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# Formulation and Evaluation of Emulgel of Justicia Gendarussa Leaves

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**ABSTRACT**

Topical drug delivery is the delivery of drugs anywhere in the body through skin, vaginal, ophthalmic and rectal routes. Drugs may be given for localized or systemic effects. Only a narrow range of drugs are available for topical use because most drugs are hydrophobic in nature and this restricts their permeation and absorption into the skin. Herbal remedies have been used in the treatment of various diseases including skin diseases for centuries and are gradually becoming acceptable as treatment options however, they are mostly hydrophobic. Emulgel has a dual control and a sustained release pattern. Emulgel improves bioavailability as well as patient compliance. The pH, viscosity, particle size, zeta potential, drug content, stability study, skin irritation test, and other properties of the prepared formulation are evaluated. The prepared herbal emulgel was evaluated for pH, spreadability, viscosity, consistency, appearance, color, washability and appearance. The proposed research work concludes that the newly formulated herbal emulgel loaded with extract of Justicia Gendarussa can be used in future for anti-inflammatory effect.

## Introduction

The leaves of Justicia Gendarussa are rich in bioactive compounds such as flavonoids and alkaloids, which exhibit anti-inflammatory, and antimicrobial activities and other activities.

The extract of Justicia Gendarussa leaves will be obtained using a suitable solvent extraction method. The phytochemical composition of the extract will be characterized to identify and quantify the presence of bioactive compounds responsible for its therapeutic effects

These compounds, known for their antioxidant and anti-inflammatory activities, are expected to contribute to the therapeutic potential of the emulgel formulation. The formulation of the emulgel will involve the selection of suitable hydrophilic and lipophilic ingredients, including polymers, emulsifiers, and penetration enhancers.

Overall, the formulation and evaluation of an herbal emulgel loaded with Justicia Gendarussa leaf extract hold promise for the development of a topical formulation that can harness the medicinal properties of this plant.

### 1.1 Botanical Description:

**Table 1:** Botanical Description of *Justicia gendarussa* leaves

| **Botanical name** | ***Justica gendarussa* leaves** |
|---|---|
| Common name | Willow-Leaved Justica, Warner Willow, Daun Rusa, Gardarusa, Ganda Rusa |
| Genus | Justica |
| Clade | Tracheophytes |
| Order | Lamiales |
| Family | Acanthaceae |
| Life cycle | Perennial |
| Mature size | Can reach upto 2-4ft height |
| Cultivation | Tropical area |
| Benefits | Children's asthma, Rheumatism and colic can be treated with this plant[9] |

**Figure 1:** Leaves of Plant

**Figure 2:** Collected Leaves of *Justicia Jendarussa*

Medicinal plants have a great history to be used in the traditional systems of medicines for human health since ancient times. These plants have scientfically established pharmacological properties which seem to correlate well with their use in treatment of a host of diseases.[7,8]

**Table 2:** Traditional Use of *Justicia gendarussa leaves*

| S.No. | Parts | Traditional use |
|---|---|---|
| 1. | Leaf, stem | Bronchitis, vaginal discharges, dyspepsia, Eye diseases, inflammation, fever, tympantitis. |
| 2. | Leaf infusion | Hemiplegia, Facial paralysis, cephalagia |
| 3. | Leaf Decoction | Emetic & Stimulant |
| 4. | Fresh Leaf juices | Earache and hemicrania |
| 5. | Oil (leaves) | Dermatitis |
| 6. | Leaf and flower top decoction | Drink or as a fumigation |
| 7. | Leaf juice | Chest cold and colic in children |
| 8. | Leaf mixed with the oil | Cures glandular swelling of throat and neck |
| 9. | Leaves and tender stalks | Joint pain and chronic rheumatism |
| 10. | Bark | Emetics |
| 11. | Flowers | Eye diseases |
| 12. | Roots | Antiseptic, antipyretic, ulcerosis |
| 13. | Roots decoction boiled in milk | Jaundice, fever, rheumatism, dysentery[10] |

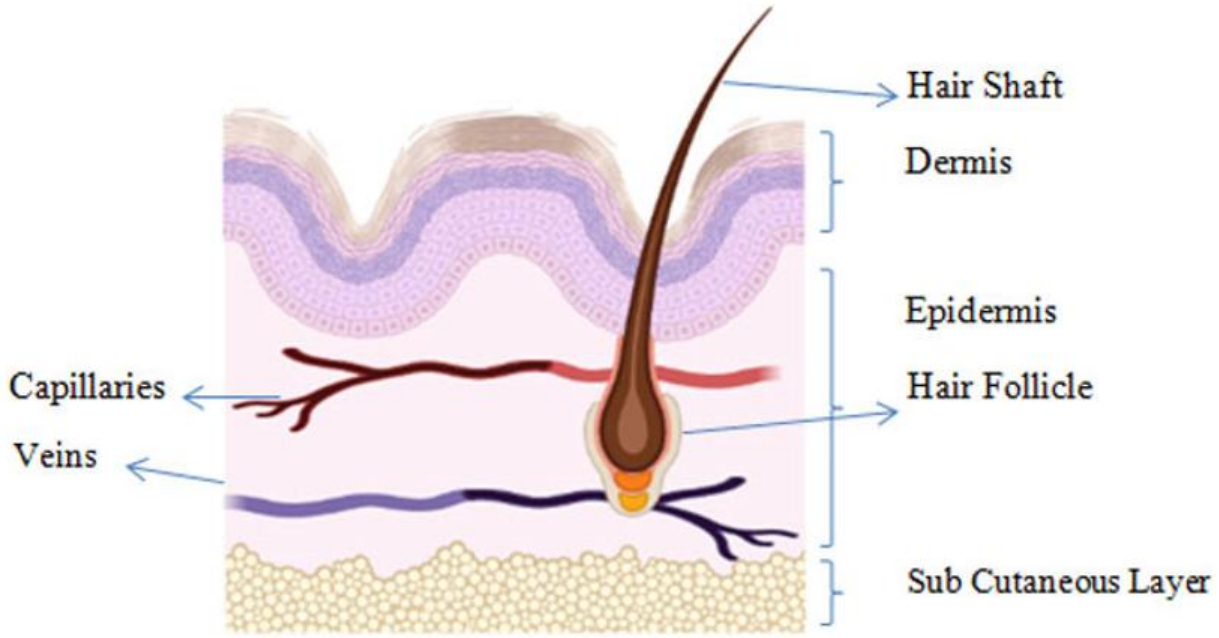



**Figure 3:** Structure of Human Skin

Topical drug delivery system is the dosage form which is administered on the skin or mucous membranes as the localized application with the approach to increase its bioavailability and reduction of side effects. [5]

It is combination of emulsion and gel, which is prepared either as oil-in-water or water-in-oil type of emulsion and then mixed with suitable gelling agent. Emulgels for dermatological use have several favourable properties such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, water-soluble, pleasing appearance, cosmetically acceptable and also have a good skin penetration. Now a days Emulgels is emerging as a potential drug delivery system in the area of dermatology.

## Emulgel:

Emulgel are emulsions, either of the water-in-oil or oil-in-water type, which are gelled by mixing with a gelling agent.[5] The emulsion acts as controlled release drug delivery system in which the drug particles are entrapped in internal phase and go through the external phase to the skin and gets absorbed slowly. The drug reaches to the external phase of the skin in a controlled manner through the internal phase which act as a reservoir of the drug. Gel captures small drug particles and provides its release in a controlled manner because of a crosslinked network. It increases the contact period of medication over the skin because of its mucoadhesive property.[6] Since Emulgel possesses the property of both gel and emulsions it acts as dual control release system.[7]

Gels that are used for dermatological property have a few positive properties, for example, being emollient[8,9], greaseless, thixotropic, easily removable, non-staining and compatible with various excipients. Release rate, and stability of incorporated drug, can be affected by the type and concentration of polymer which forms the gel. Emulgel may serve as a better option when it is concerned with the topical delivery of poorly water soluble drug. It is proven better and a stable vehicle for poorly water -soluble or hydrophobic drugs.[10]

## Types of Herbal Emulgel:

**Macro-emulsion gel:** -This refers to an emulsion (a mixture of two immiscible liquids) that has been incorporated into a gel. The emulsion component is characterized by relatively large droplet sizes (typically in the micrometer range), making them thermodynamically unstable. Essentially, it's a gel that contains dispersed larger droplets of another liquid. [6]

**Nano-emulgel:** - A fine dispersion of two immiscible liquids, where one liquid is dispersed as tiny droplets within the other. These droplets are extremely small, typically ranging from 20 to 200 nanometers in size. This small droplet size contributes to their kinetic stability and often results in a transparent or translucent appearance.

**Micro-emulsion based emulgel:** - It's a semi-solid dosage form where a microemulsion (a thermodynamically stable dispersion of oil and water with very small droplet sizes) is incorporated into a gel base.

### Advantages of Emulgel:

- ✓ Can be used for the incorporation of hydrophobic drugs
- ✓ Improved loading capacity
- ✓ Better stability
- ✓ Controlled release
- ✓ No intensive sonication
- ✓ Avoiding first pass metabolism

- ✓ Site specific action
- ✓ Increased patient compliance
- ✓ Convenient and easy to apply
- ✓ Low preparation cost
- ✓ Easy to terminate the therapy
- ✓ No gastrointestinal incompatibility
- ✓ Suitable for self-medication
- ✓ Incorporation of hydrophobic drugs
- ✓ Better loading capacity
- ✓ Better stability
- ✓ Controlled release
- ✓ No intensive Production feasibility and low preparation cost

**Disadvantages:**

The drug and/or excipients can lead to skin irritation in people with contact dermatitis. Some medications have low permeability through the skin.

Possibility of allergenic reactions:

Larger-particle-size drugs are not easily incorporated into the skin

- ✓ Skin irritation on contact dermatitis
- ✓ Possibilities of allergic reactions at the site of application
- ✓ Poor permeation of the skin for some drugs
- ✓ Poor absorption of drugs having large particle size.
- ✓ Bubble formation in the emulgel during the preparation.

## Method Used for Preparation of Emulgel:

**A.** Preparation of Emulsion: Preparation of

**Oil Phase:**

Isopropyl Myristate (2.5ml) + Liquid Paraffin (5ml)

**Preparation of Water Phase:**

5ml Tween80 in Sufficient Purified Water

+

Sol A. 0.5ml of propyl paraben in 5ml of propylene glycol
+
Sol B. Extract in 10ml Ethanol

To formulate emulsion,

Mixed oil phase into water phase at 70°C with continuous stirring.

**B. Preparation of gel base:**

Carbopol + Distilled water
+
Triethanolamine to adjust ph 6-6.5

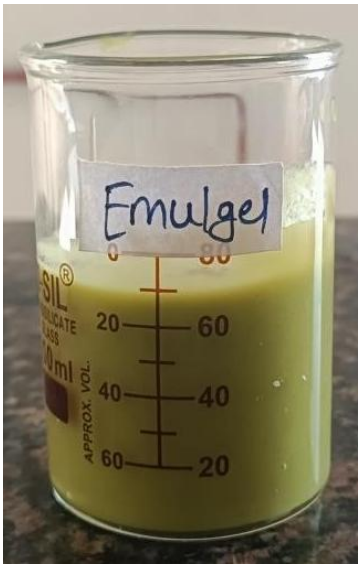
To Formulate **Emulgel**,

Mixed emulsion into gel base in 1:1 ratio with constant stirring.

## Evaluation of Emulgels

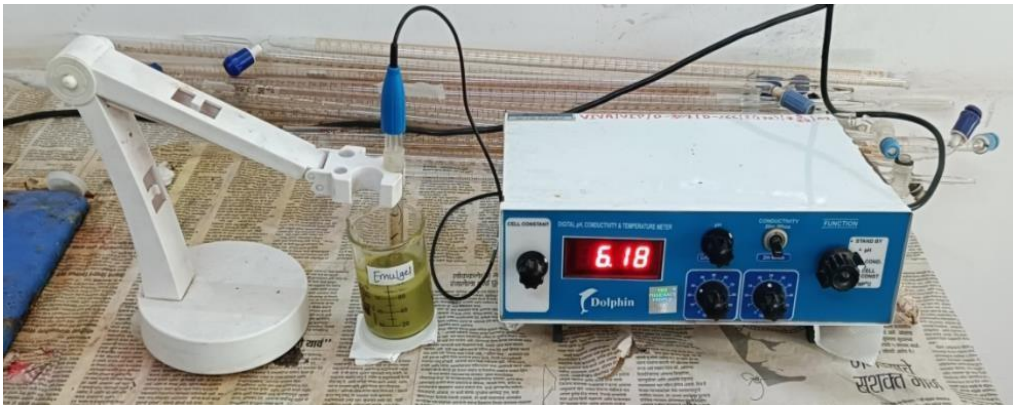
### 1. Physical Appearance: -

The emulgel formulated using *Justicia gendarussa* extract exhibits a greenish color, which is indicative of the presence of plant-based pigments and active constituents. It has a smooth and uniform texture, making it visually appealing and easy to apply. The formulation is greaseless, ensuring a non-oily feel on the skin, which enhances user compliance and comfort. Additionally, the emulgel possesses an easily spreadable consistency, allowing for even application over the desired area without excessive rubbing or residue formation. These characteristics contribute to the overall acceptability and effectiveness of the formulation.



## 2. Determination of pH :

The pH of the formulated emulgel was found to be 6.18, which falls within the ideal range for topical formulations. The pH was measured using a pH meter, ensuring accuracy and reliability in the assessment. This value is close to the natural pH of the skin, ensuring good compatibility and minimizing the risk of irritation or adverse reactions. Maintaining a slightly acidic to neutral pH is crucial for preserving the stability of the formulation while also supporting the skin's natural barrier function. The measured pH indicates that the emulgel is suitable for safe and effective topical application.




## 3. Determination of viscosity:


The viscosity of the formulated emulgel was determined using a Brookfield viscometer, ensuring precise and reliable measurement. Spindle numbers 63 and 64 were used during the evaluation to assess the consistency and flow properties of the formulation. Viscosity is a critical parameter in emulgel formulations as it influences the ease of application, spreadability, and retention on the skin. An optimal viscosity ensures that the emulgel remains stable, does not exhibit phase separation, and provides a smooth and uniform application without being too thick or too runny.

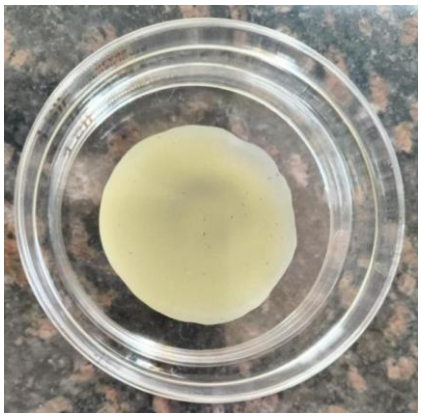
| Spindle size | 2. 0 Rpm | 3.0 Rpm | 5.0 Rpm |
|---|---|---|---|
| 63s | 39300 cP | 28880 cP | 21190 cP |
| | 65.5 % | 72.2% | 88.3% |



| Spindle size | 10 Rpm | 20 Rpm |
|---|---|---|
| 64s | 26500 cP | 18720 cP |
| | 44.3 % | 62.4 % |

## 4. Spreadability :

Spreadability refers to the ability of the emulgel to spread easily and uniformly over the skin upon application. It is an important factor that influences the product's bioavailability and therapeutic effectiveness. To evaluate spreadability, a known weight of the emulgel (2 g) is placed between two glass slides with specified dimensions. A weight is applied on top of the slides for 1 minutes to ensure uniform spreading of the emulgel. Any excess formulation around the edges is cleaned off. After the allotted time, the top slide is gently pulled away from the bottom slide, and the time taken for separation is recorded. This test helps to assess how easily the emulgel can be applied to the skin, impacting its effectiveness and patient comfort.

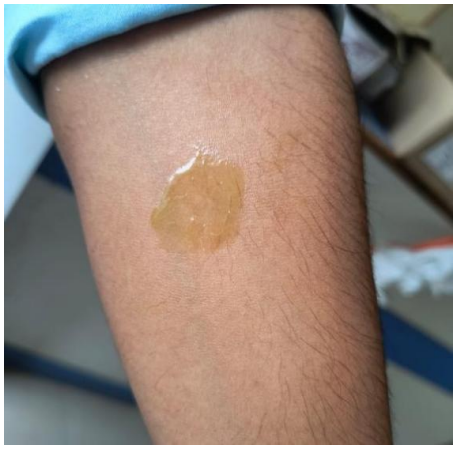


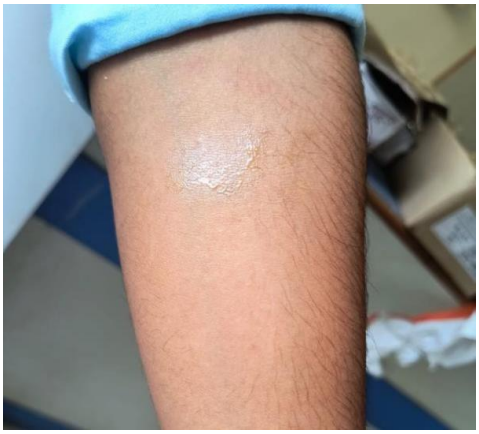
## 5. Extrudability:

Extrudability refers to the ease with which the emulgel can be expelled from a container, such as a tube, under applied pressure. It is an important parameter that affects the user experience and ensures the proper dispensing of the formulation. The extrudability of the *Justicia gendarussa* emulgel was evaluated by applying gentle pressure to the container and observing the ease of flow. An ideal emulgel should have smooth and consistent extrusion without excessive force, indicating good formulation stability and appropriate viscosity. Proper extrudability ensures convenient application and enhances patient compliance.

## 6. Skin irritation test:

The skin irritation test was conducted to evaluate the safety and dermal compatibility of the *Justicia gendarussa* emulgel. A small quantity of the formulation was applied to a specific area of the skin and observed for any signs of irritation, such as redness, itching, swelling, or rashes, over a defined period. The absence of adverse reactions indicates that the emulgel is well-tolerated and safe for tocal use. This test is essential to ensure that the formulation does not cause discomfort or allergic reactions, making it suitable for regular application.

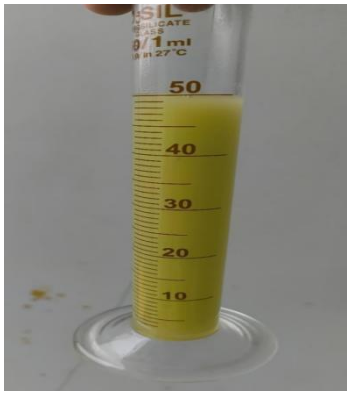




## 7. Sedimentation Test

The sedimentation test was performed to assess the physical stability of the Justicia gendarussa emulgel. An ideal emulgel should remain in a dispersed phase without any phase separation or settling of solid particles over time. The formulation was observed under standard storage conditions to check for any signs of sedimentation. The absence of visible settling or phase separation indicates good stability, ensuring uniformity and consistency throughout its shelf life. This test confirms that the emulgel maintains its homogeneity, preventing the need for shaking or re-dispersion before use.


Before

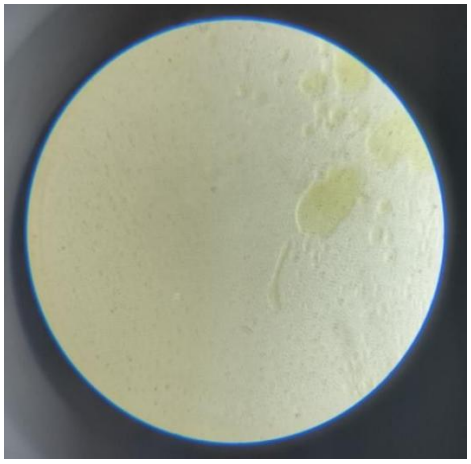


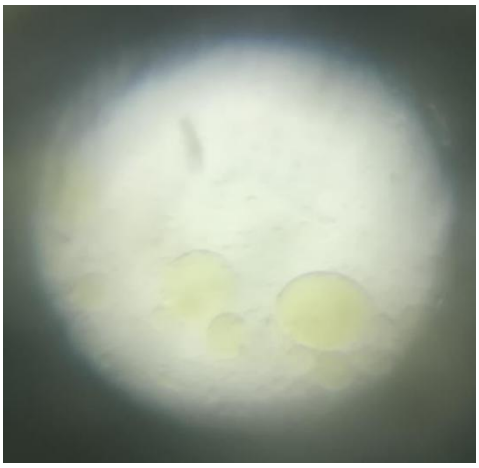

After

## 8. Microscopical Test

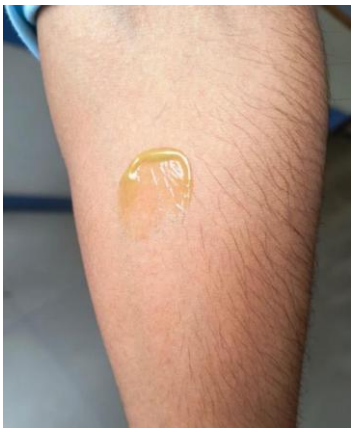
The microscopical test was conducted to examine the structural characteristics of the Justicia gendarussa emulgel. Under the microscope, oil globules were observed to be uniformly dispersed and entrapped within the gel matrix, confirming the successful formation of an emulsion-based gel system. The presence of well-distributed oil globules indicates the proper incorporation of the emulsion within the gel phase, contributing

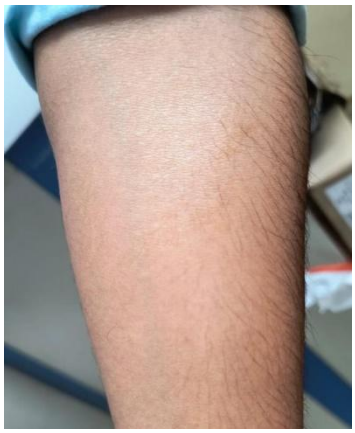
to the stability and efficacy of the formulation. This test further validates the uniformity and homogeneity of the emulgel, ensuring consistent drug delivery upon application.





### 9. Skin Permeability Test





The skin permeability test is conducted to evaluate the ability of the Justicia gendarussa emulgel to penetrate the skin and deliver its active ingredients. This test involves applying a measured amount of emulgel onto the surface of a synthetic or animal skin model under controlled conditions. The emulgel is typically placed on one side of the skin barrier, and the passage of active ingredients is monitored on the opposite side, either by collecting the permeated material or by using analytical methods such as spectroscopy. The rate and extent of permeability help to determine the emulgel's effectiveness in delivering its therapeutic agents through the skin, which is critical for its intended pharmacological action. This test also ensures that the formulation is safe, without excessive permeation, which could lead to unwanted systemic absorption.

## Discussion:

Emulgel of a polyherbal RVMP mixture for treating Rheumatoid Arthritis were successfully prepared using various concentrations of Carbopol 934, Carbopol 940, HPMC, and Na CMC. The formulations were all pale to light yellow, with a smooth, homogeneous texture and a glossy appearance. 13 All prepared formulations had pH values ranging from 6.5 to 7.1, indicating that they could be used on adult skin with a lower risk of skin irritation.14 Spreadability is the degree to which the gel can spread at the application site, and it is an essential parameter in determining the gel's efficacy because the spreadability of the emulgel formulation is dependent upon the viscosity of the formulation and the physical properties of the gelling agent.16 The emulgel containing 1 percent carbopol 934 and 940 had the best spreadability. 6 The rheological behaviour

of the emulgel indicated that they followed the shearthinning effect with thixotropic properties. The viscosity of the formulation increased with an increase in the gelling agent.21 In vitro drug release of the optimized emulgel formulation (G6) showed control release for 8 hours with maximum drug release of 91.85%. In vitro antiarthritic activity of the polyherbal RVMP mixture showed dose dependent inhibition of the protein denaturation as a result of the antioxidant potential of the polyherbal mixture to reduce inflammatory response due to free radical.

## Conclusion:

Emulgel is used as the recent technique among the topical drug delivery systems. It is mainly used for the delivery of both hydrophobic and hydrophilic drug. Emulgel technique contains both oil and aqueous (i.e. gel base) base so it can be used for hydrophobic drugs. Since emulgel shows enhanced spreadability, adhesion, viscosity and extrusion. This novel drug delivery becomes a popular formulation.

## Future Prospectives:

As compared to other topical delivery systems, gel provides an aqueous environment to the drug and favours its dissolution and provides quicker release of drug. All such advantages of emulgel over other topical delivery systems make them more superior in drug delivery. In future, these properties will be used to formulate more number of topical drugs in the form of emulgel.

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