanthan Gum and glycerine, dispersed slowly with gentle stirring for 2 min followed by addition of Propyl Paraben (preservative) with continuous stirring.
7. Finally, formulation was stored under refrigeration (2-8^0C) until further use.

Evaluation Parameters

V. PHYSICAL EVALUATION:

In this test, the cream was observed for color, odor, texture, state.

5.1. IRRITANCY:

Mark the area (1cm2) on the left- hand dorsal surface. Then the cream was applied to the hand and then the time was noted. Then it is checked for irritancy, erythema, and edema if any for an interval up to 24 hands reported.

5.2. WASHABILITY:

A small amount of cream was applied on the hand and it is then washed with tap water.

5.3. pH:

0.5g cream was taken and dispersed in 50ml distilled water and then PH was measured by using digital pH meter.

5.4. VISCOSITY:

Viscosity of cream-o-gel was done by using Brooke field viscometer at a temperature of 25 using spindle No.05 at 5.0 RPM.

5.5. PHASE SEPARATION:

Prepared cream was kept in a closed container at a temperature of 25-100 away from light. Then phase separation was checked for 24 h for 30d. Any change in the phase separation was observed / checked.

5.6. SPREADABILITY:

The Spredability was expressed in terms of time in seconds taken by two slides to slip off from the cream, placed in between the slides, under certain load. Lesser the time taken for separation of the two slides better the Spredability. Two sets of glass slides of standard dimension were taken. Then one slide of suitable dimension was taken and the cream formulation was placed on that slide. Then other slide was placed on the top of the formulation. Then a weight or certain

load was placed on the upper slide so that the cream between the two slides was pressed uniformly to form a thin layer. Then the weight was removed and excess of formulation adhering to the slides was scrapped off. The upper slide was allowed to slip off freely by the force of weight tied to it. The time taken by the upper slide to slip off was noted.

Spredability= m × l/t

Where, m= Standard weight which is tied to or placed over the upper slide (30g)

l= length of a glass slide (5 cm)

t=time taken in seconds

5.7. GREASINESS:

Here the cream was applied on the skin surface in the form of smear and checked if the smear was oily or grease-like.

5.8. FT-IR Spectroscopy:

ANALYSIS FOR SAMPLE: IR spectrum of Leaf extract and formulated herbal cream were carried out using FTIR by ATR (attenuatedtotal reflection) sampling method.

5.9. IN-VITRO DIFFUSION STUDIES:

In-vitro diffusion was carried out on Franz diffusion cell having 57ml capacity and whatman filter paper no.41 used as diffusion membrane. Pieces of whatman filter paper no.41 were soaked in phosphate buffer pH 9.0 for 24 hrs prior to experiment. Diffusion cell was filled with phosphate buffer pH 6.0 Whatman filter paper no.41 was mounted on cell. The temperature was maintained at 37±0.5° then the formulation was spread on the filter to form thin layer. The time point for cream-o-gel were different. A sample of 1ml was withdrawn at predetermined time intervals, the solution was filter with 0.45-micron filter paper and make up the volume with 5ml of PB pH 6.0 and equivalent amount of fresh dissolution fluid equilibrated at same temperature was replaced. The sample was diluted to 5ml of PB pH 6.0 for determination the standard was prepared which was of same concentration of that sample. The amount of permeated drug was determined using a UV-Spectrophotometer at 265 nm.

VI. RESULT AND DISCUSSION

6.1 Organoleptic Characteristics:

Evaluation includes the color, odour, texture & state of the cream.

Table: 5 Organoleptic Properties

Sr.no	Formulation	Colour	Odour	Texture	State
1.	F1	Greenish	Pleasant	Smooth	Semisolid
2.	F2	Greenish	Pleasant	Smooth	Semisolid
3.	F3	Greenish	Pleasant	Smooth	Semisolid
4.	F4	Greenish	Pleasant	Smooth	Semisolid
5.	F5	Greenish	Pleasant	Smooth	Semisolid
6.	F6	Greenish	Pleasant	Smooth	Semisolid

6.2 Homogeneity:

Cream applied to the glass object, covered with a glass cover. Observed homogeneity and cream surface visually.

6.3 Cream type:

Cream type evaluation using the color method. The cream is trimmed with a methylene blue solution or a solution of Sudan III on the glass object, then observed under the optical microscope

6.4 Viscosity:

The viscosity of the different sample was obtained by Brookfield viscometer (Brookfield engineering laboratories, Inc., MA, and USA) with spindle No.6at10rpm at temperatureof37± 0.5C.

Table: 6 Viscosity Result

SR.NO.	Formulation	Observation
01	F1	11,260
02	F2	9,010
03	F3	10.180
04	F4	14,060
05	F5	15,500
06	F6	5,660

6.5 Measurement of Ph:
pH measurement was carried out by using pH meter.

Table:7 pH

Sr.no	Formulation	Observation
1.	F1	6.24
2.	F2	6.25
3.	F3	6.32
4.	F4	6.52
5.	F5	7.11
6.	F6	7.06

6.6 Spredability
The Spredability was expressed in terms of time in seconds taken by two slides to slip off from the cream, placed in between the slides, under certain load. Lesser the time taken for separation of the two slides better the Spredability. Two sets of glass slides of standard dimension were taken. Then one slide of suitable dimension was taken and the cream formulation was placed on that slide. Then other slide was placed on the top of the formulation. Then a weight or certain load was placed on the upper slide so that the cream between the two slides was pressed uniformly to form a thin layer. Then the weight was removed and excess of formulation adhering to the slides was scrapped off. The upper slide was allowed to slip off freely by the force of weight tied to it. The time taken by the upper slide to slip off was noted.
Spread ability= m × l/t
Where, m= Standard weight which is tied to or placed over the upper slide (30g)
l= length of a glass slide (5 cm)
t= time taken in seconds.

Table no.8 Spredability Observation

Sr.no	Formulation	Observation
1.	F1	6.2
2.	F2	4.0
3.	F3	4.5
4.	F4	5.3
5.	F5	7.8
6.	F6	7.7

6.7 Washability:
Washability test was carried out by applying a small amount of cream-o-gel on the hand and then washing it with tap water. All six formulations were easily washable.

Table:9 Washability Observation

Sr.no	Formulation	Observation
1.	F1	Easily Washable
2.	F2	Easily Washable
3.	F3	Easily Washable
4.	F4	Easily Washable
5.	F5	Easily Washable
6.	F6	Easily Washable

6.8 Phase separation:
Prepared cream-o-gel was kept in a closed container at a temperature of 25-100°Caway from light. Then phase separation was checked for 24 h for 30 d. Any change in the phase separation was observed/checked. According to the results no phase separation was observed in all the six formulations.

Table 10: Phase separation observation table:

SR.NO.	Formulation	Observation
01	F1	No phase separation
02	F2	No phase separation
03	F3	No phase separation
04	F4	No phase separation
05	F5	No phase separation
06	F6	No phase separation

6.9 FTIR RESULT:
The FTIR analysis was simple method to assume the compatibility of a sorted excipients blend with the pure drug. Spectral examination was executed using FTIR to explore the generation of new compound or any chemical change in the functional portion of the add mixtures among the blends. Infrared spectroscopy was utilized in pharmaceutical investigation for its authentication and structure elucidation of drug. The peaks given in the Table could be considered as the characteristic peaks of Cream.

Herbal Extract Result

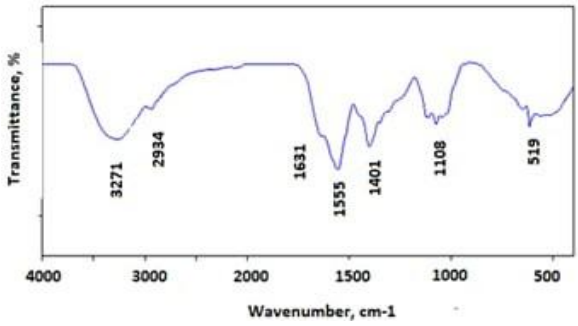

Fig.no 3 FTIR Aq Extract peak 1

Table No.11 Herbal Extract Result

Spectrum Name	Number Of Peaks
Administrator 980	07

Administrator 980 Details:

Peak Number	X (cm-1)	Y (%T)
1	3271	25
2	2934	50
3	1631	30
4	1555	20
5	1401	35
6	1108	45
7	519	80

6.10In-vitro Diffusion Study:

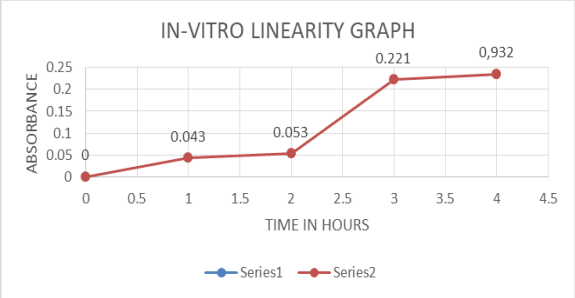

Fig.no. 4 In-vitro Linearity Graph

Table: 12 Observation of In-Vitro

Sr. NO.	Time In Hours	Wavelength in nm.	Absorbance	Conc.	Drug release	% Drug Release
.1.	1hr.	274.00	0.041	1.174	0004	0.5
2.	2hr.	274.00	0.055	2.510	0.014	1.2
3.	3hr.	274.00	0.220	6.048	0.135	13.1
4.	4hr.	274.00	0.235	6.416	0.148	14.0

VII. DISCUSSION:

This study led to the successful formulation and scientific evaluation of a herbal cream-o-gel incorporating Bougainvilli aspectabilis leaf extract known for skin benefiting properties.

Bougainvillia spectabilis may significantly contribute due to its presence of flavonoids and tannins in abundant quantity. Interestingly, the cosmetic value of this botanical remains largely untapped, lending originality to the current formulation. The prepared formulation met key quality standards such as balanced pH, uniformity, and skin compatibility. Its water-in-oil emulsion structure enhances hydration by forming an occlusive layer, making it especially beneficial for dry skin types. Although its spreadability was marginally lower than the commercial reference, its soft texture and non-greasy application provide a favorable user experience. These findings advocate for the broader use of underutilized botanicals in skincare, providing a safer, more natural alternative to conventional cosmetic

VIII. SUMMARY AND CONCLUSION:

6 batches (F1-F6) of this herbal cream-o-gel were prepared. Formulation and evaluation of all 6 batches were carried out different evaluation parameters like pH, Viscosity, spredability were performed. pH (7.11), viscosity (15,500) Spredability (7.8) depending on the result obtained from this evaluation parameter F5 batch is optimized batch. FTIR and In-vitro release study is carried out for Optimized batch.

The human skin is one of the most important organs that need constant care to keep out bacteria, fungus, and other microorganisms that can cause skin infections. The medical community is in charge of combating microbial skin infections with petrochemical medications, and medicinal plants, which produce large amounts of bioactive, are the most promising natural option to combat severe drug resistance. Herbal medicines made from medicinal plants have the potential to be the future focus of medication development and discovery. An herbal cream made from the aqueous leaf extract of Bougainvillea spectabelis, for example, performed well, indicating that the plant has the potential to be used to treat skin infections brought on by the bacteria. The bioactive components of creams—flavonoids, terpenoids, tannins, and terpenoids were largely responsible for their marked utility at the time. It may be possible to find and apply creams to treat skin infections brought on by bacteria.

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