



Formulation and Evaluation of Sustained Release Matrix Tablet of Cimetidine

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ABSTRACT

The aim of the present research study was to Formulate and Evaluate sustained release tablets of Cimetidine 500mg tablet using direct compression method. Nine formulations were prepared using different polymers like HPMC, Xanthan Gum and Sodium CMC. These Polymers were used in different proportion to control the released of the drug. All the formulations were evaluated of physicochemical tests. All the physicochemical characters of the formulated tablets were within the acceptable limits. The release pattern of the drug was observed over a period of 12 hours and determined the amount of drug by the UV-visible method. Dissolution data showed all formulations showed drug release for 12hrs. Among all the formulations C6 showed best drug release 99.08%. The optimized formulations were followed zero-order kinetics, korsmeyer-peppas and Higuchi models.

Keywords: Cimetidine Sustained release Tablets, Sodium CMC, HPMC, Xanthan Gum.

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1. Introduction

A drug delivery system (DDS) is defined as a formulation or a device that enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time, and place of release of drugs in the body¹. This process includes the administration of the therapeutic product, the release of the active ingredients by the product, and the subsequent transport of the active ingredients across the biological membranes to the site of action². The term therapeutic substance also applies to an agent such as gene therapy that will induce in vivo production of the active therapeutic agent. Sustained release tablets are commonly taken only

once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect⁴

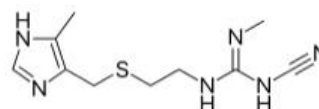


Fig.1: Cimetidine

IUPAC Name : 1-cyano-2-methyl-3-[2-[(5-methyl-1H-imidazol-4-yl) methylsulfanyl]ethyl]guanidine

Molecular Formula : C₁₀H₁₆N₆S

Molecular Weight : 252.34 g/mol

Official Pharmacopoeia : USP
 Physicochemical properties:
 Description(Physical State): Solid
 Solubility: water solubility 9380 mg/L (at 25 °C)
 Storage Conditions: 20° to 25°C
 Dosage : 400mg
 Melting point: 142°C
 pKa(strongest acidic): 13.38
 Log P: 0.40

Pharmacokinetic properties:

Bioavailability : 60–70%
 Half-life : 2 hours[
 Absorption : Rapid 60-70%
 Protein binding : 15–20%
 Metabolism : Hepatic
 Excretion : Renal

Adverse effects: Headache, dizziness, somnolence, diarrhea.

Pharmacodynamics:

Cimetidine is a histamine H₂-receptor antagonist. It reduces basal and nocturnal gastric acid secretion and a reduction in gastric volume, acidity, and amount of gastric acid released in response to stimuli including food, caffeine, insulin, betazole, or pentagastrin. It is used to treat gastrointestinal disorders such as gastric or duodenal ulcer, gastroesophageal reflux disease, and pathological hypersecretory conditions. Cimetidine inhibits many of the isoenzymes of the hepatic CYP450 enzyme system. Other actions of Cimetidine include an increase in gastric bacterial flora such as nitrate-reducing organisms.

Table.1: Drug Formulation

S.No	Drug name	Label Claim	Brand name
1	Cimetidine	400 mg	Tagamet

2. Methodology

Analytical method development:

Determination of absorption maxima:

100mg of Cimetidine pure drug was dissolved in 15ml of Methanol and make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with 100ml by using 0.1 N HCL (stock solution-2 i.e 100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1 N HCL (10µg/ml). Scan the 10µg/ml using Double beam UV/VIS spectrophotometer in the range of 200 – 400 nm.

Preparation calibration curve:

100mg of Cimetidine pure drug was dissolved in 15ml of Methanol and volume make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with 100ml by using 0.1 N HCl (stock solution-2 i.e 100µg/ml). From this take 1, 2, 3, 4, and 5ml of solution and make up to 10ml with 0.1N HCl to obtain 10, 20, 30, 40 and 50 µg/ml of Cimetidine solution. The absorbance of the above dilutions was measured at 228nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R²) which determined by least-

square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

Drug excipient interaction studies are significant for the successful formulation of every dosage form. Fourier Transform Infrared (FTIR) Spectroscopy studies were used for the assessment of physicochemical compatibility and interactions, which helps in the prediction of interaction between drug and other excipients. In the current study 1:1 ratio was used for preparation of physical mixtures used for analyzing of compatibility studies. FT-IR studies were carried out with a Bruker, ATR FTIR facility using direct sample technique.

Formulation development of Sustained release Tablets:

All the formulations were prepared by direct compression method. The compositions of different formulations are given in Table. The tablets were prepared as per the procedure given below and aim is to prolong the release of Cimetidine.

Procedure:

In the present work the Cimetidine tablets were prepared by direct compression method. The drug and the excipients were passed through 72# size mesh prior to the preparation of dosage form. The entire ingredients were weighed separately and mixed thoroughly for 10 minutes in double cone blender to ensure uniform mixing in geometric ratio. The tablets were prepared by direct compression technique using 9mm punch.

Evaluation Parameters

Pre Compression parameters

Bulk density (D_B)

Bulk density is the ratio between a given mass of the powder and its bulk volume.

Bulk density = Mass of Powder / Bulk volume of the powder

$$\text{Bulk density (D}_B\text{)} = W / V_0$$

Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and measure the bulk volume.

Tapped Density (D_T)

Tapped density is the ratio between a given mass of powder (or) granules and the constant (or) fixed volume of powder or granules after tapping.⁶⁷

Tapped density = mass of the powder/ tapped volume

Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and the cylinder was tapped on a wooden surface from the height of 2.5 cm at two second intervals. The tapping was continued until no further change in volume (until a constant volume) was obtained (V_f). The tapped density was calculated by using the formula

$$\text{Tapped density (D}_T\text{)} = W / V_f$$

Hausner's ratio

Hausner's ratio is an indirect index of ease of powder flow and was calculated by the formula,

$$\text{Hausner's ratio} = D_T / D_B$$

Where, D_T is the tapped density

D_B is the bulk density

Compressibility index

Compressibility index (CI) was determined by measuring the initial volume (V_o) and final volume (V_f) after hundred tapping's of a sample in a measuring cylinder. It indicates the powder flow properties and expressed in terms of percentage and given in table no. 14 and calculated by using the formula

$$\% \text{ Compressibility index} = V_o - V/V_o \times 100$$

Angle of repose

Angle of repose was measured by fixed funnel method. It determines flow property of the powder. It is defined as maximum angle formed between the surface of the pile of powder and the horizontal plane. The powder was allowed to flow through the funnel fixed to a stand at definite height (h). By measuring the height and radius of the heap of powder formed (r), angle of repose was calculated by using formula given below and the calculated values obtained was shown in table no. 14

$$\theta = \tan^{-1} (h / r)$$

Where, θ is the angle of repose

h is the height in cm

r is the radius in cm

Post Compression parameters

Weight variation test

Twenty tablets were randomly selected and weighed, to estimate the average weight and that were compared with individual tablet weight. The percentage weight variation was calculated as per Indian Pharmacopoeial Specification. Tablets with an average weight 250 mg so the % deviation was $\pm 5\%$.

Friability test

Twenty tablets were weighed and subjected to drum of friability test apparatus. The drum rotated at a speed of 25 rpm. The friabilator was operated for 4 minutes and reweighed the tablets. % loss (F) was calculated by the following formula.

$$F = 100 (W_0 - W) / W_0$$

Where W_0 = Initial weight,

W = Final weight

Hardness test

The hardness of tablets was measured by using Monsanto hardness tester. The results were complies with IP specification.

Thickness test

The rule of physical dimension of the tablets such as sizes and thickness is necessary for consumer acceptance and maintain tablet uniformity. The dimensional specifications were measured by using screw gauge. The thickness of the tablet is mostly related to the tablet hardness can be used as initial control parameter.

Drug content

The amount of drug in tablet was important for to monitor from tablet to tablet, and batch to batch is to evaluate for efficacy of tablets. For this test, take ten tablets from each batch were weighed and powdered. Weighed equivalent to the average weight of the tablet powder and transferred into a 100 ml volumetric flask and dissolved in a suitable quantity of media. The solution was made up to the mark

and mixed well. Then filter the solution. A portion of the filtrate sample was analyzed by UV spectrophotometer.

In vitro drug release studies

Apparatus -- USP-II, Paddle Method

Dissolution Medium -- pH 6.8 Phosphate buffer

RPM --50

Sampling intervals (hrs) --1, 2, 3, 4, 5, 6, 7, 8, 10, & 12.

Temperature -- $37^\circ\text{C} \pm 0.5^\circ\text{C}$

Procedure:

900ml Of 0.1 HCl was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The media was allowed to equilibrate to temp of $37^\circ\text{C} \pm 0.5^\circ\text{C}$. Tablet was placed in the vessel and apparatus was operated for 2 hours. Then 0.1 N HCl was replaced with pH 6.8 phosphate buffer and process was continued up to 12 hrs at 50 rpm. At specific time intervals, withdrawn 5 ml of sample and again 5ml media was added to maintain the sink condition. Withdrawn samples were analyzed at 332nm wavelength of drug using UV-spectrophotometer.

7.5 Application of Release Rate Kinetics to Dissolution

Data: Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics:

To study the zero-order release kinetics the release rate data are fitted to the following equation.

$$F = K_0 t$$

Where, 'F' is the drug release at time 't', and 'K₀' is the zero order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics: The release rate data are fitted to the following equation

$$\text{Log}(100-F) = kt$$

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

$$F = k t^{1/2}$$

Where, 'k' is the Higuchi constant.

In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model:

The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$$M_t / M_\infty = K t^n$$

Where, M_t / M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I transport), n=1; and for supercase II transport, n > 1. In this model, a plot of log (M_t / M_∞) versus log (time) is linear.

Table.2: Formulation of Cimetidine release tablets

Ingredients	C1	C2	C3	C4	C5	C6	C7	C8	C9
Cimetidine	200	200	200	200	200	200	200	200	200
Hpmc	40	80	120	-	-	-	-	-	-
Xanthan gum	-	-	-	40	80	120	-	-	-
Sodium cmc	-	-	-	-	-	-	40	80	120
Pvp	15	15	15	15	15	15	15	15	15
Talc	10	10	10	10	10	10	10	10	10
Mg sterate	5	5	5	5	5	5	5	5	5
Mcc	230	190	150	230	190	150	230	190	150
Total weight	500	500	500	500	500	500	500	500	500

Table.3: The flow property of powder blend

Flow property	Angle of repose	Compressibility index (%)	Hausner's ratio
Excellent	25-30	<10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	1.46-1.59
Very very poor	>66	>38	>1.60

3. Results and Discussion

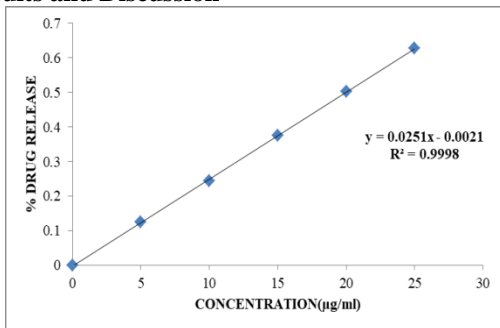


Fig.2: Calibration curve of Cimetidine in 0.1N HCl at 228

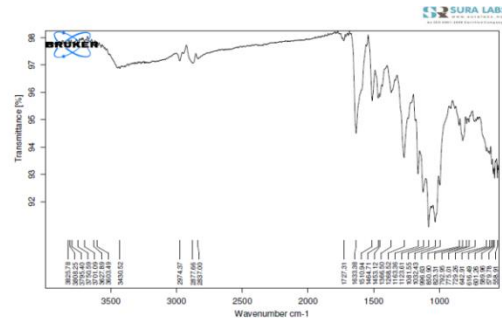


Fig.5: FTIR Graph of Optimized Formulation

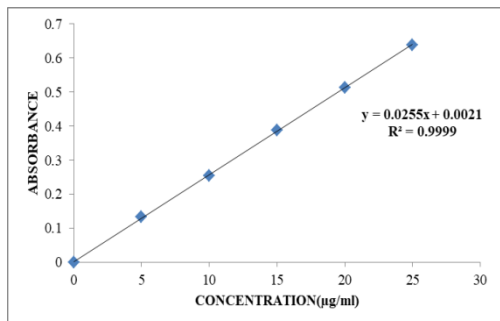


Fig.3: Calibration of Cimetidine in Phosphate buffer pH 6.8

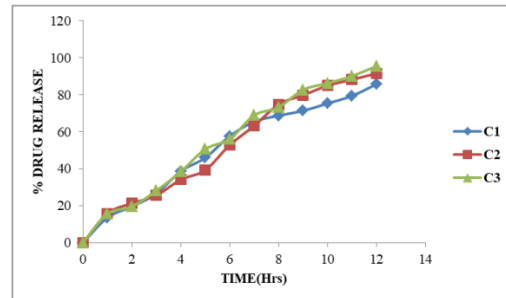


Fig.6: Dissolution study of Cimetidine Sustained tablets (C1 to C3)

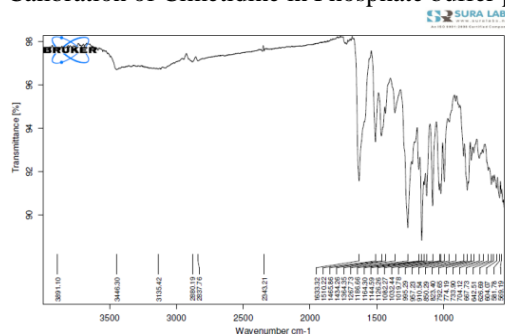


Fig.4: FTIR Graph of Pure Drug

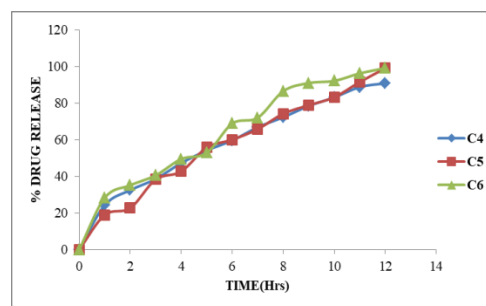


Fig.7: Dissolution study of Cimetidine (C7 to C9)

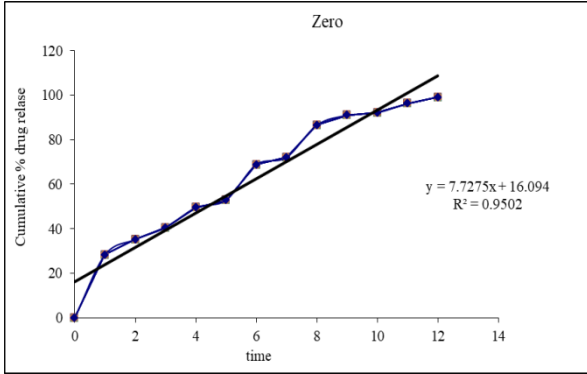


Fig.8: Graph of zero order kinetics

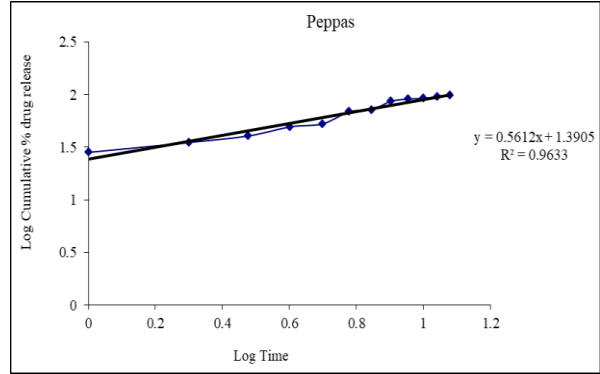


Fig.10: Graph of peppas release kinetics

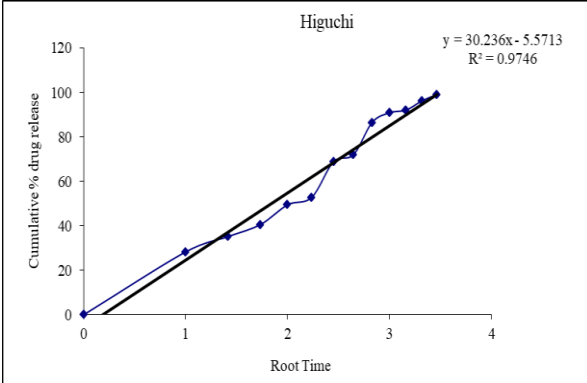


Fig.9: Graph of higuchi release kinetics

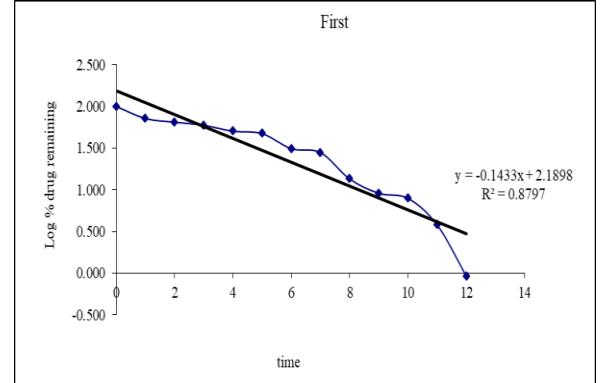


Fig.11: graph of first order release kinetics

Table.4: Standard curve of Cimetidine in 0.1N HCl

Concentration (µg/ ml)	Absorbance
0	0
5	0.125
10	0.243
15	0.375
20	0.502
25	0.627

Table.5: Standard curve of Cimetidine in Phosphate buffer pH 6.8

Concentration (µg / ml)	Absorbance
0	0
5	0.133
10	0.255
15	0.388
20	0.514
25	0.639

Table.6: Pre-compression parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
C1	30.3 ± 0.09	0.52 ± 0.08	0.64 ± 0.04	22.5 ± 0.0	1.27 ± 0.10
C2	29.6 ± 0.17	0.51 ± 0.10	0.62 ± 0.06	19.5 ± 0.06	1.23 ± 0.15
C3	31.4 ± 0.08	0.50 ± 0.07	0.62 ± 0.03	19.8 ± 0.06	1.24 ± 0.14
C4	26.2 ± 0.12	0.54 ± 0.09	0.65 ± 0.06 2	21.4 ± 0.06	1.26 ± 0.13
C5	33.4 ± 0.07	0.51 ± 0.05	0.63 ± 0.06	20.4 ± 0.12	1.23 ± 0.07
C6	40.1 ± 0.12	0.48 ± 0.04	0.57 ± 0.03	17.4 ± 0.07	1.15 ± 0.04
C7	36.2 ± 0.13	0.52 ± 0.06	0.64 ± 0.07	21.5 ± 0.03	1.23 ± 0.07
C8	37.7 ± 0.12	0.50 ± 0.02	0.62 ± 0.04	18.3 ± 0.04	1.20 ± 0.12
C9	31.8 ± 0.03	0.51 ± 0.06	0.64 ± 0.03	20.1 ± 0.08	1.23 ± 0.10

Table.7: Post Compression Parameters of Tablets

Formulation codes	Weight variation (mg)	Hardness (kg/cm ²)	Friability (%loss)	Thickness (mm)	Drug content (%)
C1	499.58	4.2	0.19	5.36	98.15
C2	500.22	4.9	0.24	5.64	97.36
C3	496.85	4.6	0.72	5.19	99.12
C4	495.14	4.3	0.48	5.85	96.49
C5	498.82	4.8	0.34	5.41	99.86
C6	499.78	4.1	0.52	5.75	99.0
C7	500.18	4.6	0.64	5.39	95.98
C8	497.82	4.9	0.38	5.54	98.34
C9	499.76	4.2	0.28	5.84	97.22

Table.8: Dissolution Data of Cimetidine Tablets Prepared with (Drug: polymer) Ratios of polymers like

Time (hr)	Cumulative percent of drug released		
	C1	C2	C3
0	0	0	0
1	13.57	15.81	15.61
2	19.58	21.32	19.59
3	26.57	25.61	28.12
4	38.69	34.15	38.45
5	45.97	39.29	50.61
6	57.62	52.84	56.18
7	65.48	63.26	68.92
8	68.74	74.82	73.29
9	71.38	79.81	82.72
10	75.35	84.96	86.24
11	79.42	88.21	90.17
12	85.75	91.55	95.54

Table.9: Dissolution Data of Cimetidine Tablets Prepared with (Drug: polymer) Ratios of polymers like

Time (hr)	Cumulative Percent of Drug Released		
	C4	C5	C6
0	0	0	0
1	24.28	18.93	28.28
2	32.47	22.66	35.15
3	38.59	38.31	40.55
4	47.26	42.69	49.47
5	54.12	55.74	52.82
6	59.63	59.98	68.83
7	66.81	65.82	72.02
8	72.27	74.21	86.52
9	78.44	78.84	90.91
10	83.11	83.23	92.11
11	88.75	91.52	96.22
12	90.81	98.99	99.08

Table.10: Dissolution Data of Cimetidine Tablets Prepared

Time (hr)	Cumulative percent of drug released		
	C7	C8	C9
0	0	0	0
1	8.28	10.97	13.40
2	12.26	15.22	19.75
3	18.62	22.35	26.05
4	24.72	28.10	30.58
5	30.73	32.34	36.57

6	35.48	39.23	40.04
7	41.29	45.76	47.96
8	48.68	50.38	58.45
9	56.30	69.45	76.11
10	67.74	74.56	82.74
11	75.19	78.15	86.04
12	77.56	82.12	98.74

4. Conclusion

Sustained release tablets of Cimetidine were prepared successfully using polymers such as HPMC, Xanthan gum and Sodium cmc in various concentrations. The particle size and drift behavior of the granules were found to be in accordance with the official standards. Direct compression method was selected on the basis of Good compressibility index of the granules. The physical properties of compressed tablets like thickness, hardness, weight variation and friability were in compliance with the official limits. Free-flowing powder facilitates the formulation of tablets with ideal properties. The drug release was primarily controlled by the type and concentration resulted in altered drug release. On the basis of these results it can be concluded that formulation was prolonged duration. In vitro drug release was 99.08% was C6 it is considered as an optimized formulation.

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