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# Development and Characterization of Zaltoprofen Solid Dispersion for Enhanced Solubility and Dissolution

**Meet K. Detroja[1], Yash N. Patel[2], Suraj R. Chauhan[3], Krishna D. Taretiya[4], Bhumi A. Raval[5], Jitendra O. Bhangale[6]**

[1-2]Student, Smt. N. M. Padalia Pharmacy College, Navapura, Ahmedabad, Gujarat, India 382210
[3]Associate Professor, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India
[4]Assistant Professor, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India
[5]Professor, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India
[6]Professor and Principal, Smt. N. M. Padalia Pharmacy College, Ahmedabad, Gujarat, 382210, India
*Corresponding Author E-mail: **jitu2586@gmail.com**

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*Solid Dispersion, Zaltoprofen, Solubility enhancement.*

**ABSTRACT:**
Zaltoprofen, a non-steroidal anti-inflammatory drug widely prescribed for the management of pain and inflammation, belongs to Biopharmaceutical Classification System (BCS) class II and exhibits poor aqueous solubility, leading to dissolution rate-limited absorption and variable oral bioavailability. The present investigation aimed to enhance the solubility and dissolution profile of Zaltoprofen through the development of a polymeric solid dispersion system using Soluplus as a hydrophilic carrier at varying drug-to-polymer ratios and methanol concentration and systematically evaluate the influence of formulation variables on various physicochemical parameters. Based on the results, the formulation ZS9 containing Zaltoprofen:Soluplus (1:4) ration and 100 ml of methanol was found to be optimized batch which showed maximum solubility of 0.36 mg/ml and % CDR of 99.27 ± 0.179 % at 12 mins among all other batches. The results of stability study of the batch ZS9 also showed that there was no significant change in Flow Properties, solubility and % CDR when stored for period of one month. From the study it was concluded that Solid Dispersion of Zaltoprofen can be successfully prepared using solvent evaporation method with enhanced solubility and hence it can be further used for the preparation of any other formulation.

## INTRODUCTION:

Pain is a disorder that everyone experiences and is often difficult to treat. An analgesic, or painkiller, is any member of the group of drugs used to achieve analgesia-relief from pain. Current drug treatment options for management of pain include opioids, nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs are limited by ceiling effect and are appropriate for relief of mild to moderate pain. NSAIDs are contraindicated in patients with acid peptic disease, renal impairment, and bleeding tendency. NSAIDs such as the salicylates, and opioid drugs such as morphine and opium. Analgesics currently represent the mainstay of pain management with an array of drugs, which are non-opiates that relieve pain without depressing the CNS. Several analgesics, unrelated to the opiates have in addition to analgesic effects anti-inflammatory and antipyretic properties. Pain consists of both sensory and affective (emotional) components.[1,2]

Solid dispersions represent a key formulation strategy in pharmaceutical sciences to overcome the challenges posed by poorly water-soluble drugs, which constitute over 40% of new chemical entities and often exhibit limited bioavailability. These systems involve the molecular-level dispersion of a hydrophobic active pharmaceutical ingredient within a hydrophilic carrier matrix, transforming the drug into a high-energy amorphous state that

enhances wettability, surface area, and dissolution kinetics upon aqueous exposure. By disrupting drug crystallinity and facilitating rapid carrier dissolution, solid dispersions improve drug release profiles, stability, and therapeutic efficacy, making them vital for developing oral dosage forms compliant with biopharmaceutical classification system (BCS) class II and IV compounds.[3,4]

## MATERIALS AND METHOD:

### Materials

Zaltoprofen was supplied by Intas Pharmaceuticals, Ahmedabad, Gujarat, India. Soluplus and Methanol were provided by Chemdyes Corporation, Ahmedabad.

### Method

Zaltoprofen solid dispersions were prepared by the solvent evaporation method using Soluplus® as the hydrophilic carrier and methanol as the solvent. Nine formulations (ZS1–ZS9) were developed according to varying the drug-to-polymer ratio and solvent volume. The drug:Soluplus ratios employed were 1:3, 1:3.5, and 1:4, while methanol volumes of 50 mL, 75 mL, and 100 mL were used. For each batch, accurately weighed quantities of Zaltoprofen and Soluplus were taken as per the specified ratio. Soluplus was first dissolved in the required volume of methanol under continuous magnetic stirring, followed by gradual addition of Zaltoprofen to obtain a clear and homogeneous solution. The solution was transferred to a glass dish and the solvent was allowed to evaporate at room temperature. The resulting solid mass was further dried to constant weight, pulverized, passed through a suitable sieve, and stored in a desiccator until further evaluation.[5,6] (Table 1)

**Table 1: Composition of Various Solid Dispersions of Zaltoprofen**

| Formulation Code | Zaltoprofen: Soluplus (gm) | Methanol (ml) |
|---|---|---|
| **ZS1** | 1: 3 | 50 |
| **ZS2** | 1: 3.5 | 50 |
| **ZS3** | 1: 4 | 50 |
| **ZS4** | 1: 3 | 75 |
| **ZS5** | 1: 3.5 | 75 |
| **ZS6** | 1: 4 | 75 |
| **ZS7** | 1: 3 | 100 |
| **ZS8** | 1: 3.5 | 100 |
| **ZS9** | 1: 4 | 100 |

## EVALUATION OF FORMULATED BATCHES

### Determination of Preformulation parameters

**Determination of melting point of Zaltoprofen:** Melting point of Zaltoprofen was measured by capillary apparatus.[7]

**Estimation of Zaltoprofen by UV-Visible Spectrophotometry:** A UV–Visible spectrophotometric method was employed for the quantitative estimation of Zaltoprofen in aqueous medium. The overlay spectra of drug were obtained by scanning different concentrations of solutions viz., 3, 6, 9, 12 and 15 ppm showed maximum absorption at 338 nm. A standard stock solution (100 µg/mL) was prepared by accurately dissolving 10 mg of Zaltoprofen in 100 mL of distilled water. The solution was appropriately sonicated to ensure complete dissolution. For determination of the maximum absorption wavelength (λmax), the prepared stock solution was scanned over the range of 200–400 nm using distilled water as blank. The wavelength corresponding to maximum absorbance was selected for subsequent analytical measurements and calibration studies.[8,9]

**Determination of Zaltoprofen by FTIR**: FTIR spectroscopy was used for drug and excipients identification and to evaluate their compatibility and FTIR spectroscopy of pure drug and physical mixture of drug and excipients was carried out to check the compatibility of drug and excipients.

**Determination of Preformulation parameters:** Preformulation characteristics including bulk density, tapped density, Hausner's ratio, Carr's compressibility index, and angle of repose were evaluated to assess the flow properties of the powder blend.[10]

**Determination of post formulation parameters**

**Determination of solubility:** The solubility of pure Zaltoprofen and its solid dispersions was evaluated using the shake flask method. An excess amount of sample was mixed with distilled water and shaken at 37 ± 0.5°C for 24 h. The obtained solutions were filtered using a 0.45 µm membrane filter, appropriately diluted, and measured using the spectrophotometric method at the predetermined $\lambda_{max}$. Solubility was determined using the calibration curve and expressed in mg/ml. All experiments were performed in triplicate, and values were reported as mean ± standard deviation.[11,12]

**% Drug Content**: The drug content of the prepared solid dispersions was analyzed by precisely weighing a sample of the formulation equivalent to 10 mg of Zaltoprofen and transferring it to a volumetric flask filled with an appropriate amount of methanol. The contents were sonicated to ensure complete dissolution of the drug, and the volume was adjusted with the same solvent. The prepared solution was filtered using a 0.45 µm membrane filter, appropriately diluted with distilled water or methanol as needed, and analyzed spectrophotometrically at the predetermined $\lambda_{max}$. The drug content was measured using the calibration curve, and the values were expressed as percentage drug content. All measurements were done in triplicate and represented as mean ± standard deviation.[13-15]

**% Cumulative Drug Release Studies:** Dissolution studies of solubility enhanced dispersions were determined by USP type II (paddle type) dissolution apparatus. This test was performed using 500 ml of water at 37 ± 0.5 °C at 50 rpm which was maintained throughout the experiment. 5 ml samples were withdrawn at 5 min time interval and the same quantity of sample was replaced with fresh dissolution media. The sample was filtered through 0.45 µm membrane filter. Absorbance of these samples was analyzed by using UV spectrophotometer at 338 nm.[16,17]

**Stability study of optimized batch:** In the present study, stability study of optimized batch was carried out at 40° ± 2°C/ 75 ± 5% RH for time period of 1 month by wrapping the formulation in aluminum foil to prevent the formulation from exposure to light under the 40° ± 2 °C/ 75 ± 5% RH for 1 month as prescribed by ICH guidelines for accelerated stability study.[18]

## RESULTS AND DISCUSSION:

**Preformulation parameters**

**Melting point of Zaltoprofen:** Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Zaltoprofen was found in the range of 135 – 141 °C, whereas the reported Melting Point of Zaltoprofen is 137.69°C[19]. This indicates that the observed melting point is in the range of reported melting point and thus it was concluded that the given drug is Zaltoprofen.

**Identification of drug by FTIR:** The FTIR of Zaltoprofen shows band corresponding to the functional groups present in the structure of Zaltoprofen. From the above interpretation it is found that major functional groups were present in the reported structure of Zaltoprofen. So it was identified that used API was Zaltoprofen.[19](Figure 1).

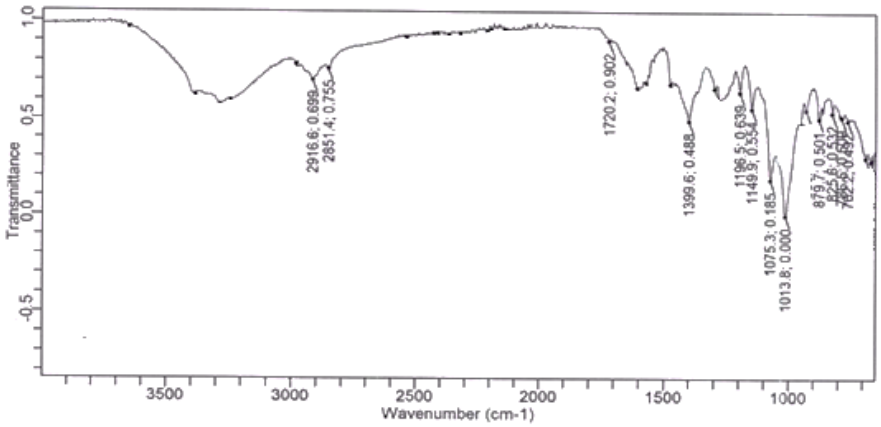


**Figure 1: FTIR of Zaltoprofen**

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**Identification of drug by UV Spectroscopy Method:** The overlay spectra of drug were obtained by scanning different concentrations of solutions viz., 3, 6, 9, 12 and 15 ppm showed maximum absorption at 338 nm. Reported $\lambda_{max}$ of Zaltoprofen is 338 nm. So, it can be concluded that the given drug was Zaltoprofen [8,9] (Table 2 and Figure 2).

**Table 2: Absorbance of different concentration of Zaltoprofen in Water**

| Sr. No. | Concentration (ppm) | Absorbance | | | Mean Absorbance ± S. D. |
|---|---|---|---|---|---|
| | | I | II | III | |
| **1.** | 3 | 0.083 | 0.084 | 0.082 | 0.083 ± 0.001 |
| **2.** | 6 | 0.162 | 0.162 | 0.159 | 0.161 ± 0.001 |
| **3.** | 9 | 0.215 | 0.214 | 0.219 | 0.216 ± 0.002 |
| **4.** | 12 | 0.289 | 0.285 | 0.286 | 0.286 ± 0.002 |
| **5.** | 15 | 0.372 | 0.379 | 0.376 | 0.375 ± 0.003 |

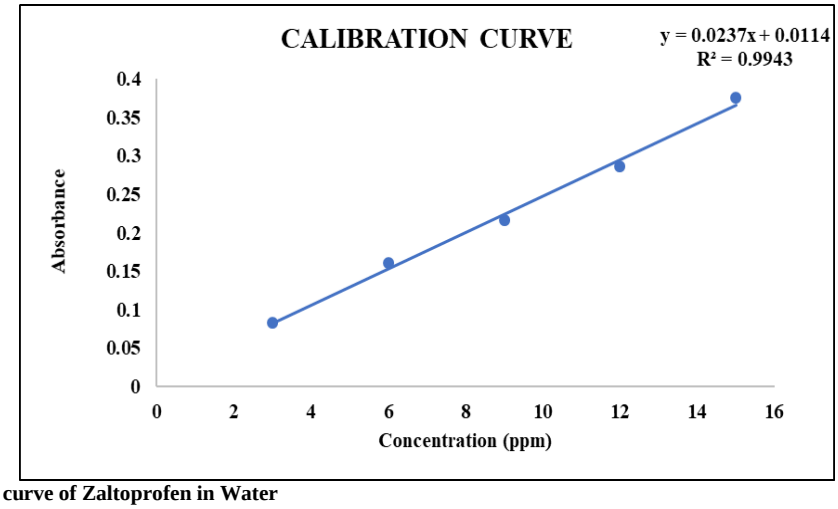


**Figure 2: Calibration curve of Zaltoprofen in Water**

**Post formulation Parameters:**

**Evaluation of Flow Properties of Zaltoprofen Solid Dispersions:** The powder blend's bulk density, Tapped density, Hausner's ratio, Carr's index, and angle of repose were measured and it was discovered that every parameter demonstrated acceptable flow characteristics. The tapped density ranged from 0.64 ± 0.026 to 0.73 ± 0.050 gm/ml, while the bulk density was found to be between 0.62 ± 0.005 and 0.70 ± 0.005 gm/ml. Carr's compressibility index was computed using the two data points mentioned above. The range of the compressibility index was 14.51 ± 0.026 to 18.57 ± 0.026 percent. Data on compressibility and flow ability showed that all powder mixes had adequate flow characteristics. Angle of repose also demonstrated the superior flow characteristics of all powder blends. The angle of repose was range of 26.44 ± 0.211 to 29.74 ± 0.216 so it indicated good flow property. (Table 3)

**Table 3: Evaluation of Flow and Packing Properties of Zaltoprofen Solid Dispersions**

| Batch | Bulk Density (gm/ml) ± S. D. | Tapped Density (gm/ml) ± S. D. | Carr's Index (%) ± S. D. | Hausner's Ratio (%) ± S. D. | Angle of Repose (°Θ) ± S. D. | Void Volume± S. D. | % Porosity± S. D. |
|---|---|---|---|---|---|---|---|
| **ZS1** | 0.66±0.002 | 0.71±0.065 | 15.15±0.045 | 1.22±0.026 | 27.75±0.482 | 0.56±0.005 | 18.30±0.754 |
| **ZS2** | 0.70±0.005 | 0.71±0.062 | 18.57±0.026 | 1.24±0.026 | 28.07±0.252 | 0.57±0.004 | 19.71±0.710 |
| **ZS3** | 0.68±0.005 | 0.64±0.026 | 14.70±0.010 | 1.23±0.030 | 27.14±0.150 | 0.58±0.004 | 18.75±0.250 |
| **ZS4** | 0.68±0.004 | 0.69±0.036 | 16.17±0.030 | 1.27±0.010 | 28.39±0.253 | 0.57±0.001 | 21.73±0.252 |
| **ZS5** | 0.63±0.005 | 0.71±0.045 | 15.87±0.020 | 1.24±0.020 | 28.72±0.192 | 0.53±0.010 | 19.71±0.300 |
| **ZS6** | 0.66±0.002 | 0.73±0.030 | 18.18±0.040 | 1.30±0.010 | 29.74±0.216 | 0.54±0.010 | 23.28±0.330 |
| **ZS7** | 0.65±0.002 | 0.73±0.050 | 16.92±0.030 | 1.30±0.020 | 26.44±0.211 | 0.54±0.004 | 23.28±0.330 |
| **ZS8** | 0.62±0.005 | 0.71±0.052 | 14.51±0.026 | 1.18±0.020 | 28.19±0.285 | 0.53±0.005 | 15.49±0.253 |
| **ZS9** | 0.66±0.002 | 0.69±0.052 | 15.15±0.045 | 1.21±0.020 | 28.07±0.252 | 0.56±0.005 | 17.39±0.356 |

**Solubility:** The solubility data reveal a significant difference among the prepared solid dispersion samples. Among all the samples, ZS9 showed the highest solubility (0.36 ± 0.035 mg/mL), followed by ZS5 (0.13 ± 0.028 mg/mL),

indicating a substantial improvement compared to other samples. Moderate solubility enhancement was found in ZS2 (0.12 ± 0.028 mg/mL) and ZS6 (0.29 ± 0.020 mg/mL), while the least solubility was found in ZS7 (0.14 ± 0.028 mg/mL). The results clearly show that the ratio of drug to polymer and solvent concentration significantly affected the solubility enhancement, and higher polymer concentration led to increased aqueous solubility of Zaltoprofen. Data are showed in table 4.

**Drug content:** Drug content of the solid dispersion ZS1 to ZS9 was found to be in the range of 96.36 % to 99.63 %. (Table 4)

**Table 4: Solubility and Drug Content of Zaltoprofen Solid Dispersion Batches**

| Batch | Solubility (mg/ml) ± S. D. | Drug Content (%) ± S. D. |
|---|---|---|
| **ZS1** | 0.07 ± 0.016 | 96.36 ± 0.623 |
| **ZS2** | 0.12 ± 0.028 | 97.28 ± 0.720 |
| **ZS3** | 0.23 ± 0.021 | 98.93 ± 0.769 |
| **ZS4** | 0.09 ± 0.016 | 99.61 ± 0.751 |
| **ZS5** | 0.13 ± 0.028 | 98.26 ± 0.433 |
| **ZS6** | 0.29 ± 0.020 | 97.28 ± 0.761 |
| **ZS7** | 0.14 ± 0.028 | 99.25 ± 0.784 |
| **ZS8** | 0.21 ± 0.031 | 98.17 ± 0.430 |
| **ZS9** | 0.36 ± 0.035 | 99.63 ± 0.789 |

**% Cumulative Drug Release study**: % CDR study was performed using dissolution test apparatus type II (paddle) in 500 ml of water as a dissolution medium at 37 ± 0.5 °C at 50 rpm. From the results it was found that more than 50% of drug was released in less than 6 mins. *In-vitro* drug release study stated that more than 50% of the drug was released within 09 minutes for all formulations. Formulations ZS1–ZS9 showed 3 min drug release ranging from 32.56 ± 0.040 % to 71.53 ± 0.299 % and achieved over 92% release within 15–18 minutes. From the data of % CDR it was found that as the amount of Soluplus and methanol increased the drug release profile also increased as showed in figure 3.

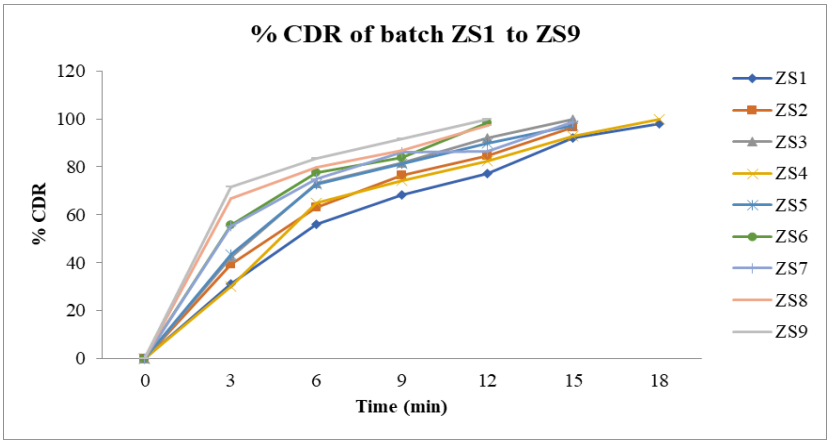


**Figure 3: Cumulative Drug Release of Batches ZS1 to ZS9**

**Stability studies:** Based on the evaluation of all batches, formulation ZS9 was identified as the optimized batch. This formulation exhibited satisfactory flow characteristics along with superior solubility compared to the pure drug. Notably, ZS9 achieved 99.27% drug release within 12 minutes and demonstrated a solubility of 0.36 mg/mL, which was the highest among all developed formulations. To assess formulation stability, the optimized batch was subjected to accelerated stability conditions (40 ± 2°C and 75 ± 5% RH) for one month. After the storage period, flow properties, solubility, and percentage cumulative drug release were re-evaluated. The findings, summarized in table 5 and 6 and illustrated in figure 4, indicated that the optimized formulation maintained its performance characteristics under the tested conditions.

**Table 5: Result of the Stability Study**

| Evaluation parameter | | Results of optimized batch | Result after 1 month at 40 ± 2°C and 75 ± 5 % RH |
|---|---|---|---|
| Flow Properties | Carr's Index (%) | 17.38 ± 0.118 | 19.82 ± 0.285 |
| | Hausner's Ratio (%) | 1.21 ± 0.010 | 1.24 ± 0.010 |
| | Angle of Repose (°Θ) | 25.62 ± 0.190 | 27.75 ± 0.308 |
| Amount of Drug Soluble (mg/ml) | | 0.36 ± 0.010 | 0.36 ± 0.006 |
| Drug Content (%) | | 99.63 ± 0.130 | 98.74 ± 0.207 |

**Table 6: Cumulative Drug Release Study of Stability Batch**

| Time (Min.) | % CDR of Optimized Batch Initially (%) | % CDR of batch After Time Period of 1 Month (%) |
|---|---|---|
| 0 | 0 | 0 |
| 3 | 71.53 ± 0.336 | 65.39 ± 0.442 |
| 6 | 82.46 ± 0.331 | 80.19 ± 0.311 |
| 9 | 91.77 ± 0.307 | 87.25 ± 0.344 |
| 12 | 99.27 ± 0.260 | 97.62 ± 0.375 |

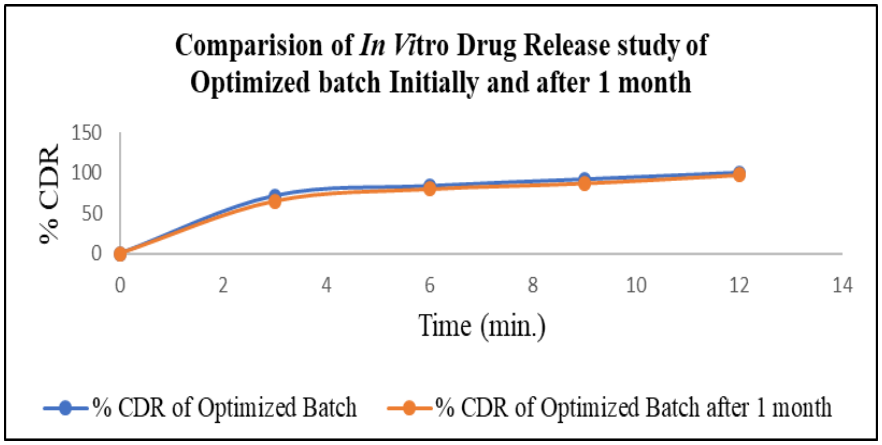


**Figure 4: Comparison of % Cumulative Drug Release study of Optimized batch initially and after 1 month**

## CONCLUSION:

Zaltoprofen, a BCS Class II drug with poor water solubility, was formulated as a solid dispersion using the solvent evaporation method to enhance its solubility. The optimized formulation (ZS9) exhibited maximum solubility (0.36 ± 0.035 mg/ml) and % cumulative drug release (99.27) within 12 minutes. Stability studies confirmed the formulation's robustness, indicating that solid dispersion is an effective approach for improving Zaltoprofen solubility. The improved performance can be attributed to enhanced drug dispersion within the hydrophilic polymer matrix, resulting in increased wettability and probable reduction in crystallinity. In addition, ZS9 exhibited satisfactory flow properties and maintained its solubility and dissolution profile after one month of accelerated stability testing, confirming its formulation robustness. Collectively, these findings justify the selection of ZS9 as the optimized batch.

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## CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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