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Development and Characterization of Midodrine Hcl Sustained Release Matrix Tablets

Rahul J. Sanghani[1], Sahilraza Ghanchi[2], Suraj R. Chauhan[3], Gazala Y. Ansari[4], Bhumi A. Raval[5], Jitendra O. Bhangale[6], Alpesh D. Patel[7]

[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.
[7]Professor and Principal, Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa, Gujarat 383315, India

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ABSTRACT
Midodrine HCl is an α_1-adrenergic agonist used in the treatment of hypotension. Due to its short biological half-life (3–4 hours), it requires multiple daily dosing, which may lead to fluctuations in plasma drug concentration and reduced patient compliance. Therefore, the development of a sustained release formulation is desirable to prolong drug release and maintain therapeutic levels for an extended period. Sustained release matrix tablets containing Midodrine HCl were prepared by the wet granulation method using polymers such as Polyox WSR 303, Acrypol 971, and Acrypol 912 in varying concentrations. The prepared granules were evaluated for pre-compression parameters. The compressed tablets were evaluated for post-compression parameters such as thickness, weight variation, hardness, friability, drug content and In vitro drug release studies. The pre-compression parameters indicated good flow properties of the powder blends. All tablet formulations met pharmacopeial specifications for post-compression parameters. In vitro dissolution studies of MS9 batch was demonstrated sustained drug release of drug over 24 hours. Cumulative drug release of optimized batch was found to be 98.48% whisch was higher than other 8 batches. Stability studies confirmed that the optimized formulation remained stable without significant changes in physicochemical properties or drug release behavior. The developed hydrophilic polymer-based matrix tablets successfully provided sustained release of Midodrine HCl for up to 24 hours. This formulation approach may help reduce dosing frequency and improve patient compliance in the management of hypotension.

INTRODUCTION:

Midodrine HCl is used for the treatment of hypotension. It is a class of α1-agonist drugs and acts as a peripheral vasoconstrictor, which increases effective blood volume circulation and renal perfusion by increasing systemic and splanchnic blood pressure.[1] Midodrine is a prodrug which is well absorbed from the GI tract, but it has low half of just 3-4 hours and thus needs to be administered in multiple doses in a day. Patient suffering from hypotension suffers sudden symptoms like fainting, dizziness, nausea and vomiting, thus it becomes difficult for a patient to take medicines at own. Due to multiple dosing regimen there are chances of disruption in steady state plasma concentration and thus it is leads to severe toxicity and lower efficacy.[2]

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The maximum dose of Midodrine HCl is 30 mg per day it belongs to BCS Class I, having excellent solubility and permeability and as it is well absorbed from GIT an attempt is being made to formulate sustained release matrix tablets which will help to release drug in the stomach for a prolonged period of time, reducing side effect and enhancing it's efficacy.[3,4]

MATERIALS:

Acrypol 912 and Acrypol 971 were received from Corel pharmachem, Gujrat. while Polyox WSR 303, Microcrystalline Cellulose, PVP K30, Talc and Magnesium stearate was received from Chemdyes Corporation, Rajkot.

METHOD:

Sustained release matrix tablets of Midodrine HCl were prepared by wet granulation method according to the formula given in table. All the ingredients were passed through 40 mesh sieve separately. The drug and diluents were mixed by small portions of both each time and blending it to get a uniform mixture kept a side. Then add purified water as binder then granules kept for drying for 1 h at 55 ˚C then dried granules are lubricated with magnesium stearate and talc. Prepared granules were compressed using Cadmach Machine.[5] The Tablets were prepared by using ingredients with different concentrations as mentioned in table 1.

Table 1: Formulation of Sustained Release Matrix Tablets of Midodrine HCl

Ingredients (mg)	MS1	MS2	MS3	MS4	MS5	MS6	MS7	MS8	MS9
Midodrine HCl	30	30	30	30	30	30	30	30	30
Polyox WSR 303	25	50	75	-	-	-	-	-	-
Acrypol 971	-	-	-	25	50	75	-	-	-
Acrypol 912	-	-	-	-	-	-	25	50	75
MCC	156	131	106	156	131	106	156	131	106
PVP K30	30	30	30	30	30	30	30	30	30
Talc	6	6	6	6	6	6	6	6	6
Magnesium stearate	3	3	3	3	3	3	3	3	3
Purified Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
Total weight	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

Determination of Melting point of Midodrine HCl:

Melting point of Midodrine HCl was measured by melting point apparatus. Minimum amount of drug was placed in a thin-walled capillary tube closed at one end. This capillary was then mounted in a melting point apparatus with thermometer and then their temperature range over which Midodrine HCl melts is measured. The readings were taken in triplicate.[6]

Estimation of Midodrine HCl by UV spectroscopy method:

Midodrine HCl (10 mg) was dissolved in small volume of methanol in 100 ml of volumetric flask and diluted quantitatively with 0.1 N HCl to obtain a solution having a known concentration of 100 µg/ml. The standard solution of Midodrine HCl was subsequently diluted with 0.1 N HCl to obtain a series of dilutions containing 3, 6, 9, 12 and 15 µg/ml solution of Midodrine HCl. The absorbance of these solutions was measured in analytical technologies Limited, UV-Visible Spectrophotometer at 289 nm using 0.1 N HCl as blank.[7]

Pre-compression Parameters[8-10]:

Bulk density: Apparent bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume and weight of the powder was determined.

$$\text{Bulk density} = \frac{\text{Mass of Powder (gm)}}{\text{Bulk volume of Powder (ml)}}$$

Tapped density: The measuring cylinder containing a known mass of blend was tapped for 100 times. The minimum volume occupied in the cylinder and weight of the blend was measured.

$$\text{Tapped density} = \frac{\text{Mass of Powder (gm)}}{\text{Tapped volume of Powder (ml)}}$$

Compressibility Index: Compressibility is indirectly related to the relative flow rate, cohesiveness and particle size distribution of the powder. Tapped density and Bulk density measurements can be used to estimate the compressibility of a material.

$$\%\ \text{Carr's Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}}\ X\ 100$$

Hausner's ratio: The Hausner's ratio is used for estimation of the flow property of either particles or granules. Hausner's ratio is the ratio of tapped density to bulk density of particles or granules.

Its value less than 1.25 indicates excellent flow of particles and value more than 1.25 indicates poor flow property. The Hausner's ratio of the granules was determined by the equation.

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$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Angle of repose: Angle of repose has been defined as the maximum angle possible between the surface of pile of powder and horizontal plane. Angle of repose of different formulations was measured according to fixed funnel standing method. The granules mass was allowed to flow out of the funnel orifice on a plane paper kept on the horizontal surface. This forms a pile of granules on the paper. The Angle of repose is calculated by the equation.

$$\text{Tan } \theta = \frac{\text{Height of pile (h)}}{\text{radius of pile (r)}}$$

Post Compression Parameters

Thickness[11]**:** Thickness of tablets were measured by Digi-Matic Vernier calipers. 3 tablets were randomly collected and their thickness were measured by placing between two arms of Vernier calipers.

Weight variation test[11]**:** 20 tablets were selected randomly from each batch and weighed individually. The average weight of each batch of tablet was calculated. Individual weights of the tablets were compared with the average weight.

Hardness[12]**:** The crushing strength (kg/cm^2) of prepared tablets was determined for tablets of each batch by using Monsanto tablet hardness tester. Hardness indicates the ability of a tablet to withstand mechanical shocks while handling.

Friability Test[13]**:** The friability of tablets was determined using Roche friabilator. It is expressed in percentage (%). Tablets were initially weighed (Wo) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 min or run up to 100 revolutions.

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} X\ 100$$

Drug content[14]**:** 10 tablets were weighed and average weight was calculated. All 10 tablets were crushed in mortar. The powder equivalent to 30 mg of Midodrine HCl was dissolved in small quantity of methanol and then made up to 10 ml with 0.1 N HCl. The drug solution was filtered through Whatman filter paper. The sample was analyzed for drug content by UV Spectrophotometry at 289 nm after suitable dilutions.

% Cumulative drug release[15]**:** The release rate of Midodrine HCl from Sustained Release Matrix Tablets was determined using USP dissolution testing apparatus II (paddle type). The dissolution test was performed using 900 ml at 37 ± 0.5 ^{0}C at 50 rpm in 0.1 N HCl. Aliquot 5 ml was withdrawn from the dissolution apparatus at the time intervals of 3 hours and the samples were replaced with fresh dissolution medium. After filtration, the amount of drug released was determined from the standard calibration curve of pure drug.

Stability Study[16]**:** The tablets of optimize batch was stored at 40 ºC ± 2 ºC and 75 % ± 5 % RH for one month (accelerated testing) to access their stability. It was carried out as per ICH guideline. During this whole study tablets were put in chamber by double wrapped aluminium foil. Samples were evaluated after 1 month time for drug content, weight variation, hardness and In vitro drug release study.

RESULTS AND DISCUSSION:

Melting point of Midodrine HCl:

Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Midodrine HCl was found in the range of 221 -231 °C. Reported melting point of Midodrine HCl is 227-229°C and is thus similar to the melting point of Midodrine HCl.

Estimation of drug by UV overlay spectra:

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 289 nm. Reported λ_{max} of Midodrine HCl is 289 nm. So, it can be concluded that the given drug was Midodrine HCl. The absorbance of different concentration of Midodrine HCl in 0.1 N HCl are shown in Table 2. A calibration curve of Concentration versus Mean absorbance was plotted (Figure 1), the calibration curve for the prepared working solutions of Midodrine HCl (3-15 µg/ml) was constructed in which Regression equation 0.0204x + 0.0209 and 0.999 Correlation coefficient (R^2) was found.

Table 2: Absorbance of different concentration of Midodrine HCl in 0.1 N HCl

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ± S. D.
		I	II	III	
1.	3	0.081	0.081	0.082	0.081 ± 0.001
2.	6	0.142	0.145	0.143	0.143 ± 0.002
3.	9	0.191	0.213	0.218	0.207 ± 0.014
4.	12	0.261	0.251	0.271	0.261 ± 0.010
5.	15	0.311	0.321	0.352	0.328 ± 0.021

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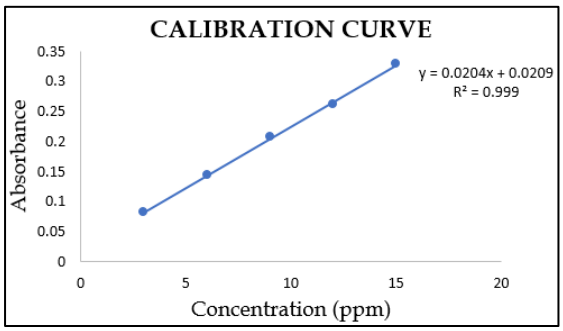

Figure 1: Calibration curve of Midodrine HCl in 0.1 N HCl

Pre-Compression parameters:

The micromeritic properties of the powder blends (MS1–MS9) were evaluated by determining bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose. The bulk density of the formulations ranged from 0.50 ± 0.01 to 0.88 ± 0.02 g/mL, while the tapped density varied between 0.56 ± 0.00 and 1.17 ± 0.03 g/mL. The calculated Carr's index values ranged from 4.52 ± 2.06 to 24.67 ± 3.09%, indicating acceptable to good compressibility of the powder blends. Similarly, the Hausner's ratio values were found between 1.05 ± 0.02 and 1.33 ± 0.05, suggesting generally good flow characteristics.

The angle of repose values ranged from 27.16 ± 0.60° to 30.97 ± 0.43°, indicating satisfactory flow behaviour of the formulations. Overall, the micromeritic parameters demonstrated that most powder blends exhibited good flowability and compressibility, which are suitable for further processing in tablet formulation.

The Bulk density, tapped density, Carr's index, Hausner's ratio and Angle of Repose data of prepared granules are mentioned in Table 3.

Table 3: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose data

Batch	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index	Hausner's ratio	Angle of repose (Ø)
MS1	0.82 ± 0.04	0.93 ± 0.10	11.71 ± 11.66	1.15 ± 0.16	27.78 ± 1.06
MS2	0.53 ± 0.01	0.57 ± 0.01	7.74 ± 1.18	1.08 ± 0.01	27.97 ± 0.37
MS3	0.85 ± 0.02	0.94 ± 0.02	9.08 ± 1.90	1.10 ± 0.02	28.61 ± 0.38
MS4	0.53 ± 0.01	0.57 ± 0.00	7.03 ± 1.13	1.08 ± 0.01	27.36 ± 0.69
MS5	0.50 ± 0.01	0.56 ± 0.00	9.39 ± 1.06	1.10 ± 0.01	27.16 ± 0.60
MS6	0.86 ± 0.00	0.94 ± 0.05	8.05 ± 5.27	1.09 ± 0.06	29.05 ± 0.00
MS7	0.84 ± 0.02	0.88 ± 0.04	4.52 ± 2.06	1.05 ± 0.02	27.60 ± 1.38
MS8	0.88 ± 0.02	1.09 ± 0.05	18.76 ± 4.99	1.23 ± 0.08	29.74 ± 0.00
MS9	0.88 ± 0.02	1.17 ± 0.03	24.67 ± 3.09	1.33 ± 0.05	30.97 ± 0.43

Post Compression parameters:

The prepared sustained release matrix tablets (MS1–MS9) were evaluated for post-compression parameters including thickness, weight variation, hardness, friability, and drug content to ensure compliance with pharmacopeial standards. The tablet thickness ranged from 4.7 ± 0.12 to 4.9 ± 0.06 mm, indicating uniform die filling during compression. The average tablet weight varied between 249.20 ± 1.44 mg and 250.35 ± 1.14 mg, demonstrating minimal weight variation and good content uniformity among the batches.

The hardness of the tablets was found in the range of 7.83 ± 0.29 to 9.17 ± 0.29 kg/cm², suggesting adequate mechanical strength required for sustained release matrix systems. The friability values ranged from 0.34 ± 0.02% to 0.81 ± 0.05%, which are well below the acceptable pharmacopeial limit of 1%, indicating good tablet integrity and resistance to abrasion.

Furthermore, the percentage drug content of all formulations was within the range of 97.60 ± 0.57 % to 99.78 ± 0.74 %, confirming uniform distribution of the drug within the matrix tablets. Overall, the results demonstrate that all prepared batches complied with standard quality control limits and were suitable for further in vitro drug release studies of sustained release matrix tablets.

The Thickness, Weight variation, Hardness, Friability and Drug Content Data of Tablets are mentioned in Table 4.

Table 4: Thickness, Weight variation, Hardness, Friability and Drug Content Data

Batch	Thickness (mm)	Weight variation (mg)	Hardness (kg/cm²)	Friability	% Drug Content
MS1	4.9 ± 0.06	250.25 ± 1.21	7.83 ± 0.29	0.81 ± 0.05	97.60 ± 0.57
MS2	4.7 ± 0.12	250.20 ± 1.06	8.00 ± 0.50	0.77 ± 0.08	97.58 ± 0.59
MS3	4.9 ± 0.06	249.85 ± 1.18	8.33 ± 0.29	0.68 ± 0.08	97.66 ± 0.61
MS4	4.9 ± 0.06	249.50 ± 1.36	8.50 ± 0.50	0.64 ± 0.05	98.69 ± 0.58
MS5	4.7 ± 0.15	249.20 ± 1.44	8.67 ± 0.29	0.56 ± 0.07	98.37 ± 0.62
MS6	4.8 ± 0.06	250.35 ± 1.14	9.00 ± 0.50	0.43 ± 0.05	99.78 ± 0.74
MS7	4.9 ± 0.06	249.50 ± 1.57	8.17 ± 0.29	0.73 ± 0.09	98.93 ± 0.77
MS8	4.8 ± 0.10	250.25 ± 1.37	8.83 ± 0.76	0.51 ± 0.04	98.83 ± 0.67
MS9	4.8 ± 0.12	249.35 ± 1.31	9.17 ± 0.29	0.34 ± 0.02	99.47 ± 0.59

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In Vitro Drug Release Study:

The in vitro drug release profiles of the sustained release matrix tablet formulations (MS1–MS9) were evaluated over a period of 24 hours to assess their controlled release behaviour. All formulations exhibited a gradual increase in drug release with time, indicating effective matrix-controlled release characteristics. At 3 hours, the initial drug release ranged from 3.77 ± 0.43% to 29.36 ± 0.15%, suggesting variation in the release rate among the formulations due to differences in matrix composition. By the end of 24 hours, the cumulative drug release ranged from 78.78 ± 0.91% to 98.48 ± 0.49%, demonstrating successful sustained drug release behaviour from the matrix tablets. Among the tested formulations, MS9 exhibited the highest drug release, while MS1 showed the slowest release profile, indicating that the polymer concentration and matrix composition significantly influenced the release kinetics. Overall, the results confirm that the developed formulations effectively sustained drug release over a 24-hour period, making them suitable candidates for sustained release matrix tablet systems (Figure 2).

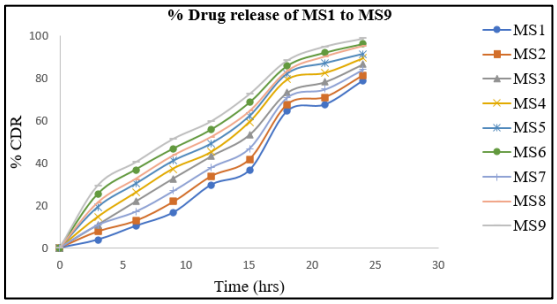

Figure 2: % CDR vs Time of batch MS1 to MS9

STABILITY STUDY:

The comparison of different parameters and In *Vitro* Drug Release of Optimized batch and after 1 months are presented in Table 5 and Figure 3 respectively.

Table 5: Result of the Stability study

Parameters	Optimized batch (MS9)	Optimized batch after 1 month
Thickness (mm)	4.8 ± 0.12	4.8 ± 0.15
Hardness (kg/cm²)	9.17 ± 0.29	9.00 ± 0.00
Drug Content (%)	99.47 ± 0.59	98.03±0.99

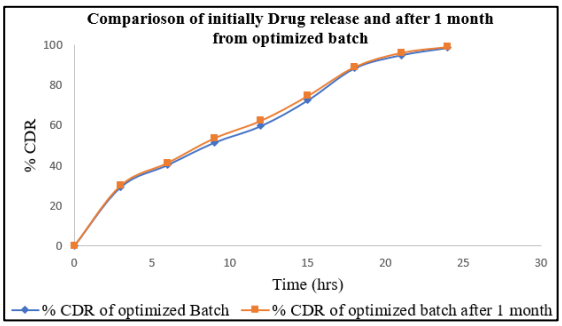

Figure 3: Comparison of % CDR of Optimized batch and Stability batch

CONCLUSION:

This study aimed to develop and evaluate sustained release matrix tablets of Midodrine HCl to prolong drug release and improve therapeutic efficacy in the management of hypotension. Midodrine HCl, an α_1-adrenergic agonist with a short half-life of approximately 3–4 hours, requires multiple daily dosing. Therefore, a sustained release formulation was designed to maintain a prolonged plasma drug concentration and enhance patient compliance.

Sustained release matrix tablets were prepared by the wet granulation method using different hydrophilic polymers, namely Polyox WSR 303, Acrypol 971, and Acrypol 912, in varying concentrations. The prepared powder blends were evaluated for micromeritic properties which indicated satisfactory flow and compressibility suitable for tablet compression. The compressed tablets were further evaluated for thickness, weight variation, hardness, friability, and drug content, and all batches complied with pharmacopeial limits. Among all batches, MS9 showed the highest and most desirable sustained release profile, releasing approximately 98.48% of drug within 24 hours. Stability studies conducted under accelerated conditions (40°C ± 2°C / 75% ± 5% RH) for one month indicated no significant changes in tablet properties or drug release behaviour. Overall, the results demonstrated that hydrophilic polymer-based matrix tablets of Midodrine HCl successfully provided sustained drug release for up to 24 hours, suggesting that the developed formulation could reduce dosing frequency and improve patient compliance in hypotension therapy.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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