

Comparative Study of Various Super disintegrants in the Development and Evaluation of Moxonidine Mouth-Dissolving Tablets

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ABSTRACT: Mouth-dissolving tablets (MDTs) disintegrate quickly in the oral cavity, enhancing patient compliance, particularly in paediatric and geriatric populations. The aim of this study was to formulate MDTs of antihypertensive drug Moxonidine hydrochloride using solid dispersion to improve solubility, mask bitterness, and achieve rapid disintegration and dissolution. Solid dispersions of Moxonidine HCl were prepared and characterized by FT-IR and DSC. MDT formulations (F1–F10) were developed via direct compression with super disintegrants: Sodium starch glycolate (SSG; F1–F5), crospovidone (CP; F6–F10) at varying concentrations (2–7.5%). All formulations exhibited acceptable characterization of powder blend and compressed tablets parameters. *In vitro* dissolution in 6.8 phosphate buffer showed cumulative drug release of 78–98% (SSG) and 78–99% (CP) within 20 min. F5 containing 7.5% sodium starch glycolate also showed a high drug release of 98% at 20 minutes while Formulation F10 (7.5% crospovidone) demonstrated shortest disintegration time, superior taste masking, and highest drug release (99% at 20 min). Drug release kinetics best fitted the first-order model ($R^2 = 0.995$).⁽¹⁻³⁾

KEYWORDS: Super disintegrants, Taste masking, Antihypertensive, Dissolution studies.

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INTRODUCTION

Patient compliance is a crucial aspect of pharmacy practice. To enhance drug effectiveness and reduce side effects, pharmaceutical companies are increasingly developing innovative drug delivery systems. One such move ahead is the development of Mouth Dissolving Tablets (MDTs). These mouth dissolving formulations are designed to rapidly disintegrate quickly in the oral mucosa usually without water or chewing. [Click or tap here to enter text.](#) To improve palatability, these systems often incorporate taste-masking agents for the active pharmaceutical ingredient (API). Once placed in the mouth, the tablet dissolves with the aid of saliva, allowing both the active ingredient and excipients (soluble and insoluble) to be swallowed naturally. This makes MDTs especially suitable for paediatric, geriatric, and dysphagic (swallowing-impaired) patients. Mouth Dissolving Tablets represent a smart, patient-friendly drug delivery method, as they disintegrate, disperse, and dissolve efficiently in the buccal mucosa. This feature improves patient adherence, particularly among those who struggle to swallow conventional dosage form, Mouth dissolving tablets are ideal for drugs with significant first-pass metabolism, enabling a faster onset of action. Upon contact with saliva, MDTs swell and release the active

ingredient, which is then absorbed into the systemic circulation.⁽⁴⁻⁶⁾

Material and Method

Material

Moxonidine HCl was a gift by Micro Labs Pvt. Ltd. (India). Soluplus®, Crospovidone, sodium starch glycolate and other excipients were provided by S.D. Fine Chemicals (Mumbai).

Methods

Pre formulation studies

Several fundamental physical and chemical properties of the drug molecule, and other derived features of the drug powder were identified prior to the development of dosage forms. The pre formulation method is the initial step in the manufacturing of a drug's dosage forms.

Determination of λ_{max} of moxonidine using UV

Spectroscopy A standard stock solution (100 µg/mL) of Moxonidine HCl was prepared by dissolving the drug in phosphate buffer (pH 6.8). The λ_{max} was determined using a JASCO double-

beam UV-Vis spectrophotometer (200–400 nm range; buffer as blank). A calibration curve (2–12 µg/mL) was linear ($R^2 > 0.99$), obeying Beer-Lambert's law.⁽⁹⁻¹⁰⁾

Preparation of Standard Calibration Curve in Phosphate Buffer (pH 6.8)

The sample solution was obtained by dissolving 10 mg of the drug in an appropriate solvent. and adjusting the volume to 100 ml. A series of working standard solutions (2–12 µg/mL) were prepared by suitable dilution of the stock solution. The absorbance of these solutions was measured with a UV-Vis spectrophotometer, using phosphate buffer (pH 6.8) as reference.^(11,12)

Preparation of solid dispersion

The solid dispersions of Moxonidine hydrochloride and soluplus in 1:1 ratio were investigated for their drug content using UV method at 254 nm and the % drug content obtained was 99.2±0.58% w/w. The formulated solid dispersions were found to be uniform in their drug content.

Formulation of mouth dissolving tablets of Moxonidine HCL

The direct compression technique was used to prepare Moxonidine HCl mouth-dissolving tablets. Formulation F1 -F10. Solid dispersions of Moxonidine HCl and Soluplus® (1:1 w/w ratio, chosen based on the optimum drug loading study) to mask the taste. These dispersions were mixed with super disintegrants such crospovidone,, and sodium starch glycolate, as well as other excipients.(Table 1) Before combining, all the components were screened through a 40- mesh sieve. The appropriate portions were weighed, thoroughly combined, and then screened and magnesium stearate was previously passed through an 80-mesh screen. Using a 16-station rotary tablet press with appropriate tools, the final powder blend was pressed into tablets.⁽⁷⁻⁸⁾

Table 1 Formulation of Moxonidine MDT

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Solid Dispersion (drug+polymer)	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Mannitol	66	65	64	63	60.5	66	65	64	63	60.5
Lactose	20	20	20	20	20	20	20	20	20	20
Sodium Starch Glycolate	2	3	4	5	7.5	—	—	—	—	—

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Crospovidone	—	—	—	—	—	2	3	4	5	7.5
Aerosil	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Sodium Saccharine	10	10	10	10	10	10	10	10	10	10
Mg Stearate	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Total Weight (mg)	100	100	100	100	100	100	100	100	100	100

Evaluation parameter of prepared blend

Pre formulation studies were performed to understand the important physicochemical properties of the drug before developing the mouth-dissolving tablet formulation. The drug was examined for its physical appearance, colour, odour, taste, melting point, solubility, pH, moisture content, and loss on drying. The flow and packing properties of the drug powder were also evaluated by determining bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio.^(16,17)

Post compression parameter The prepared tablets were evaluated for appearance, weight variation, thickness, diameter, hardness, friability, wetting time, water absorption ratio, disintegration time, drug content, and in-vitro dissolution USP type II (Paddle type). These tests were performed to assess the physical quality, mechanical strength, uniformity, rapid disintegration, and drug-release behaviour of the formulated mouth-dissolving tablets.⁽¹³⁻¹⁴⁾

Result and discussion

Preformulation studies

The absorption Maximum of Moxonidine was measured by uv visible spectrophotometer and found to be 254 nm. Calibration curve was prepared and linearly regressed The correlation coefficient for standard curve was found to be very near to one which indicate good co linear correlation Between concentration (2–12 µg/mL) Table 2 fig 1

Table 2 Calibration curve of Moxonidine at 254 nm

Concentration (µg/ml)	Absorbance
2	0.243 nm
4	0.449 nm
6	0.680 nm
8	0.904 nm
10	1.114 nm
12	1.330 nm

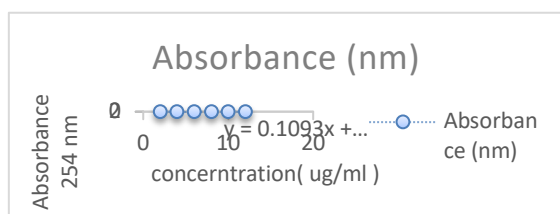


Figure 1 Calibration curve of MOXONIDINE HCL

Pre compression evaluation

The micromeritic test of the tablet formulations showed that the bulk densities were between 0.286 ± 0.01 and 0.408 ± 0.02 g/cc and the tapped densities were between 0.392 ± 0.02 and 0.436 ± 0.01 g/cc. Carr's compressibility indices were between $4.54 \pm 1.08\%$ and $15.54 \pm 1.13\%$, while the angles of repose were between $22.19^\circ \pm 1.22$ and $25.22^\circ \pm 1.06$. These results show that the flow qualities are quite good (Carr index $<15\%$ and $\theta < 30^\circ$), hausner's ratio were 1.01 and 1.07. This indicates that formulation have good flow property. The various results are shown in table 3

Table 3 pre composition parameters

Formulation	Bulk Density (g/cc)	Tapped Density (g/cc)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.296 ± 0.01	0.414 ± 0.01	6.604 ± 1.33	1.076 ± 0.01	22.34 ± 1.36
F2	0.296 ± 0.01	0.425 ± 0.01	5.621 ± 1.23	1.065 ± 0.02	22.19 ± 1.22
F3	0.271 ± 0.02	0.392 ± 0.02	6.076 ± 1.23	1.0125 ± 0.00	22.56 ± 1.13
F4	0.286 ± 0.01	0.409 ± 0.03	5.623 ± 1.22	1.059 ± 0.01	22.44 ± 1.12
F5	0.298 ± 0.01	0.427 ± 0.02	6.792 ± 1.01	1.073 ± 0.01	22.99 ± 1.09
F6	0.402 ± 0.03	0.420 ± 0.03	6.29 ± 1.32	1.06 ± 0.02	22.54 ± 0.84
F7	0.402 ± 0.04	0.420 ± 0.05	15.54 ± 1.13	1.05 ± 0.05	24.32 ± 1.13
F8	0.331 ± 0.01	0.430 ± 0.03	6.71 ± 1.23	1.07 ± 0.07	23.54 ± 0.84
F9	0.378 ± 0.03	0.396 ± 0.02	4.545 ± 1.08	1.047 ± 0.02	22.67 ± 1.12
F10	0.408 ± 0.02	0.436 ± 0.01	6.422 ± 1.03	1.068 ± 0.01	25.22 ± 1.06

Table 4 Post evaluation parameters

Formulation	Weight Variation (%) $\pm$ SD (n=20)	Friability (%) $\pm$ SD (n=20)	Hardness (Kg/cm ²) (n=3)	Thickness (mm) (n=3)	Drug Content (%)	In-vitro Disintegration Time (sec)
F1	99.33 ± 0.28	0.88 ± 0.001	3.5 ± 0.12	4.0 ± 0.11	95.0 ± 0.12	27 ± 0.12
F2	99.33 ± 0.57	0.66 ± 0.03	3.5 ± 0.11	4.2 ± 0.12	97.0 ± 0.11	23 ± 0.25
F3	99.66 ± 0.57	0.48 ± 0.03	4.0 ± 0.13	4.0 ± 0.12	95.3 ± 0.12	29 ± 0.34
F4	99.16 ± 0.28	0.41 ± 0.01	4.5 ± 0.01	4.1 ± 0.13	97.4 ± 0.09	29 ± 0.13
F5	99.33 ± 0.57	0.54 ± 0.01	4.0 ± 0.13	4.0 ± 0.09	95.6 ± 0.11	24 ± 0.11
F6	99.44 ± 0.57	0.55 ± 0.01	3.5 ± 0.10	4.0 ± 0.12	96.0 ± 0.15	22 ± 0.19
F7	99.44 ± 0.57	0.54 ± 0.01	4.0 ± 0.11	4.0 ± 0.02	98.0 ± 0.11	29 ± 0.19
F8	99.44 ± 0.57	0.53 ± 0.01	3.5 ± 0.12	4.0 ± 0.11	96.0 ± 0.16	28 ± 0.19
F9	99.44 ± 0.57	0.55 ± 0.01	3.5 ± 0.12	4.0 ± 0.09	98.0 ± 0.11	26 ± 0.19
F10	99.44 ± 0.57	0.55 ± 0.01	3.5 ± 0.13	4.0 ± 0.08	99.0 ± 0.12	27 ± 0.19

Table 5 Dissolution profile of Moxonidine HCl using superdisintegrants such as sodium starch glycolate and croscopvidone

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
4	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
6	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
8	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04
10	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
12	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06
14	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07
16	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08
18	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09
20	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10

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5	4	5	4	5	6	4	4	4	5
	3	0	5	5	5	0	8	0	8
	±	±	±	±	±	±	±	±	±
	0.	0.	0.	0.	0.	0.	0.	0.	0.
	1	1	2	1	1	3	6	4	3
10	3	2	1	9	6	2	2	1	3
	6	7	6	7	8	7	6	6	7
	8	0	0	5	2	0	8	0	2
	±	±	±	±	±	±	±	±	±
	0.	0.	0.	0.	0.	0.	0.	0.	0.
15	1	2	2	2	1	5	1	3	3
	5	1	3	3	4	1	4	4	5
	7	7	8	8	9	7	7	7	8
	0	6	0	0	2	5	5	5	6
	±	±	±	±	±	±	±	±	±
20	0.	0.	0.	0.	0.	0.	0.	0.	0.
	1	1	1	1	2	3	2	3	1
	1	5	3	7	3	4	3	1	5
	7	8	9	9	9	7	7	7	8
	8	5	0	0	8	8	6	7	1
20	±	±	±	±	±	±	±	±	±
	0.	0.	0.	0.	0.	0.	0.	0.	0.
	2	2	1	1	1	2	3	2	4
	3	3	0	3	1	3	4	2	2
									6

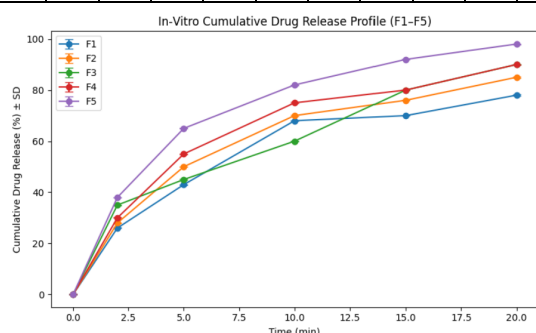


Figure dissolution study F1-F5

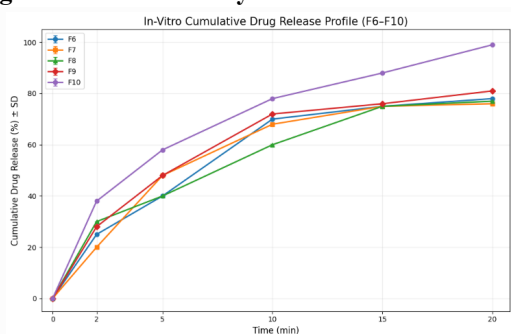


Figure 3 Dissolution profile F6-F10

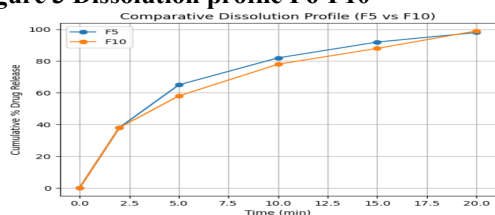


Figure 4 dissolution study compression F5 And F10

Conclusion

The present study successfully demonstrated the feasibility of developing **Moxonidine**

hydrochloride mouth-dissolving tablets (MDTs) using different superdisintegrants by the direct-compression method. The Moxonidine HCl–Soluplus® solid dispersion prepared in a 1:1 ratio showed a high drug content of $99.2 \pm 0.58\%$, supporting its suitability for incorporation into the MDT formulations. The pre-compression studies indicated satisfactory flow and packing characteristics of the formulation blends, while the prepared tablets exhibited acceptable physical and mechanical properties.

A comparative evaluation of **sodium starch glycolate (F1–F5) and crospovidone (F6–F10)** demonstrated that the type and concentration of superdisintegrant influenced the disintegration and dissolution behaviour of the MDTs. Among all formulations, **F10 containing 7.5% crospovidone** showed the best overall performance, with a **disintegration time of 27 ± 0.19 seconds**, **drug content of $99.0 \pm 0.12\%$** , and **99% cumulative drug release within 20 minutes**. F5 containing 7.5% sodium starch glycolate also showed a high drug release of 98% at 20 minutes.

The findings indicate that crospovidone, particularly at the optimized concentration used in F10, provided a more favourable balance between rapid tablet disintegration and drug dissolution compared with the sodium starch glycolate formulations. The enhanced performance of F10 suggests that appropriate selection and concentration of superdisintegrant can be an important formulation variable for achieving rapid drug release from Moxonidine MDTs.

Overall, F10 can be considered the optimized formulation in the present study and provides a promising formulation approach for the development of Moxonidine mouth-dissolving tablets. However, further studies such as stability testing, detailed taste evaluation, and in-vivo pharmacokinetic/bioavailability studies would be required to establish its long-term stability and clinical performance.

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