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Research Article

Formulation and Evaluation of Pulsatile-Release Multiple-Unit Pellets of Meloxicam

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Abstract



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The present research aimed to design, formulate, and evaluate pulsatile-release multiple-unit pellets of Meloxicam. In the pellet coating and evaluation, five formulations (F1 to F5) were prepared with varying ratios of Eudragit L100 and Ethyl Cellulose. All batches exhibited excellent flow properties with Carr's index values below 15% and Hausner's ratio close to 1.12–1.14. The angle of repose for all batches was $<30^\circ$, suggesting free-flowing properties essential for uniform capsule filling. Friability remained well below 1% across all formulations, indicating strong mechanical stability of the coated pellets. Drug content ranged from 97.1% to 99.4%, with formulation F4 showing the highest drug content ($99.4 \pm 1.2\%$). All formulations showed negligible release for the first 2 hours in acidic medium, confirming the integrity of the enteric coating. Formulation F1, containing only Eudragit L100, exhibited the shortest lag time with burst release starting at 3 hours and complete release by 8 hours. Formulation F4 (1.5 g Eudragit L100 : 3 g EC) demonstrated a well-defined lag time of ~ 5 hours followed by a sharp and complete drug release ($\sim 96.8 \pm 2.3\%$ at 8 hours), making it the optimized formulation for pulsatile drug delivery. A stability study of the optimized batch F4 under accelerated conditions ($40^\circ\text{C}/75\% \text{RH}$) for three months showed minimal changes in drug release (from 96.8% to 95.3%) and drug content (from 99.4% to 98.2%).

Keywords: Meloxicam, Pulsatile, Multiple unit Pellets, Eudragit L100.

INTRODUCTION

Pulsatile drug delivery is defined as the rapid and transient release of certain amount of molecules within a short time period immediately after a predetermined off-release period, i.e., lag time, or these systems have a peculiar mechanism of delivering the drug rapidly and completely after a lag time, i.e., a period of no drug release. Such a release pattern is known as pulsatile release. Pulsatile systems are designed in a manner that the drug is available at the site of action at the right time in the right amount. These systems are designed according to the circadian rhythm or biological clock of the body.¹

Pulsatile pellets consist of small, spherical, multiparticulate units that can be coated with polymers or formulated with specific excipients to delay drug release until a desired time has elapsed after administration. The lag time can be tailored by manipulating the thickness and composition of the coating materials—typically using pH-sensitive, time-dependent, or enzyme-degradable polymers. Once the lag period is over, the pellet core rapidly releases the drug in a burst manner. This system is particularly

beneficial for drugs used in conditions such as rheumatoid arthritis, asthma, cardiovascular diseases, and gastric ulcers, which show peak symptom intensity at specific times of the day. The multiparticulate nature of pellets offers several advantages over single-unit systems, including uniform distribution in the gastrointestinal tract, reduced risk of dose dumping, and improved patient compliance. Moreover, pulsatile pellets can be filled into capsules or compressed into tablets, offering versatility in dosage form design. Their ability to provide site-specific and time-controlled drug release makes them an ideal choice for targeting²

Diseases with time-dependent pathophysiology, ultimately improving therapeutic efficacy.

Meloxicam selectively inhibits the enzyme cyclooxygenase-2 (COX-2), which is responsible for the synthesis of prostaglandins involved in inflammation and pain. It has a lower affinity for COX-1, thus reducing gastrointestinal side effects compared to non-selective NSAIDs.³

MATERIALS AND METHODS

Materials

Meloxicam was obtained as kind gift sample from Cipla Ltd. Mumbai, Eudragit L100 was purchased from S.D. Fine Chem. Ltd & Ethyl Cellulose was purchased from Colorcon Asia Pvt Ltd. All other chemicals and solvent are analytical grade.

Methods

Drug Excipients Compatibility Studies

Drug-excipient compatibility studies are an essential part of pre-formulation and formulation development processes in the pharmaceutical industry. These studies assess the compatibility of a drug substance with various excipients that are used to formulate the final dosage form. The primary purpose of drug-excipient compatibility studies is to evaluate potential interactions between the drug substance and excipients. These studies aim to identify any chemical, physical, or mechanical interactions that could affect the stability, efficacy, or safety of the final dosage form. By assessing compatibility early in the development process, formulation scientists can make informed decisions regarding excipient selection, formulation design, and process optimization. Compatibility study of drug with the excipients was determined by I.R. Spectroscopy (Shimadzu, Japan). The pellets were prepared at high compaction pressure by using KBr and the ratio of

sample to KBr is 1:100. The pellets thus prepared were examined and the spectra of the drug and other ingredients in the formulations were compared with that of the pure drug.⁴

Preparation of Core Drug Loaded Pellets of Meloxicam

Drug loaded pellets was prepared by solution layering technique. (15 mg meloxicam/dose in 0 Size capsule). To begin the formulation, accurately weighed 44.4 g of non-pareil seeds (0.6–0.8 mm) were taken as inert cores for all batches. Separately, 1.67 g of Meloxicam and 2 g of PVP K30 were dissolved in a sufficient quantity of isopropyl alcohol (IPA) to prepare a clear drug-binding solution. The non-pareil seeds were transferred into a coating pan (25 rpm), and the drug solution was sprayed onto them in a controlled manner (1 ml/min). Spraying was carried out intermittently, allowing partial drying between each spray cycle to prevent pellet aggregation. The inlet air temperature was maintained at 45°C. This layering process continued until the entire drug solution was applied evenly. After the final spray, the drug-loaded pellets were subjected to drying in a tray dryer until a dry and free-flowing product was obtained. The pellets were then passed through a sieve #20 to remove any clumps and ensure uniform particle size distribution.^{5,6}

Table 1: Composition of Drug Loaded Pellets (50g Batch Size)

Ingredients	F1	F2	F3	F4	F5	Function
Meloxicam	1.67 g	1.67 g	1.67 g	1.67 g	1.67 g	Active pharmaceutical ingredient
Non-pareil seeds	44.4 g	44.4 g	44.4 g	44.4 g	44.4 g	Inert core
PVP K30	2.00 g	2.00 g	2.00 g	2.00 g	2.00 g	Binder
Isopropyl Alcohol (IPA)	q.s.	q.s.	q.s.	q.s.	q.s.	Binder solvent

Formulations of coated Pellets

The coating of Meloxicam drug-loaded pellets was carried out using the pan coating technique to apply a

pulsatile-release polymeric layer. Each formulation (F1 to F5) was prepared with a total of 5 g of coating material for 10% weight gain over 50 g of drug-loaded pellets.

Table 2: Formulation of Coated Pellets

Formulation	Eudragit L100 (g)	Ethyl Cellulose (g)	Total Polymer (g)	Dibutyl Phthalate (2%) (g)	Talc (g)	Total Coating Solid (g)
F1	4.50	0.00	4.50	0.09	0.41	5
F2	0.00	4.50	4.50	0.09	0.41	5
F3	2.25	2.25	4.50	0.09	0.41	5
F4	1.50	3.00	4.50	0.09	0.41	5
F5	3.00	1.50	4.50	0.09	0.41	5

Initially, the required quantities of Eudragit L100 and Ethyl Cellulose (10 cps) were accurately weighed based on the specific formulation ratios (Table 6.4). These polymers were gradually dispersed in a mixture of isopropyl alcohol and water (60:40 v/v) under continuous stirring to form a uniform polymer solution. To this solution, Dibutyl Phthalate (2% of total polymer weight) was added as a plasticizer to enhance the flexibility and adhesion of the coating film. Talc (0.41 g) was then incorporated as an anti-adherent to prevent sticking of pellets during coating.⁷

The drug-loaded pellets (50 g) were placed into a rotating stainless steel coating pan (25 rpm), pre-warmed to around 35–40°C. The prepared coating solution was sprayed onto the pellets using a spray gun at the rate of 1 ml/min. The inlet air temperature were carefully controlled at 40–45°C to achieve uniform coating without over wetting or clumping. The coating was applied in thin, successive layers, allowing sufficient drying time between each pass to ensure solvent evaporation and film buildup. The process was continued until the pellets achieved a 10% weight gain, corresponding to complete deposition of 5 g of coating solids. After completion of coating, the pellets were allowed to dry in a tray dryer at 40°C for 1 hour to ensure complete solvent removal and curing of the polymer layer. The coated pellets were then stored in airtight containers and subjected to further evaluation.^{8,9}

Evaluation of pellets

Friability

Friability of pellets was determined by subjecting 10 g of pellets in (Roche friabilator) at 4 min at 25 rpm. The abraded samples were sieved and the pellets retained on the sieve were weighed and percent friability was calculated from the difference in the weight of the pellets before and after friability.¹⁰

Flow Properties

The flow properties of polymer coated pellets were studied by determining its Carr compressibility index and Hausner ratio. The data of the tapped density and bulk densities were utilized for the determination of flow properties of the coated pellets.¹¹

Drug Content

Required weight of drug loaded pellets containing equivalent weight of 15 mg of meloxicam were taken and crush to powdered. The powder was then transferred in to 100 ml volumetric flask and dissolved in 100 ml of methanol. The solution was shaken and then filtered. After appropriate dilution the drug content was measured using a UV spectrophotometer by taking absorbance of sample at 362 nm.¹²

Particle Size and Size Distribution

Particle size is a critical parameter in pellet formulation

as it influences flowability, uniformity, drug release, and packing. The particle size and size distribution of pellets can be determined using sieve analysis, where dried pellets are passed through a series of standard sieves. (Labline India) The weight retained on each sieve is measured, and the distribution is calculated. Uniform particle size is desirable to ensure consistent drug content and reproducible dissolution profiles.^{13,14}

In Vitro Drug Release Study

The in vitro dissolution study of the Meloxicam pulsatile-release pellet formulations (F1 to F5) was performed using a USP Type I (Basket) apparatus to assess the drug release profile over 8 hours. Each formulation, equivalent to 15 mg of Meloxicam, was placed in size '0' hard gelatin capsules. The study was conducted in two sequential phases to mimic physiological pH changes in the GI tract.

Initially, the capsules were subjected to 900 mL of 0.1 N HCl (pH 1.2) maintained at $37 \pm 0.5^\circ\text{C}$ and stirred at 100 rpm for 2 hours to simulate gastric conditions. After 2 hours, the dissolution medium was replaced with 900 mL of phosphate buffer (pH 6.8) to simulate intestinal fluid conditions for the remaining 6 hours. Samples of 5 mL were withdrawn at predetermined time intervals (0, 1, 2, 3, 4, 5, 6, 7, and 8 hours) and replaced with an equal volume of fresh medium to maintain sink conditions. The withdrawn samples were filtered through Whatman filter paper No. 41, and the drug concentration was determined spectrophotometrically at λ_{max} 362 nm using UV-Visible spectrophotometer. The cumulative percentage of drug release was calculated and plotted against time to evaluate the release pattern. Each formulation was tested in triplicate ($n=3$), and results were reported as mean \pm standard deviation.¹⁵⁻¹⁷

Stability Study

The accelerated stability studies were carried out according to ICH guidelines on optimized formulation. The formulation was packed in strip of aluminum foil and was stored in stability chamber maintained at 40°C and 75% RH for the period of 3 months. The beads formulation was evaluated before and after 3 months for change in floating behaviours, drug content and in -vitro drug release.^{18,19}

RESULTS AND DISCUSSION

Compatibility Studies (FT-IR)

Both the polymer and pure drug's infrared spectra are examined. It has been found in this investigation that there is no chemical interaction between the polymer and Meloxicam. The major peak in the drug and polymer mixture's infrared spectra was found to remain unchanged, indicating that there was no physical interaction due to bond formation between the two substances.

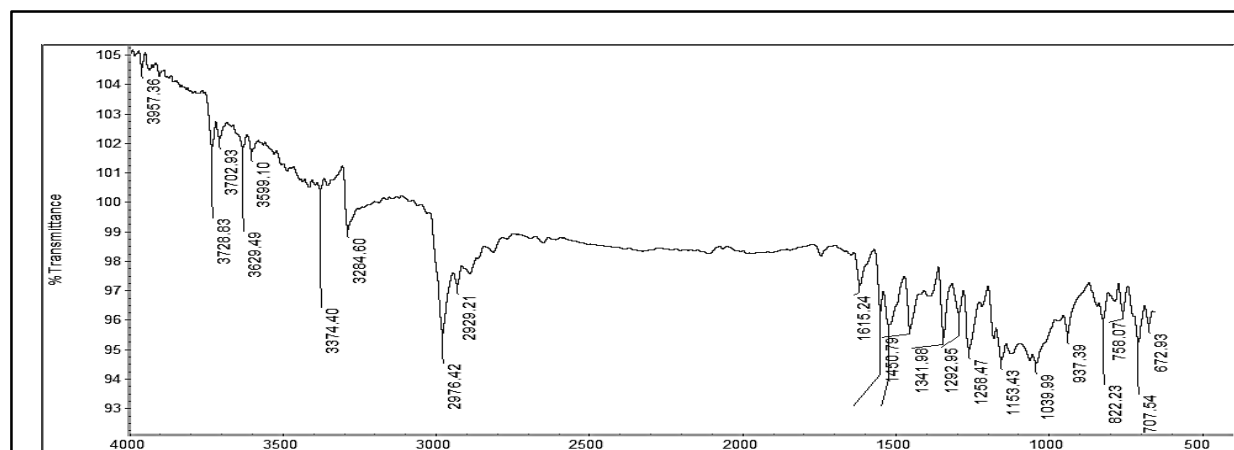


Figure 1: IR Spectra of Pure Drug Meloxicam

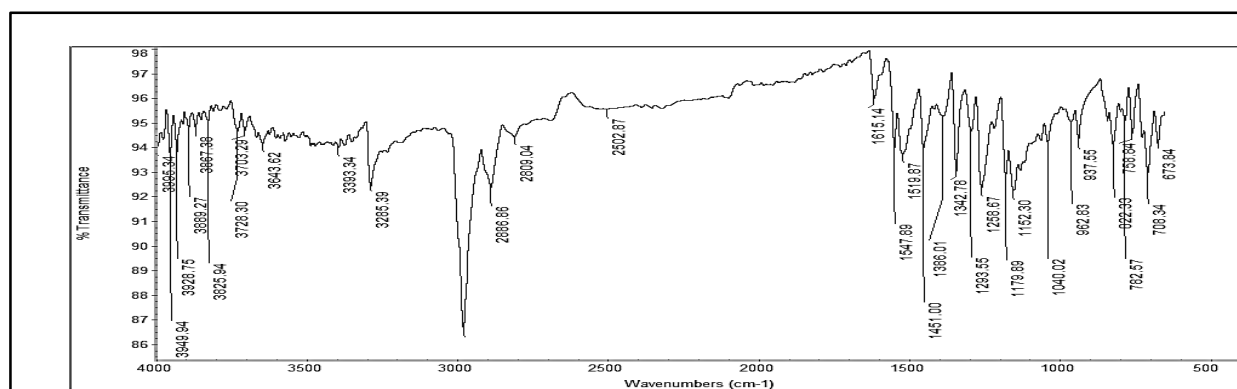


Figure 2: IR Spectra of Meloxicam Physical Mixture

Friability

Friability testing showed that all batches had excellent mechanical strength, with values below 1%. The lowest friability was observed in F4 ($0.42 \pm 0.05\%$), suggesting superior film strength and integrity, while F1 had slightly higher friability ($0.58 \pm 0.05\%$), possibly due to the exclusive use of Eudragit L100, which may produce a relatively brittle film compared to blends with ethyl cellulose. Still, all formulations displayed sufficient robustness to withstand handling and processing. The results are shown in table 3

Flow Properties

Flow properties of pellets were evaluated through Carr's Index, Hausner's Ratio, and Angle of Repose. Carr's Index ranged from $10.4 \pm 0.6\%$ (F1) to $12.3 \pm 0.5\%$ (F2). Values below 15% are indicative of excellent to good flow, suitable for capsule filling processes. Hausner's Ratio was within the range of 1.12 to 1.14, further supporting good flow characteristics.

Angle of Repose was found between $26.4 \pm 1.2^\circ$ (F4) and $28.4 \pm 1.3^\circ$ (F2). All values are within acceptable limits for free-flowing powders ($<30^\circ$). F4 showed the best flow profile, with the lowest angle of repose and moderate compressibility, possibly due to the balanced polymer ratio that resulted in smooth, spherical pellet morphology. The results are shown in table 3

Drug Content

The drug content across all batches ranged between $97.1 \pm 0.9\%$ (F3) to $99.4 \pm 1.2\%$ (F4), indicating

effective and uniform drug layering on the pellet cores. All values fall within the pharmacopeial acceptance criteria of 90–110%. The highest drug content was observed in F4, which may be attributed to more efficient binder and polymer utilization during the drug layering step. The low standard deviations further reflect the reproducibility of the layering process. The results are shown in table 3

Particle Size and Size Distribution

The particle size of the coated pellets ranged from $840 \pm 12 \mu\text{m}$ (F1) to $860 \pm 10 \mu\text{m}$ (F2). The variation in particle size is attributable to differences in the polymer ratios used in the coating composition, which affects the coating thickness and thus the overall pellet size. All formulations maintained a narrow particle size distribution within acceptable limits for multiparticulate dosage forms. Uniform particle size is essential for consistent drug release and capsule filling. The results are shown in table 3.

From the study it was concluded that, all coated pellet formulations (F1 to F5) exhibited acceptable particle size distribution, high drug content, low friability, and good flow properties, indicating successful coating and formulation processes. Among them, F4 demonstrated the best overall performance, with the highest drug content, lowest friability, and excellent flowability, making it the most promising batch for further in vitro dissolution and performance evaluation. The results confirm the suitability of pan coating for the development of pulsatile-release multiparticulate systems.

Table 3: Evaluation of Coated Pellets F1 to F6).

Parameter	F1	F2	F3	F4	F5
Particle Size (μm)	840 \pm 12	860 \pm 10	850 \pm 11	855 \pm 13	845 \pm 9
Drug Content (%)	98.2 \pm 1.1	97.5 \pm 1.3	97.1 \pm 0.9	99.4 \pm 1.2	98.9 \pm 1.0
Friability (%)	0.58 \pm 0.05	0.45 \pm 0.04	0.48 \pm 0.06	0.42 \pm 0.05	0.50 \pm 0.05
Carr's Index (%)	10.4 \pm 0.6	12.3 \pm 0.5	11.2 \pm 0.7	11.7 \pm 0.6	10.9 \pm 0.4
Hausner's Ratio	1.12 \pm 0.03	1.14 \pm 0.02	1.13 \pm 0.03	1.14 \pm 0.02	1.12 \pm 0.02
Angle of Repose ($^\circ$)	26.7 \pm 1.1	28.4 \pm 1.3	27.2 \pm 1.0	26.4 \pm 1.2	26.8 \pm 1.1

All values represent mean \pm standard deviation (n=3)

In-Vitro Dissolution Study

The in-vitro dissolution study of pulsatile-release coated pellets of Meloxicam (F1 to F5) was conducted over an 8-hour period using a two-stage dissolution medium. The pellets were first exposed to 0.1 N HCl (pH 1.2) for 2 hours followed by phosphate buffer pH 6.8, simulating the gastrointestinal pH transition. The study aimed to evaluate the effect of different ratios of Eudragit L100 (pH-sensitive polymer) and Ethyl Cellulose (time-dependent polymer) on the lag time and drug release behavior.

Formulation F1 (100% Eudragit L100) showed the earliest release, with 15.6 \pm 1.4% drug released at 3 hours, and a rapid increase to 98.9 \pm 1.0% by 8 hours. This suggests a short lag time (~2–2.5 hours) and burst release, typical of pH-dependent systems. However, the absence of Ethyl Cellulose limits its ability to control the timing of drug release precisely. In contrast, Batch F2 (100% Ethyl Cellulose) displayed the longest lag time, with negligible drug release until 6 hours, and only 28.5 \pm 2.5% release at 8 hours. This highlights the strong barrier property of EC, which delays drug release significantly. However, the absence of pH sensitivity results in incomplete release within the target time frame, making it unsuitable for pulsatile systems requiring a defined release window.

Formulation F3 (1:1 ratio of Eudragit L100 and EC) showed a moderate delay, with release initiating after 5 hours (7.4 \pm 1.0%) and reaching 76.4 \pm 1.9% at 8 hours.

This indicates a balanced combination of time- and pH-dependent release, though total drug release was slightly lower.

Formulation F4, the optimized formulation (Eudragit L100 1.5 g : EC 3 g), exhibited a clear lag phase up to 5 hours, with no release until the sixth hour. A sharp rise to 28.2 \pm 1.2% at 6 hours and 96.8 \pm 2.3% at 8 hours confirmed a defined and effective pulsatile pattern. The higher proportion of EC helped extend the lag time, while the presence of Eudragit enabled quick release once the lag phase ended. This pattern is ideal for chronotherapeutic delivery, such as treating early morning symptoms in arthritis.

Formulation F5 (2:1 ratio of Eudragit L100 to EC) showed release initiation around 4 hours, with 36.4 \pm 1.6% drug release, increasing to 97.8 \pm 1.1% at 8 hours. The higher proportion of Eudragit led to a shorter lag time than F4, but with complete release achieved within 8 hours, offering an alternative pulsatile profile.

The dissolution study confirmed that modifying the ratio of Eudragit L100 and Ethyl Cellulose in the coating layer effectively alters the lag time and release kinetics of Meloxicam pellets. Among all formulations, F4 emerged as the optimized batch, exhibiting a well-defined lag time (~5–6 hours) followed by rapid and complete drug release, making it suitable for pulsatile drug delivery targeting circadian-related conditions. The percentage drug release of meloxicam from the coated pellets is graphically shown in figure 3.

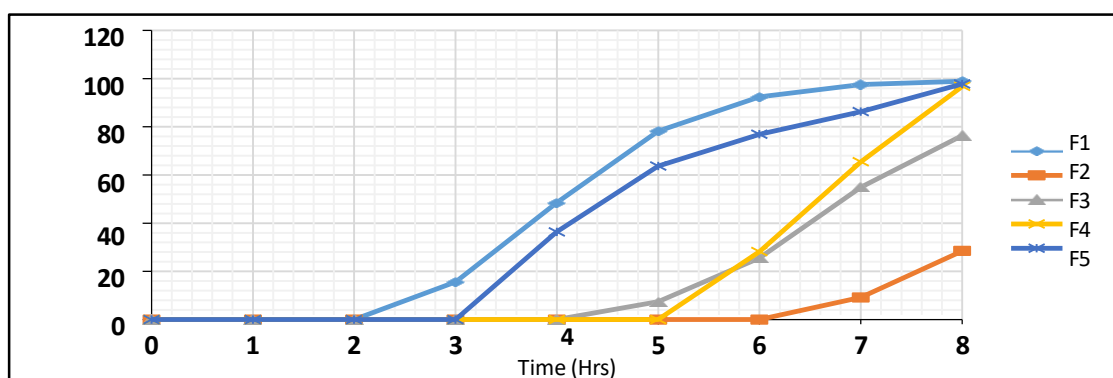


Figure 3: Competitive In vitro Dissolution profile of Pulsatile Release Pellets of Meloxicam (F1 to F5)

Stability Study

The stability data confirm that formulation F4 maintains its drug release profile and potency even after three months of accelerated storage, demonstrating excellent

chemical and physical stability. This suggests that the optimized coated pellet system of Meloxicam is a robust and reliable formulation suitable for pulsatile drug delivery. The results of stability data were shown in table 4.

Table 4: Stability Data of Optimized Formulation F4

Formulation	Parameter	Before storage (0 months)	After storage (3 months)
F4	% Drug Release	96.8± 2.3	95.3±1.45
	Drug Content (%)	99.4 ± 1.2	98.2 ±0.6

CONCLUSION

The research successfully demonstrated the feasibility of formulating pulsatile release coated pellets of Meloxicam using pan coating with Eudragit L100 and Ethyl Cellulose. The study revealed that varying the polymer ratios effectively modulated lag time and release kinetics. Among all, Formulation F4 emerged as the most promising candidate, exhibiting optimal physicochemical properties, flow characteristics, controlled lag time (~5 hours), and complete release post-lag, aligning with chronotherapeutic needs. The drug release kinetics were best described by the Korsmeyer-Peppas model, indicating a polymer relaxation-erosion mechanism. Furthermore, the formulation exhibited excellent stability, making it a strong candidate for further clinical development in managing conditions with circadian rhythm-based symptoms such as early morning arthritis pain. This study confirms the potential of multiple-unit pellets for use in pulsatile drug delivery systems, enhancing therapeutic outcomes through time-specific drug release.

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