

Formulation and in Vitro Evaluation of Niacin 500 Mg Extended Release Tablets

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ABSTRACT

The study aimed to develop and optimize Niacin 500 mg extended release (ER) tablets to address challenges associated with conventional formulations, such as frequent dosing and adverse effect like flushing and hepatotoxicity. The novelty of the work lies in designing ER tablets using hydroxypropyl methylcellulose (HPMC) E10M and K15M polymers, comparing direct compression and wet granulation methods. Wet granulation with HPMC E10M was identified as superior based on in vivo dissolution and other evaluation parameters. A systematic formulation approach explored varying concentrations of polymer, binder, and lubricant across different batches (F1 to F13) to obtain optimal drug release profiles. F3 formulation demonstrated a gradual and extended release, closely matching the marketed product (MP) in in vitro dissolution equivalence studies with dissimilarity factor (f1) and similarity factors (f2) of 4.15% and 78.87%, respectively. Stability testing over two months under accelerated conditions confirmed the robustness of the optimized formulation, with consistent in vitro dissolution and physical attributes. Finally, the study successfully established a formulation for Niacin ER tablets (F3) that offers extended release, improved patient compliance, and less side effects, making it promising alternative for dyslipidemia management.

Keywords: Niacin, Extended Release (ER), Hydroxypropyl Methylcellulose (HPMC), Polyethylene Oxide (PEO), Dyslipidemia.

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INTRODUCTION

Niacin (Nicotinic acid), when used as vitamin (Vitamin B3), is typically prescribed in lower doses, ranging from 14 or 18 mg daily, to prevent deficiencies like pellagra. However, in the treatment of hyperlipidemia, much higher doses are required, usually between 500-2000 mg daily, to effectively reduce cholesterol and triglyceride levels. To manage the side effects associated with these higher doses, Niacin is often formulated as an extended release (ER) tablet. Immediate release Niacin is known to cause side effects such as flushing, a vasodilatory response triggered by prostaglandins, and gastrointestinal discomfort, both of which are related to rapid increases in plasma concentrations. ER formulations address the issue by releasing Niacin gradually, minimizing side effects while maintaining its therapeutic action. Given Niacin's short half-life of around 1-2 hours, frequent dosing with immediate release form is required, which can affect patient adherence. ER tablets, however, provide sustained plasma concentrations, enabling once daily dosing

improving patient compliance. Additionally, ER formulations help reduce the risk of hepatotoxicity, as the high plasma peaks associated with immediate release Niacin, which can lead to liver enzyme elevation, are avoided. ER Niacin works in sync with body's natural process of producing cholesterol, which peaks at night, making it super effective at lowering lipid, increasing lipid lowering effect. With controlled absorption and a reduction in harmful metabolites, ER Niacin offers a better tolerated and more effective solution for managing hyperlipidemia, enhancing both clinical outcomes and patient care^{1,2,3}.

In the current study, Niacin ER tablets were designed initially by choosing direct compression method with the use of two hydroxypropyl methyl cellulose (HPMC) grades- E10M and K15M. And found HPMC E10M as best grade to formulate niacin ER tablets based on *in vitro* evaluation, and then Niacin ER tablets with HPMC E10M was supposed to prepare by wet granulation method and to

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compare with poly ethylene oxide (PEO WSR N60K). Niacin ER tablets with HPMC E10M were found to be best compared to Niacin ER tablets with PEO WSR N60K based on *in vitro* evaluation tests. Finally, the formula was optimized by considering various concentrations of HPMC E10M as intra-granular and extra-granular polymer, various concentrations of polyvinylpyrrolidone (PVP K90) as binder and various concentrations of stearic acid as a lubricant. The final optimized formula was selected based on performed *in vitro* evaluation tests and compared with marketed formulation (MP) for *in vitro* equivalency, and the methodology for the same as follows,

METHODS

UV analytical method

A stock solution of Niacin (1000 µg/ml) was prepared by dissolving 10 mg in 10 ml deionized water. Dilution were made to obtain concentration of 5, 10, 15, and 25 µg/ml. The λ_{max} was determined by scanning the 15µg/ml solution (200-400 nm) using a UV spectrophotometer. Absorbance values were then measured for all concentrations, and a linearity curve was plotted (concentration vs. Absorbance, Fig.No. 1).

Formulation of Niacin ER Tablet

Table.1. Formulation Table for Niacin 500 mg Extended Release Table

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Niacin	500	500	500	500	500	500	500	500	500	500	500	500	500
HPMC (E10M)	185	-	57	-	67	47	37	57	57	57	57	57	57
HPMC (K15M)	-	185	-	-	-	-	-	-	-	-	-	-	-
PEO (WSR N60K)	-	-	-	57	-	-	-	-	-	-	-	-	-
Povidone (K90)	18	18	18	18	18	18	18	18	18	13	23	18	18
PEO (WSR N60K Extra-granular)	-	-	-	128	-	-	-	-	-	-	-	-	-
HPMC (E10M Extra-granular)	-	-	128	-	118	138	148	98	148	128	128	128	128
Stearic Acid	7	7	7	7	7	7	7	7	7	7	7	2	12
Total Weight (mg)	710	710	710	710	710	710	710	680	730	705	715	705	715

The tablets were prepared using both methods, direct compression and wet granulation, and compared both two methods to choose best method among. Direct compression method is an economical method for tablet and wet granulation method is a suitable method for preparation of ER tablets. Because wet granulation method produces granules with great moisture content, this moisture content enhance compactness of tablet and results tablet with great hardness. Hardness decreases dissolution and by that rate of dissolution, hence extends drug release for extended period. So both the methods were used for tableting and one method was chosen based on in vitro evaluation parameters, and for the chosen method the formula was optimized by designing tablets with the design of Niacin ER tablets with various concentrations of polymers, binder and lubricant^{6,7}. The design of Niacin ER tablets was as follows,

The development of Niacin ER tablets involved the creation of multiple formulations, starting with F1 and F2, which utilized HPMC E10M AND HPMC K15M as polymers to achieve extended drug release. These formulations incorporated with PVP K90 as binder and stearic acid as lubricant. The quantities and proportions of each ingredient in these formulations are outlined in the formulation Table 1.

Formulations F3 and F4 were developed to enhance the extended release of Niacin using HPMC E10M and PEO WSR N60K polymers. These were manufactured through the wet granulation method, Niacin, HPMC E10M/ PEO WSR N60K, and PVP K90 polymers served as intra-granular agents. HPMC E10M/ PEO WSR N60K and stearic acid served as extra granular agents, and the concentration and proportions of all ingredients used were shown in the formulation Table 1. All the ingredients were selected after physical compatibility studies.

In formulation F5 to F13, a series of modifications were carried out to optimize the ER profile of Niacin ER tablets. Formulations F5 through F9 focused on varying the concentrations of HPMC E10M used as extra-granular polymer. Formulations F10 and F11 explored different levels of PVP K90 as the binder, and F12 and F13 adjusted the stearic acid concentrations. These systemic evaluations helped in finalizing an optimized formula for the Niacin ER tablets, and the concentration and proportions of all ingredients used were shown in the formulation Table 1.

Procedure for Direct compression method (F1 & F2)

Required quantity of Niacin, HPMC E10M/ HPMC K15M, PVP K 90 and stearic acid were passed separately through sieve number #36. Initially, drug (Niacin), polymer (HPMC E10M/ HPMC K15M), and binder (PVP K90) were placed in a poly bag and mixed for three minutes. Then, stearic acid was added to the above mix and lubricated for two minutes, and compressed as tablet by weighing one individual tablet equal weight using 16-station Cadmach compression machine^{8,9}.

Procedure for Direct compression method (F1 & F2)

Required quantity of all ingredients drug (Niacin), polymer (HPMC E10M/ PEO WSR N60K), binder (PVP K90), and stearic acid were separately passed through the sieve number #36. Initially, drug (Niacin), polymer (HPMC E10M/ PEO WSR N60K), and binder (PVP K90) were placed in a mortar and finely grounded. The mix was prepared as a dough-like consistency was achieved by adding a controlled amount of water, the mixture was then pushed through #20 sieve to create uniform granules. These granules were subsequently dried at 60°C for 45 minutes to remove excess moisture & passed through sieve number #22, and lubricated with stearic acid for two minutes in a poly bag. One tablet equivalent weight of granules were weighed and compressed as tablet with the use of 16 station compression machine^{10,11}.

Evaluation of Niacin ER Tablets

Pre compression evaluation

The Niacin ER tablet mixes underwent pre-compression testing, including evaluation of bulk density, compressibility, tapped density, angle of repose, & Hausner's ratio^{12,13}. findings are presented in Table 3.

Post compression evaluation

The Niacin ER tablet mixes were subjected to the post compression tests such as hardness, thickness, friability, tablet weight & assay^{14,15}. The results were shown in Table 4.

In vitro drug dissolution test studies

The dissolution profiles of niacin 500 mg ER tablets (various formulations) and a marketed product (MP) were evaluated over 24 hours in deionized water using USP apparatus 1(basket).Dissolution medium used was 900 ml deionized water maintaining temperature 37°C ± 0.5°C with agitation speed 100rpm.sampling intervals were 1,3,6,9,12,16,20 and 24 hours with sample volume 10 ml (replaced with fresh medium).the samples were analyzed using UV spectrophotometer at 260 nm wavelength^{16,17} to determine the cumulative percentage of drug released.

$$\text{Cumulative \% drug released} = [(A_T/A_S) \times (D_S/D_T) \times 100]$$

Where, A_T – absorbance of test, A_S- absorbance of standard, D_T- dissolution of test and D_S- dissolution of standard. Results were showed in Table 5.

In vitro pharmacokinetic data

To determine the release kinetics of Niacin from ER tablets, various models were applied, including zero-order, first-order, Higuch and Korsmeyer-Peppas kinetics. correlation coefficient was calculated to identify the best-fit model, revealing the order and mechanism of release (table 6).

In vitro dissolution equivalent test

The *in vitro* dissolution equivalent was performed by dissimilarity factor (f1) & similarity factor (f2) by comparing F3 & marketed product (MP)^{20,21}. The studies are performed to know the closeness of *in vitro* dissolution characteristics of designed formulation (F3) with MP, and the results were showed in Table 7.

Stability data

The optimized formulation underwent accelerated stability testing at 40°C/75% RH for 2 months. Samples were evaluated monthly and compared^{22,23,24,25,26} to control samples, in vitro performance, assay, and physical parameters were assessed (ICH guidelines), with results presented in tables 8 & 9.

RESULTS AND DISCUSSION

UV analytical method

Table 2. Standard curve of Niacin in DM water

Concentration in µg/ml	Absorbance
0	0
5	0.175

10	0.342
15	0.53
20	0.711
25	0.891

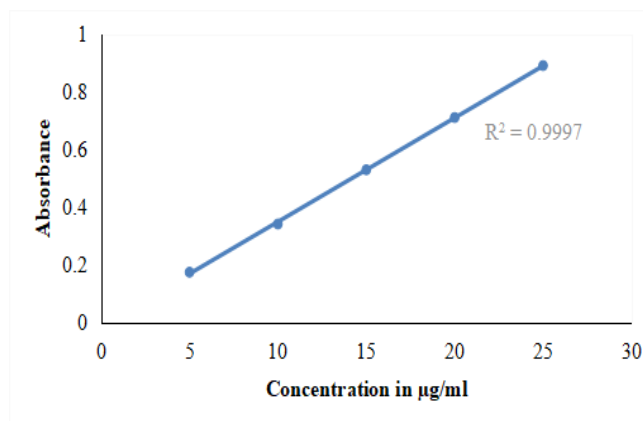


Fig.No. 1. Standard curve of Niacin in DM water

It was observed that for Niacin in DM water by using UV Spectrophotometer was observed to be 260 nm. From Table 2 & Fig.No. 1, which implies that correlation coefficient (R²) between absorbance Vs concentration was 0.999.

It was concluded that the used drug for constructing standard curve was identified and confirmed as Niacin because the λ_{max} (260 nm) of the used Niacin is near to standard Niacin drug λ_{max} in DM water with the use UV Spectrophotometer. And UV Spectrophotometer was suitable to evaluate the Niacin in various dosage forms, because the correlation coefficient (R²) was in between 0.997 to 0.999. The concentrations between 5 to 25 µg/ml were obeying Beer-Lambert's law with the use of UV Spectrophotometer by Niacin.

Evaluation of Tablets

Table 3. Pre compression parameters for Niacin 500 mg ER formulations

Parameter	F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8	F 9	F 10	F 11	F 12
Bulk Density(g/ml)	0.444	0.499	0.499	0.488	0.433	0.433	0.444	0.444	0.433	0.444	0.444	0.444
Tapped density(g/ml)	0.722	0.666	0.666	0.662	0.555	0.555	0.555	0.558	0.566	0.558	0.558	0.555
Compressibility	39.0	25.0	25.0	22.5	22.1	22.2	22.0	22.3	22.2	22.3	22.4	21.8

(%)				8	3	6	6	5	9	5	1	8
Hausner's ratio	1.64	1.33	1.33	1.29	1.28	1.22	1.22	1.31	1.29	1.33	1.28	1.22
Angle of Repose (°)	26.5	27.0	26.8	26.0	27.5	28.8	28.8	27.7	27.7	27.5	28.2	26.5

The pre compression parameters and their values for formulations from F1 to F13 were shown in Table 3 and as follows- bulk density range from 0.425 to 0.495 g/ml (F2, F3), while tapped density ranged from 0.535-0.72 g/ml (F7, F1), indicating variation in particle packing. Compressibility indices, indicative of flowability, varied significantly, with F1 showing poor flowability and F12 exhibiting excellent flow (18.18%). Similarly, Hausner's ratio ranged from 1.22(F12) - 1.64 (F1) , supporting the compressibility results. Angle of repose, which assess powder flow, were between 26.0° and 28.2° (F4 and F2 & F12), with all formulations exhibiting acceptable flow properties for pharmaceutical use.

Overall, formulations F12 and F13 demonstrated superior flowability and compressibility, suggesting better performance during compression. Conversely, F1 and F2 may require process modifications like granulation to improve flow and packaging properties. These findings highlight the impact of excipients composition and powder characteristics on pre compression behavior.

Table.4. Post compression parameters for Niacin 500 mg ER formulations

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Color	White	White	White	White	White	White	White	White	White	White	White	White	White
Surface	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth

Thickness (mm)	5.58	5.93	6.16	5.66	6.22	6.33	6.33	6.10	6.33	5.90	5.90	6.23	6.23
Hardness (kg)	11.12	11.12	11.12	8.10	11.10	11.13	11.13	11.13	11.13	11.13	11.13	11.13	11.13
Weight (mg)	695.72	730.45	700.71	610.30	728.90	728.90	728.90	728.90	728.90	728.90	728.90	728.90	728.90
Assay (%)	95.22	95.93	100.26	82.26	92.27	92.27	92.27	92.27	92.27	92.27	92.27	92.27	92.27

As per Table 4, the post compression parameters for all formulations (F1- F13) exhibited consistent physical properties, with white color and smooth surface. Thickness ranged from 5.50 to 6.33 mm, meeting uniform standards. F3, F5, and F9 showed slightly higher thickness (6.26 to 6.33 mm), reflecting their ingredient composition. Hardness values were within 8 to 13 kg, indicating satisfactory mechanical integrity, with F4 softer (8 to 10 kgs), potentially contributing faster drug release. Weight uniformity was maintained across formulations, with F4 being the lightest (610 to 630 mg) and F9 the heaviest (728 to 730 mg), correlating with respective excipients proportions. Assay values indicated acceptable drug content (91.27 to 100.90%), except F4 formulation (82.26%) remaining all formulations ensuring reliable

dosing. Notably F4 showed the lowest assay (82.26%), suggesting potential variability during preparation. Finally, it was found that except F4 formulation remaining all formulations have good physical integrity to handle them until they administered by a patient efficiently.

In vitro dissolution data

Table.5. *In vitro* dissolution data for formulations F1 to F13 & MP

Time (h)	Cumulative % drug released													
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	MP
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	10	14	11	10	9	8	4	4	1	1	9	7	2	1
3	19	27	20	20	20	6	2	2	2	2	1	2	1	2
6	33	43	33	36	34	4	4	4	3	4	3	3	3	3
9	45	64	47	54	49	5	5	5	9	3	5	3	9	5
12	57	82	60	69	57	6	6	6	6	7	5	6	6	6
16	69	96	71	81	68	7	7	7	7	8	6	7	7	7
20	78	100	84	96	77	8	8	8	8	8	8	8	8	8
24	86.9	100	96	96.5	95.2	9	9	9	9	9	9	9	9	100

The *in vitro* dissolution studies for all formulations as showed in Table 5 reveal varying release pattern over 24 hours. F2 achieved the fastest complete release, reaching 100% at 20 hours, followed by F4 and F10, which reached 96% and 96.5%, respectively, by 20 hours. F3 demonstrated a consistent extended release pattern, achieving 95.2% dissolution at 24 hours, closely mirroring the marketed product (MP), which reached 100%. F1, F11 and F13 showed slower release rates, with 86.9%, 90.1%, and 92% at 24 hours, respectively. F3 stands out as the most effective ER formulation. Its dissolution profile ensures gradual drug release, with 33.5% release at 6

hours, 73.1% at 16 hours, and 95.2% at 24 hours, demonstrating a balanced and controlled release pattern. While F2 and F4 achieved faster release rates, their profiles are more suited for immediate release (IR) formulations, making them unsuitable for ER applications. F3 closely matches the MP in terms of overall *in vitro* dissolution, but with a more gradual release in the early phase, ensuring prolonged drug availability and therapeutic effect.

Initially, HPMC selected as polymer for deigning of Niacin ER tablets, used two viscosity grades E10M (F1) and K15M (F2), and prepared the tablets by direct compression method as an economical method of manufacturing. And found F1 is best formulation among F1 and F2 based on *in vitro* drug rate release studies. Then, with same ingredients tablets were prepared using wet granulation technique (F3) and compared with another polymer PEO WSR N60K (F4). All three formulations (F2, F3 and F4) were compared for *in vitro* drug release studies and found F3 formulation was having good *in vitro* dissolution. Then, the formula for F3 was optimized by changing intra-granular polymer concentration (F5, F6, and F7 formulations), intra-granular concentration (F8 & F9 formulations), binder concentration (F10 & F11 formulations) and lubricant concentration (F12 & F13 formulations). All formulations were compared with marketed product (MP), and finally it was found that F3 had close *in vitro* dissolution similarities to MP. Hence, F3 was considered as final formulation based on *in vitro* dissolution.

In vitro pharmacokinetic data

Table.6. *In vitro* pharmacokinetic data for F1 to F13 and MP

Formulation code	Zero-order (R ²)	First-order (R ²)	Higuchi (n)	Korsmeyer-Peppas (n)
F1	0.97	0.99	0.98	0.99
F2	0.90	0.95	0.97	0.98
F3	0.98	0.93	0.97	0.99
F4	0.77	0.92	0.91	0.92
F5	0.97	0.94	0.98	0.99
F6	0.95	0.97	0.99	0.99
F7	0.95	0.98	0.99	0.99
F8	0.95	0.98	0.99	0.99
F9	0.93	0.99	0.98	0.98
F10	0.95	0.94	0.98	0.98
F11	0.98	0.95	0.98	0.99
F12	0.96	0.93	0.98	0.99
F13	0.97	0.97	0.97	0.99
MP	0.98	0.98	0.98	0.98

From Table 6, the R² values for Zero-order plot were among 0.77 to 0.98, R² values for first-order plot were in between 0.91 to 0.99, n values for Higuchi plot were in between 0.91 to 0.99 and n values for Korsmeyer-Peppas plot were in between 0.92 to 0.99.

From above findings it was noted that most formulations dominating resulted as drug from the Niacin ER tablets was first order kinetics, release of drug from was following diffusion mechanism, and especially non-Fickian diffusion, Super Case II transport mechanism.

In vitro dissolution equivalent studies

Table 7. Dissimilarity and similarity factors of F3

Parameter	Value (%)
Dissimilarity factor, f_1	4.15
Similarity factor, f_2	78.87

As shown in Table 7, the dissimilarity factor of F3 compared to MP was 4.15% and similarity factor was 78.877%. From the findings it was found that F3 was showing *in vitro* dissolution equivalent to MP, hence it can be considered as final formulation or optimized formulation of Niacin ER tablets.

Marketed product (MP) is an approved product by regulatory authority, hence the final formulation should be compared for *in vitro* characteristics such as *in vitro* dissolution with MP. If product is having close or similar values to the MP can consider having similar characteristics to authenticated product.

Stability studies

Table 8. Physical evaluation of tablet blend & tablets of optimization of stability formulations

Parameters	Initial month	One month	Two months
color	White	White	White
Surface	Smooth	Smooth	Smooth
Thickness (mm)	6.16 - 6.22	6.16 - 6.22	6.19 - 6.22
Hardness (kg/cm ²)	11.0 - 12.0	11.0 - 12.0	11.0 - 13.0
Assay (%)	100.26	99.72	99.7

Table 9. Cumulative % release of stability studies of optimized formulation

Time(h)	Cumulative % release		
	Initial month	One month	Two months
0	0	0	0
1	11.8	10	11.1
3	20.5	20	21.5
6	33.5	35	36
9	47	47	48.6
12	60.8	57	59.5
16	73.1	72	74.8
20	84.4	80	84.1
24	95.2	92.7	92.3

As per the findings of Table 8, the tablet retained their white color and smooth surface, with no visual changes observed, Thickness remained consistent (6.16 to 6.22 mm), while hardness showed slight increase, remaining within the acceptable range (11 to 13 kg/ cm²). Assay

values showed minimal reduction from 100.26% initially to 99.7% at two months, confirming chemical stability. Overall, the results indicate that the formulation maintained its quality attributes under the tested conditions.

The *in vitro* dissolution profile of formulations of initial month, first month and second month exhibited highly consistent drug release pattern across all time points as shown in Table 9. Minor variations observed are within acceptable limits, with all formulations demonstrating comparable release rates, achieving over 90% *in vitro* dissolution by 24 hours. The results confirm uniformity in the release characteristics across formulation. Finally, from all findings it was observed that the formulation exhibited excellent stability over two months because of no considerable variations in physical findings and *in vitro* dissolution profile.

CONCLUSIONS

Niacin has a short-life of approximately 20 to 45 minutes and low bioavailability due to rapid metabolism, necessitating frequent administration of conventional tablets (three times daily) at a total daily dose of 1500 to 3000 mg. This often leads to adverse effects such as flushing, gastrointestinal discomfort, and hepatotoxicity. Niacin extended release tablets address these issues by providing a controlled release of the drug, extending its half-life, improving bioavailability, and reducing the frequency of administration to once daily. This allows for a lower total daily dose, typically 500 mg, while minimizing side effects and maintaining therapeutic efficacy for dyslipidemia management. Niacin 500 mg ER tablets were designed using HPMC as the polymer to extend drug release, with viscosity grades E10M (F1) and K15M (F2) selected for evaluation. Tablets were prepared via direct compression, and E10M showed superior *in vitro* characteristics compared to K15M. The direct compression method was then compared with wet granulation (F3) using HPMC E10M and another polymer, PEO WSR N60K (F4). Among these, F3, prepared by wet granulation with HPMC E10M, demonstrated the best *in vivo* performance. Further optimization of F3 involved varying intra-granular (F5 to F7) and extra-granular (F8 to F9) polymer concentrations, binder (F10 to F11), and lubricant (F12 to F13) concentrations. F3 remained the most promising formulation, showing *in vitro* dissolution equivalency with the marketed product (MP). Stability testing under accelerated conditions, following ICH guidelines, confirmed F3 as stable, establishing it as final formulation.

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