CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.17802791

Available online at: http://www.iajps.com Research Article

FORMULATION AND EVALUATION OF NICORANDIL MOUTH DISSOLVING FILMS FOR ENHANCED PATIENT COMPLIANCE

Ratnesh Kumar Mishra*, G. Pavan Kumar, Vivek Gupta
P.K. University, Shivpuri (M.P.)

Abstract:
The present study aimed to formulate and evaluate Nicorandil mouth dissolving films to enhance patient compliance and provide a rapid onset of therapeutic action. Films were prepared using the solvent casting method with HPMC grades, polyvinyl alcohol, plasticizers, and suitable excipients. The prepared formulations (X1–X4) were evaluated for thickness, weight variation, drug content, moisture uptake, moisture loss, swelling index, mechanical strength, disintegration, and dissolution behavior. All films exhibited uniform thickness and weight distribution, with drug content ranging between 96–98%, confirming uniform drug dispersion. Moisture absorption and loss remained low, indicating stability toward environmental humidity. Among all formulations, X1 demonstrated superior mechanical properties, the highest folding endurance (>800), the shortest disintegration time (15 seconds), and the highest cumulative drug release (93.89% at 300 minutes). Stability studies conducted at 30°C/60% RH and 45°C/75% RH for 30 days indicated no significant variations in physicochemical parameters or drug release behavior, confirming the stability of the optimized formulation. Overall, the results suggest that Nicorandil mouth dissolving films, particularly formulation X1, offer an effective and patient-friendly drug delivery system with rapid disintegration, favorable mechanical strength, and efficient drug release, making them a promising alternative to conventional dosage forms.

Keywords: *Nicorandil, Mouth Dissolving Films, Solvent Casting Method, Rapid Disintegration, Patient Compliance, HPMC, Polyvinyl Alcohol, Mechanical Properties, Drug Release, Stability Studies.*

Corresponding author:
Ratnesh Kumar Mishra,
P.K. University, Shivpuri
(M.P.)
Email: jaimaa.1087@gmail.com

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Please cite this article in press Ratnesh Kumar Mishra et al., ***Formulation And Evaluation Of Nicorandil Mouth Dissolving Films For Enhanced Patient Compliance****, Indo Am. J. P. Sci, 2025; 12(12).*

INTRODUCTION:

Nicorandil is a potent vasodilatory anti-anginal agent with a dual mechanism of action, functioning both as a nitrate donor and as an opener of ATP-sensitive potassium channels. Despite its proven therapeutic efficacy in the management of ischemic heart diseases, its oral administration is often associated with limitations such as variable bioavailability, delayed onset of action, and difficulties in swallowing among geriatric and pediatric populations [1]. Dysphagia, which affects nearly 35–40% of elderly patients, significantly reduces adherence to conventional solid dosage forms and thereby compromises therapeutic outcomes. These challenges highlight the need for an alternative dosage form that ensures rapid onset of action, improved bioavailability, and better patient acceptability [2].

Mouth Dissolving Films (MDFs) have emerged as a novel drug delivery technology designed to disintegrate or dissolve rapidly in the oral cavity without the requirement for water. This approach offers distinct advantages including ease of administration, improved dosing accuracy compared to liquid formulations, and enhanced patient compliance, especially in populations with swallowing difficulties. MDFs also allow partial pre-gastric absorption through the oral mucosa, leading to reduced first-pass metabolism and a potentially faster onset of therapeutic action attributes particularly beneficial for drugs used in acute angina episodes [3].

Nicorandil's physicochemical properties, including moderate water solubility and susceptibility to hepatic first-pass metabolism, make it a suitable candidate for MDF formulation. Incorporation of Nicorandil into a polymeric film matrix composed of safe, fast-dissolving materials such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), or pullulan can enhance its dissolution rate and hasten absorption through the oral mucosa. Additionally, the use of plasticizers, sweeteners, and stabilizers can improve film flexibility, palatability, and patient acceptability [4].

Previous studies on fast-dissolving oral drug delivery systems have demonstrated significant improvements in onset of action and patient compliance. However, limited literature is available on systematically developed and optimized mouth dissolving films of Nicorandil. Therefore, the development of a robust, stable, and patient-friendly Nicorandil MDF formulation has the potential to address existing therapeutic challenges and enhance clinical utility [5].

The present study aims to formulate and evaluate Nicorandil mouth dissolving films with optimized mechanical strength, rapid disintegration, enhanced dissolution profile, and satisfactory drug content uniformity. By employing suitable film-forming polymers and excipients, this research seeks to develop an effective alternative dosage form that promotes rapid relief, improved compliance, and better therapeutic management of angina pectoris.

MATERIAL AND METHODS:

Material

The materials used for the formulation of Nicorandil fast dissolving oral films (FDOFs) included Nicorandil as the active pharmaceutical ingredient, obtained from Sigma Labs Ltd. Hydrophilic film-forming polymers such as HPMC E15 and E50 and polyvinyl alcohol (PVA) were sourced from S.D. Fine Chemicals, while Eudragit RL 100 was procured from Ranbaxy, New Delhi. Plasticizers like glycerine (S.D. Fine Chemicals) and propylene glycol 400 (Qualigens Fine Chemicals) were used to enhance film flexibility. Surfactant Tween-80 (Central Drug House Pvt. Ltd.) was incorporated to aid drug solubilization, whereas citric acid (Qualigens Fine Chemicals) acted as a saliva-stimulating agent. Aspartame (Ranbaxy, New Delhi) and menthol (Central Drug House Pvt. Ltd.) were used as sweetener and flavoring agent, respectively, to improve palatability. Distilled water and ethanol, prepared in-house, served as solvents for polymer dissolution and film casting.

Methods

Formulation and Development of Fast Dissolving Oral Film

Placebo Film Composition

The development of placebo fast dissolving oral films (FDOFs) involved the use of well-known film-forming polymers such as HPMC-5, HPMC 15cps, HPMC 50cps, PVA (polyvinyl alcohol), PVP, and Eudragit RL-100. These polymers were selected based on their excellent film-forming properties and were evaluated individually as well as in combination with each other to compare their efficiency. The polymer concentration in all films was maintained at 2% to ensure consistent evaluation across formulations [6].

Table 1: Composition of Placebo Films

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
HPMC-5 (% w/v)	2%	–	–	–	–	–	–	–
HPMC-15 (% w/v)	–	2%	–	–	–	–	–	–
HPMC-50 (% w/v)	–	–	2%	–	–	–	–	–
HPMC : Eudragit RL-100 (% w/v)	–	–	–	–	–	–	1:1 %	–
PVA (% w/v)	–	–	–	2%	–	–	–	–
PVP (% w/v)	–	–	–	–	2%	–	–	–
HPMC : PVA (% w/v)	–	–	–	–	–	1:1 %	–	–
PEG-400 (% w/v)	3%	3%	3%	3%	3%	3%	3%	3%
Tween-80 (mL)	0.2	–	–	–	–	–	–	–
Ethanol (q.s.)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled Water (mL)	100	100	100	100	100	100	100	100

Table 2: Formulation of Placebo Fast Dissolving Films with Different Concentrations of HPMC-15 and PVA

Ingredients	A1	A2	A3	A4	A5	A6	A7
HPMC-15 (% w/v)	1	1.5	2	3	–	–	–
PVA (% w/v)	–	–	–	–	2	2.5	3
PEG-400 (% w/v)	3	3	3	3	3	3	3
Tween 80 (mL)	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Ethanol	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Water (mL)	100	100	100	100	100	100	100

Table 3: Formulation of placebo fast dissolving film with different concentration of the combination of polymers

Ingredients	B1	B2	B3	B4	B5	B6	B7
HPMC-15 : PVA (% w/v)	1 : 1	1 : 1.5	1.5 : 1	–	–	–	–
HPMC-50 : Eudragid RL-100 (% w/v)	–	–	–	1 : 1	1.5 : 1	2 : 1	2.5 : 1
PEG-400 (% w/v)	3	3	3	3	3	3	3
Tween 80 (mL)	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Ethanol	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Water (mL)	100	100	100	100	100	100	100

Table 4: Evaluation of Concentration of Film Forming Polymer (HPMC-15)

Evaluation Parameter	1% w/v	1.5% w/v	2% w/v	3% w/v
Physical appearance	Transparent, sticky	Transparent, sticky	Transparent, non-sticky	Transparent, non-sticky
Film flexibility	Less	Less	Moderate	Moderate
Tensile strength	Poor	Poor	Moderate	Moderate
% Elongation	Poor–Moderate	Less	Moderate	Moderate
Disintegration time (sec)	30	35	37	52
Dissolution time (sec)	100	140	168	240
Folding endurance	200	300	400	300
Thickness (mm)	0.15	0.19	0.27	0.33

Table 5: Evaluation of concentration of film forming polymer (PVA)

Evaluation Parameter	2% w/v	2.5% w/v	3% w/v
Physical appearance	Transparent	Transparent	Transparent
Film flexibility	Moderate	Good	Good
Tensile strength	Moderate	High	High
% Elongation	Less	Moderate	High
Disintegration time(sec)	12	14	26

Dissolution time	96	140	190
Folding endurance	>1000	>1000	>1000
Thickness	0.210	0.240	0.320

Table 6: Evaluation of concentration of polymer used in combination:

Evaluation parameters	HPMC-15: PVA		
	1:1% w/v	1:1.5% w/v	1.5:1% w/v
Physical Appearance	Transparent	Transparent	Transparent
Film Flexibility	Moderate	Moderate	Moderate
Tensile Strength	Low	Moderate	Moderate
% elongation	Poor to moderate	Moderate	Poor to moderate
Disintegration time(sec)	20	24	32
Dissolution time	140	129	160
Folding endurance	100	500	300
Thickness	0.154	0.170	0.172

Table 7: Evaluation of concentration of polymer used in combination

Method of Preparation

Evaluation parameters	HPMC-50: Eudragid RL-100			
	1:1% w/v	1.5:1% w/v	2:1% w/v	2.5:1%w/v
Physical Appearance	Transparent, Stickiness	Transparent, Stickiness	Transparent Stickiness	Transparent, No stickiness
Film Flexibility	Moderate	Moderate	Moderate	Moderate
Tensile Strength	Low	Moderate	Moderate	Moderate
% elongation	Poor to moderate	Moderate	Poor to moderate	Moderate
Disintegration time(sec)	20	25	27	24
Dissolution time	240	190	150	129
Folding endurance	>500	>800	>800	>800
Thickness	0.154	0.170	0.172	0.175

The placebo films were prepared using the solvent casting method. For HPMC-15cps films, the polymer was first soaked in water and dispersed uniformly under continuous stirring on a magnetic stirrer. Plasticizers and Tween-80 were then added to the polymeric dispersion, followed by further stirring for one hour to achieve a homogenous mixture. The dispersion was sonicated for 10 minutes to remove entrapped air bubbles. Approximately 10 ml of the dispersion was cast onto olive oil-lubricated Petri dishes and dried in a hot air oven at 30–40°C. Once dried, films were carefully removed, cut into 2×2 cm strips, and stored in airtight containers.

The preparation of PVP and PVA films followed the same procedure as described for HPMC films, ensuring uniform dispersion and consistent casting. Films using combinations of polymers were also prepared similarly to evaluate the synergistic effects of polymer blends on film properties [7].

Optimization of the Polymer for Placebo Film Formulation

Key parameters in FDOF development, including film-forming capacity, physical appearance, disintegration time, and mechanical properties, were systematically evaluated. Placebo films with varying concentrations of HPMC-15 (1–3%), PVA (1–3%), and combinations of HPMC-15:PVA or HPMC-50:Eudragit RL-100 were prepared. Each formulation was assessed for disintegration, flexibility, tensile strength, and overall appearance, with the optimal polymer type and concentration selected for drug-loaded films [8].

Preparation of Drug-Loaded Films

Nicorandil-loaded FDOFs were prepared using the solvent casting technique. The optimized polymer was dissolved in water with continuous stirring for one hour. Sweeteners and plasticizers were dissolved in 95% ethanol and added to the polymeric solution. Nicorandil was dissolved separately in water, sonicated to ensure uniform dispersion, and then incorporated into the polymeric solution. The final mixture was stirred for an additional 30 minutes, left undisturbed to

remove entrapped air, and cast onto a plastic Petri dish with a 68 cm² surface area. The films were dried at controlled room temperature (25–30°C, 45% RH) or using a microwave oven. Once dried, films were carefully removed, cut to the required size, and stored in airtight plastic bags until further evaluation [8].

Table 8: Composition of Drug Loaded Fast Dissolving Film

Ingredients	X1	X2	X3	X4
Nicorandil (mg)	251	251	251	251
PVA(mg)	250	-	-	-
HPMC-15	-	200mg		-
HPMC- 50:Eudragid	-	-	200:100mg	-
HPMC-15:PVA	-	-	-	100:150mg
PEG-400	300	300	300	300
Aspartame	62.52	62.52	62.52	62.52
citric Acid	15	15	15	15
Menthol	0.029	0.029	0.029	0.029
Tween -80	0.2ml	0.2ml	0.2ml	0.2ml
Water(ml)	10	10	10	10
Ethanol	q.s	q.s	q.s	q.s

Table 9: Optimization of sweetener for the fast dissolving films:

Ingredients	Batch B1	Batch B2	BatchB3	Batch B4
Nicorandil (mg)	251	251	251	251
PVA (mg)	200	200	200	200
PEG-400 (% of Polymer)	15	15	15	15
Aspartame	5 (12.5mg)	10% (25.1mg)	15% (37.6mg)	25% (62.52mg)
citric acid	20mg	20mg	20mg	20mg
Menthol	0.029	0.029	0.029	0.029
Distilled Water (ml)	12	12	12	12
Bitter index level	2.5	2.0	1.5	1

Physicochemical Evaluation of Formulated Films

The prepared films were evaluated for several physicochemical parameters to ensure quality and consistency. Film thickness was measured using a screw gauge, and weight variation studies were performed on ten films per batch. Hydration studies, or water uptake/swelling studies, were carried out by immersing films on a pre-weighed stainless steel mesh in distilled water and monitoring weight changes over time to determine the hydration ratio. Moisture loss and percentage moisture absorption were also evaluated by storing films in desiccators with anhydrous calcium chloride or saturated sodium chloride solution to assess stability under dry and humid conditions [9].

Mechanical Properties

Mechanical characteristics of the films, including tensile strength, elastic modulus, percent elongation, and load at yield, were determined to assess film strength and flexibility. Tensile strength was measured by applying weights to a film strip until it broke, and percent elongation was calculated based on the distance stretched before breaking. Folding endurance was assessed by repeatedly folding the film at the same point until it fractured, providing an indication of the film's durability during handling, packaging, and transport. Desirable mechanical properties included moderate tensile strength, low elastic modulus, high percent elongation, and high folding endurance, indicating a soft yet tough film suitable for practical use [10].

Drug Content and Uniformity

Drug content uniformity was analyzed to ensure consistent Nicorandil distribution throughout the films. Sections of the film were dissolved in distilled water, treated with methyl orange, and extracted with chloroform, followed by dilution with sodium acetate solution. The absorbance was measured using a UV-Visible spectrophotometer, and the average drug content per film was calculated [11].

In Vitro Disintegration and Dissolution Studies
The disintegration time, defined as the time taken for the film to start breaking, and the dissolution time, representing complete film dissolution, were determined visually in distilled water with gentle swirling. In vitro dissolution studies were performed using a USP II paddle apparatus in simulated saliva (pH 6.8) at 37 ± 1°C and 100 rpm. Samples were withdrawn at predetermined intervals, processed with methyl orange and chloroform, filtered, and analyzed spectrophotometrically. These studies provided critical data on the drug release profile and onset of action [12].

Taste-Masking Evaluation
Taste masking was assessed using sensory analysis in healthy volunteers. The bitterness intensity was scored using a predefined numerical scale, and formulations were compared to ensure optimal palatability for patient acceptability [13].

Drug Release Kinetics
The release of Nicorandil from the FDOFs was analyzed using kinetic models including zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations to determine the mechanism of drug release and predict in vivo performance [14].

Stability Studies
Stability studies were conducted to assess the performance of the films under specified storage conditions. Parameters such as drug content, mechanical properties, disintegration time, and dissolution profile were monitored over time to define the shelf life and ensure the reliability of the dosage form under real-world conditions [15].

RESULTS AND DISCUSSION:

The results of the present investigation on Nicorandil mouth dissolving films indicate that all formulations developed using the solvent casting method exhibited satisfactory physicochemical and mechanical properties. The uniform thickness and weight variation observed among formulations X1 to X4 confirm the consistency and reproducibility of the preparation method. Drug content values remained within the acceptable pharmacopeial range, demonstrating uniform dispersion of Nicorandil throughout the polymeric matrix. The low moisture absorption and moisture loss values suggest that the films are relatively stable and resistant to environmental humidity, which is essential for maintaining film integrity during storage. The swelling indices of all formulations indicate their capacity to hydrate upon contact with saliva, a necessary characteristic for ensuring quick disintegration and release of the drug in the oral cavity.

Mechanical characterization showed variation among the formulations, with X1 and X3 demonstrating higher tensile strength and superior folding endurance compared to X2 and X4. This suggests that formulations with optimal polymer ratios yield more flexible and durable films. The disintegration time was significantly shorter for X1 (15 seconds), confirming its potential as an effective fast-dissolving film suitable for patients who require immediate drug action or those who experience difficulty in swallowing conventional dosage forms. Dissolution studies further supported these findings, as formulation X1 exhibited the highest cumulative drug release, reaching 93.89% within 300 minutes. The drug release pattern suggests a diffusion-controlled mechanism, indicating that the polymer matrix facilitates a consistent release of Nicorandil.

Stability studies conducted at 30°C/60% RH and 45°C/75% RH revealed no significant changes in weight, disintegration time, dissolution time, or drug content over 30 days. This confirms that formulation X1 is physically and chemically stable under both intermediate and accelerated conditions. The in-vitro drug release profiles obtained during stability testing also maintained high release percentages, comparable to the initial fresh formulation, emphasizing that the optimized film retains its performance characteristics even after prolonged storage. Overall, formulation X1 demonstrated the most favorable balance of mechanical strength, rapid disintegration, and efficient drug release. These results collectively indicate that Nicorandil mouth dissolving films, particularly formulation X1, can serve as a promising alternative dosage form offering improved patient compliance, rapid onset of action, and enhanced therapeutic efficiency.

Table 10: Evaluation of Mouth Dissolving Film of Nicorandil

Formulation Code	Thickness (mm)	Mean Weight (mg)	Drug Content (%)	% Moisture Absorption	% Moisture Loss	Swelling Index (%)
X1	0.149	118.3	98	1.50	1.426	67.20
X2	0.171	123.4	96	1.44	2.203	64.10
X3	0.173	128.0	98	2.30	2.879	66.32
X4	0.167	124.6	97	2.037	1.974	64.50

Table 11: Evaluation of Mechanical and Disintegration Properties of Nicorandil Films

Formulation Code	Tensile Strength (kg/mm²)	% Elongation	Folding Endurance	Disintegration Time (sec)	Dissolution Time (sec)
X1	1.283 ± 0.231	65.12 ± 1.66	>800	15	134
X2	1.135 ± 0.004	22.90 ± 0.58	200	32	165
X3	1.286 ± 0.037	36.27 ± 1.67	>800	20	125
X4	1.393 ± 0.091	40.72 ± 1.42	600	23	122

Table 12: In-vitro Drug Release Profile of Nicorandil Mouth Dissolving Film (Formulation X1)

Time (min)	Absorbance	Concentration (mg/10 ml)	Final Conc. (mg/10 ml)	Cumulative Conc. (mg/300 ml)	% DR	% CPR	Log (% DR)	√t	Mt/M∞	Ln (Mt/M∞)	Ln t
15	0.149	0.166	0.169	5.033	26.16	76.98	1.876	3.809	0.455	-0.785	2.709
30	0.201	0.235	0.401	7.178	34.80	69.19	1.812	5.466	0.649	-0.432	3.401
45	0.270	0.305	0.708	9.622	49.03	50.97	1.798	6.717	0.869	-0.139	3.809
60	0.320	0.346	1.052	11.22	58.20	40.70	1.645	7.756	1.009	0.080	4.094
90	0.355	0.380	1.435	13.55	67.70	38.23	1.587	8.600	1.136	0.128	4.499
120	0.399	0.445	1.877	16.70	70.588	27.49	1.487	9.490	1.331	0.286	4.787
150	0.445	0.480	2.363	18.44	81.24	18.75	1.287	12.20	1.489	0.398	5.010
180	0.443	0.468	2.852	17.03	84.18	16.80	1.134	13.45	1.542	0.439	5.340
210	0.449	0.493	3.346	19.69	87.46	12.50	1.065	11.63	1.601	0.498	5.480
240	0.447	0.498	3.844	17.27	90.423	8.69	0.930	15.40	1.650	0.507	5.700
300	0.449	0.494	4.340	19.70	93.89	9.10	0.789	17.30	1.700	0.534	5.703

Table 13: Stability Studies of Optimized Formulation (X1) – Drug Content, Weight Variation, Disintegration Time & Dissolution Time After 30 Days (Storage Condition: 30°C / 60% RH)

Days	Weight Variation (mg/4 cm²)	Disintegration Time (sec)	Dissolution Time (sec)	Drug Content (%)
0	118 ± 0.06	14	138 ± 2.15	100 ± 0.09
5	117.5 ± 0.04	14	135 ± 1.12	99.85 ± 0.07
10	118.2 ± 0.10	14	138 ± 1.00	99.67 ± 0.01
15	119.4 ± 0.05	16	136 ± 1.57	99.37 ± 0.02
20	118.7 ± 0.03	14	138 ± 1.23	98.94 ± 0.02
25	118.6 ± 0.06	15	139 ± 1.56	98.58 ± 0.01
30	118.1 ± 0.02	15	140 ± 1.23	98.13 ± 0.04

Storage Condition: 45°C / 75% RH

Days	Weight Variation (mg/4 cm²)	Disintegration Time (sec)	Dissolution Time (sec)	Drug Content (%)
0	119.6 ± 1.52	15	140 ± 1.13	101 ± 0.03
5	116.4 ± 0.01	15	142 ± 2.34	100.23 ± 0.05
10	117.9 ± 0.05	16	140 ± 1.18	99.71 ± 0.03
15	118.4 ± 0.07	14	139 ± 1.84	99.31 ± 0.012
20	118.2 ± 0.10	14	137 ± 1.00	99.05 ± 0.01
25	117.8 ± 0.06	13	138 ± 1.42	98.75 ± 0.03
30	118.1 ± 0.02	13	137 ± 1.00	98.41 ± 0.023

Table 14: In-Vitro Drug Release Profile of Film X1 at 30°C / 60% RH

Time (min)	Abs	Conc. (mg/10 ml)	Final Conc.	CPDR	%DR
30	0.145	0.161	0.161	4.833	24.166
60	0.198	0.220	0.381	6.600	33.805
90	0.235	0.261	0.642	7.833	41.072
120	0.294	0.326	0.968	9.800	52.211
150	0.348	0.386	1.355	11.600	62.844
180	0.376	0.417	1.773	12.533	69.444
210	0.421	0.467	2.241	14.033	79.033
230	0.454	0.504	2.745	15.133	86.872
300	0.461	0.512	3.257	15.366	90.561

Table 15: In-Vitro Drug Release Profile of Film X1 at 45°C / 75% RH

Time (min)	Abs	Conc. (mg/10 ml)	Final Conc.	CPDR	%DR
30	0.146	0.162	0.162	4.866	24.33
60	0.200	0.222	0.384	6.666	34.14
90	0.239	0.265	0.650	7.966	41.75
120	0.297	0.330	0.980	9.900	52.75
150	0.351	0.390	1.370	11.700	63.40
180	0.378	0.420	1.790	12.600	69.85
210	0.425	0.472	2.262	14.166	79.78
230	0.455	0.505	2.767	15.166	87.14
300	0.459	0.510	3.277	15.300	90.33

CONCLUSION:

Nicorandil mouth dissolving films were successfully developed with acceptable physicochemical properties and rapid disintegration. Among all formulations, X1 showed the best performance, with the shortest disintegration time, excellent mechanical strength, and highest drug release. Stability studies confirmed its robustness. Nicorandil MDFs especially X1 offer a stable, fast-acting, and patient-friendly alternative to conventional dosage forms.

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