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Original Article

Formulation and optimization of nimesulide fast dissolving tablet by using mucilage

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ABSTRACT

The aim of these research to develop the fast dissolving tablet using natural superdisintegrant Plantago ovate (Psyllium husk) commonly known as isapghula husk because of its biodegradable and non toxic effects. The isapghula husk is widely available in local market at very low cost in the comparision with other synthetic superdisintegrants. The various optimization process is carried out like find out the optimum concentration of mannitol as a solubilizing agent, check out the activity of mucilage as disintegrating agent and Optimum concentration of mucilage as a super disintegrating agent and it was concluded that higher dissolution of tablet could be obtained when mucilage concentration is 10% and also the mannitol concentration was 10%. To study the effect of process parameters on release behavior of Nimesulide fast dissolving tablets the various parameters were selected for study like Effect of mixing time, Effect of tablet thickness, Effect of solvent for the precipitation of mucilage, Effect of boiling time and the results showed that all optimized parameters were precise and they showed good results cumulatively. On comparing the results with selected batch M5, the physical parameters, micromeritic properties and *in-vitro* drug release study was done.

Keyword: FDDTs, Natural superdisintegrants, Plantago ovata, novel drug delivery system, Nimesulide, Mucilage

INTRODUCTION

Recently, pharmaceutical preparations used for elderly and pediatric patients have been investigated to improve the treatment compliance of such patients. A tablet which can rapidly disintegrate in saliva (rapidly disintegrating tablet) is an attractive dosage form and a patient-oriented pharmaceutical preparation.[3]A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates quickly in the oral cavity upon the contact with saliva, resulting in solution or suspension of the administered medicine.[4] Fast dissolving disintegrating tablets (FDDTs

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disintegrate and/or dissolve in the saliva without the need for water. Some tablets are designed to dissolve in saliva rapidly, within a few seconds, and are true fast-dissolving tablets. Superdisintegrants are the substances to increase the rate of tablet disintegration in the oral cavity, as they may take up to a minute to completely disintegrate.[5] A disintegrant is an essential component of all immediate-release tablets. The function is to ensure prompt break-up of tablets after oral administration to enable drug release.[6] Superdisintegrants are added to tablet and some encapsulated formulations to promote the breakup of the tablet "slugs" into smaller particle in an aqueous environment thereby it increasing the availablibility of surface area and promoting a more rapid release of the drug component. They promote moisture penetration and dispersion of the tablet.[7-9] The disintegration of dosage forms are depends on various physical factors of superdisintegrants.[10,11] Mucilage of plantagoovata seed husk (isapghula) is also used as superdisintegrants. The mucilage of plantagoovata is a recent innovation for its super disintegration property when compared with sodium starch glycolate (SSG) and It shows faster disintegration time than the superdisintegrants SSG.[12]

MATERIALS AND METHODS

The Seeds of Plantago ovate (Ishapghula) were purchased from the local market of Udaipur, Rajasthan, and Nimesulide was obtained as sample from Sehat Pharma. Pvt. Ltd. Himatnagar and Other materials used in the study were of standard pharmaceutical grade.

Isolation of Mucilage From Seed: The Plantagoovata husks were soaked in distilled water for 48 hrs. Then boiled for 20 minutes. The collected material was squeezed through muslin cloth to separate them. Then, an equal volume of ethanol was added to the filtrate for precipitation of the mucilage. The separated mucilage was dried at 40^{o}C in a tray dryer. The dried mucilage was powdered and sieved in sieve no # 80.The resultant powder was stored in a desiccator and used for the present study.

1. Formulation prepared for optimization of mannitol as a solubilizing agent

Composition for optimization of mannitol used as a solubilizing agent in fast dissolving formulation is shown in Table 1. Different formulations of fast dissolving tablets were prepared by direct compression method. All the powders were passed through sieve no # 80 to decrease the particle size. Required quantity of drug and excipient mixed throughly. The blended mixture was compressed in 12 Station Rotary Tablet Machine and Each tablet contained 100 mg of Nimesulide and other ingredients as Listed in table 1.

Table 1: Formulation prepared for optimization of mannitol as a solubilizing agent of batch PM to PM5

	PM1	PM2	PM3	PM4	PM5
Drug	100	100	100	100	100
Micro crystalline cellulose MCC	129.5	117	104.5	92	79.5
Manitol (%)	0	5	10	15	20
sodium starch glycolate SSG (%)	5	5	5	5	5
Mg Stearate	3	3	3	3	3
Talc	5	5	5	5	5
Total Weight	250	250	250	250	250

*** All Quantity in Miligram (mg)**

Interpretation: Batch PM to PM5 prepared with different concentration of Micro crystalline cellulose and mannitol for optimization of mannitol as a solubilizing agent.

2. Formulation prepared for to check the activity of mucilage as disintegrating agent

Composition of mucilage batch PM and sodium starch glycolate batch PS preliminary trials batches to check the activity of mucilage as disintegrating agent shown in table 2. Different fast dissolving tablets formulations were prepared by direct compression method. All the powders were passed through sieve no.80 to decrease the particle size. Required quantity of drug and excipient mixed thoroughly. The blended mixture was compressed using Rotary Tablet Machine-12 Station.

Table 2: Two trial batches to check the activity of mucilage as disintegrating agent		
	PM	**PS**
Drug	100	100
MCC	107	107
Manitol	25	25
Mucilage	5%	-
SSG	-	5%
Mg Stearate	3	3
Talc	5	5
Total Weight	250	250
*** All Quantity in Miligram (mg); Interpretation:-** PM Mucilage Batch and PS SSG Batch		

3. Optimization of mucilage concentrations as superdisintegranting agent: Composition for optimization of mucilage as a superdisintegrating agent for fast dissolving formulation is shown in Table 3. Different formulations of fast dissolving tablets were prepared by direct compression method. All the powders were passed through sieve no.80 to decrease the particle size. Required quantity of drug and excipient mixed thoroughly and the blend was compressed using Rotary Tablet Machine-12 Station.

Table 3: Optimization of mucilage concentration as dissolution and disintegration time enhancing agent of Batch M1 to M7							
	M1	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**
Drug	100	100	100	100	100	100	100
MCC	112	108	104	100	96	92	88
Manitol	25	25	25	25	25	25	25
Mucilage (%)	2	4	6	8	10	12	14
Mg Stearate	3	3	3	3	3	3	3
Talc	5	5	5	5	5	5	5
Total Weight	250	250	250	250	250	250	250
*** All Quantity in Miligram (mg)** **Interpretation:-** Batch M1-M7 was prepared with different concentration of Mucilage and MCC							

Characterization of prepared tablet

4. Optimization of mannitol as a solubilizing agent: Fast Dissolving Tablet formulation of Nimesulide using mannitol as a solubilizing agent by direct compression method using Rotary Tablet Machine-12 Station. In preliminary study, different batches of fromulation were prepared as per the composition given in Table 1. All the batches were evaluated for *in vitro* dissolution study as per the procedure. Different other evaluation parameters were also studied. Considering release profile, batches PM_1- PM_5 shows drug release with slight variations and, Batch PM3 gives desirable fast release action. Moreover the hardness, disintegration time of tablet were found 4±0.2 kg/Cm^2, 42 sec, it gives 66.33% release of drug with in 30 minute. Therefore, the mannitol concentration 10% was selected for further work.

Table 4 : Evaluation parameters of Nimesulide fast dissolving tablet					
Batch code	**Hardness (n=5) kg/cm^2**	**Disintigration time (Sec)**	**Wetting time (Sec)**	**%Friability (n=10)**	**Weight Variation (n=20) in mg**
PM_1	4.35 ± 1.20	48	52	0.43	249 ± 2.50
PM_2	4.12 ± 0.89	45	49	0.52	252 ± 2.00
PM_3	4.00 ± 0.55	43	51	0.36	250 ± 2.74
PM_4	4.62 ± 0.89	41	48	0.41	250 ± 2.15
PM_5	4.56 ± 1.20	38	42	0.43	254 ± 2.54
Interpretation:- Batch PM3 gives desirable results Moreover the hardness, disintegration time of tablet were found 4±0.55kg/Cm^2, 43 sec.					

Table 5 : Cumulative % drug release of batches PM_1 to PM_5 of NimesulideFDT					
Time (min)	**PM_1**	**PM_2**	**PM_3**	**PM_4**	**PM_5**
0	0	0	0	0	0
2	18.98	25.76	33.86	31.98	28.39
5	25.49	32.38	40.47	38.50	35.01
10	41.76	48.55	56.64	54.76	51.18
15	43.89	50.87	58.96	56.90	53.50
20	47.33	54.00	62.22	60.39	56.86
25	51.78	55.87	63.55	62.38	58.82
30	53.08	55.16	66.33	64.63	60.64
Interpretation: Considering release profile, batches PM_1- PM_5 shows drug release with slight variations and, Batch PM3 gives desirable fast release action and it gives 66.33% release of drug with in 30 minute.					

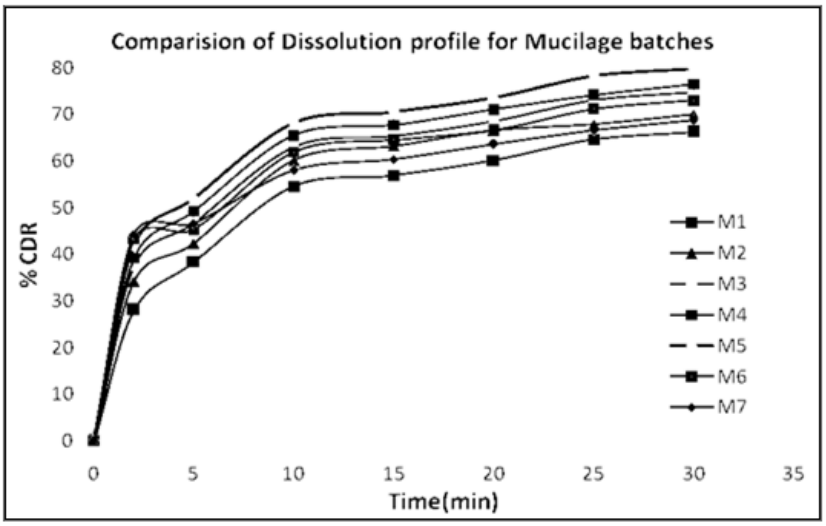
5. Preliminary trails batches to check the activity of mucilage as Superdisintegrating agent: in this investigation prepare Fast Dissolving Tablet formulation of Nimesulide using mucilage agent in one batch and in another batch SSG as a disintegrating by direct compression method. In preliminary study, different batches of formulation were prepared as per the composition given in Table 2. All the batches were evaluated for *in vitro* dissolution study as per the procedure. From the result, it was found that mucilage batch gives desirable fast release action.

Table 6 : Cumulative % drug release of batches PM to PS of Nimesulide FDT		
Time (min)	**PM**	**PS**
0	0.00	0.00
2	40.23	25.42
5	52.32	40.52
10	62.93	44.26
15	65.34	53.90
20	68.50	56.54
25	69.76	61.80
30	73.65	67.67
Interpretation:- It was found that mucilage batch gives desirable fast release action.		

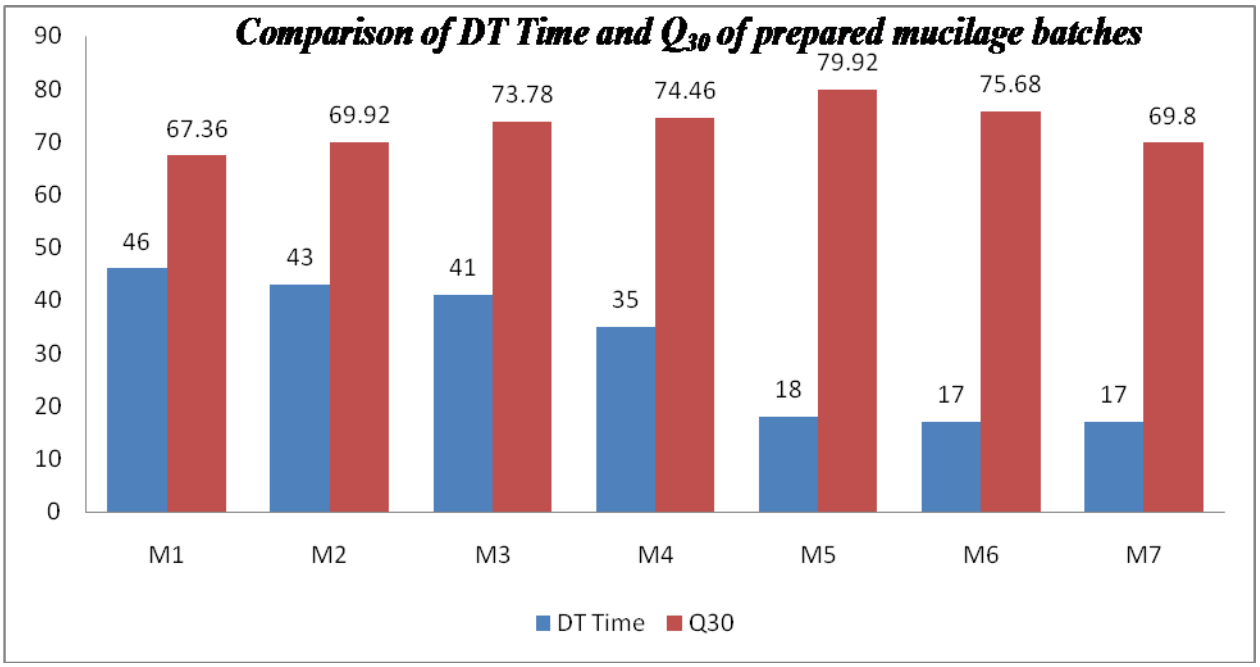
6. Optimization of mucilage concentration as a super disintegrating agent: In these investigation prepare Fast Dissolving Tablet formulation of Nimesulide using mucilage as a super disintigrating agent by direct compression method using Rotary Tablet Machine-12 Station. In preliminary study, different batches of formulation were prepared as per the composition given in Table 3 to find out the optimum concentration of mucilage. All the M_1 to M_7 batches were evaluated for in vitro dissolution study as per the procedure. Different other evaluation parameters were also studied. Considering release profile, batches M_1- M_7 shows drug release with slight variations. From M_1- M_7 batches and it was found that Batch M_5 (Table 3) gives desirable fast drug release action. Moreover, hardness, disintegration time of tablet were found 4±0.3 kg/cm^2, 18 sec, it gives 79.92% release of drug with in 30 minute. Therefore, the concentration of mucilage 10% was selected for further work.

Table 7 : Cumulative % drug release of batches M1 to M7 of Nimesulide fast dissolving tablet							
Time (min)	**M1**	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**
0	0	0	0	0	0	0	0
2	32.83	37.39	41.28	42.64	42.84	40.17	41.5
5	39.54	43.90	47.80	50.12	51.16	46.95	48.98
10	55.70	59.16	64.11	65.47	66.22	63.12	67.07
15	56.94	61.48	66.34	66.76	67.54	65.44	60.48
20	61.30	64.74	69.67	72.13	73.64	68.70	63.79
25	65.36	68.86	72.13	73.67	78.30	73.15	68.16

30	67.36	69.92	73.78	74.46	79.92	75.68	69.8
Interpretation:- From M_1- M_7 batches it was found that Batch M_5 gives desirable fast drug release action.							



(Figure 1 : Comparative cumulative drug release profile for different mucilage batches)
Interpretation:- From M_1- M_7 batches it was found that Batch M_5 gives desirable fast drug release action.



(Figure 2 : Comparison of disintegration time and Q_{30} for prepared mucilage batches)
Interpretation:- From M_1- M_7 batches it was found that Batch M_5 gives desirable fast drug release action.

PROCESS PARAMETER

(A) Process parameter related to Nimesulide tablet

Effect of mixing time

Composition of Nimesulide tablets

Composition of Nimesulide tablet to check the effect of mixing time on drug release behavior shown in table 9.Different formulations of fast dissolving tablets were prepared by direct compression method. All the powders were passed through sieve no.80 to decrease the particle size. Required quantity of drug and excipient mixed thoroughly. The blended mixture was direct compressed using Rotary Tablet Machine-12 Station. Each tablet contained 100 mg of Nimesulide and other pharmaceutical exipients as Listed in table 9.

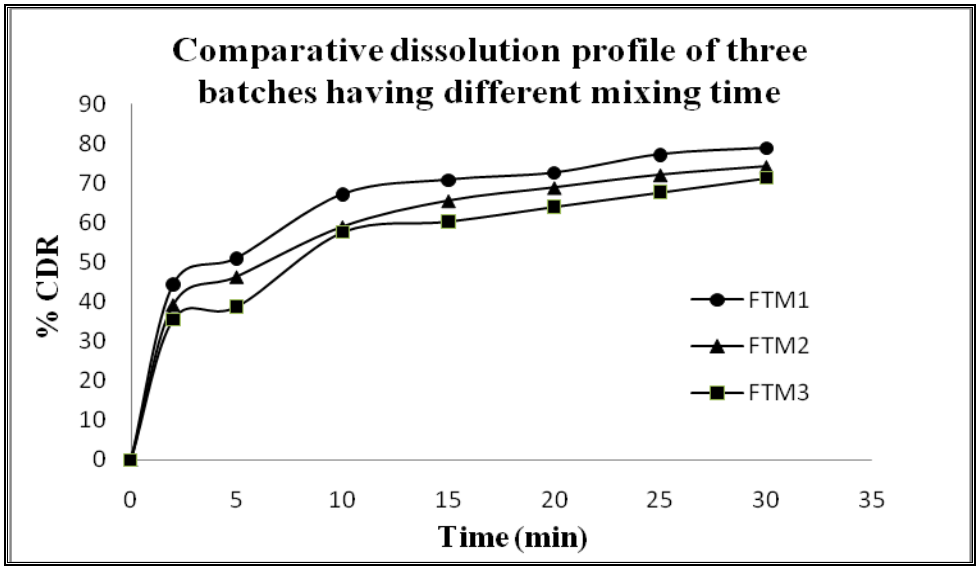
Table 9 : Formulation of selected batch of Nimesulide fast dissolving Tablet with different mixing time			
Ingredients	**FMT_1**	**FMT_2**	**FMT_3**
Nimesulide	100	100	100
MCC	92	92	92
Mannitol	25	25	25
Mucilage	25	25	25
Magnesium Stearate	3	3	3
Talc	5	5	5
Total weight	**250 mg**	**250 mg**	**250 mg**
Mixing time (minutes)	**5**	**10**	**15**
*** All Quantity in mg**			
Interpretation:- Three batch composition with different mixing time			

To know the effect of mixing time taken for the mixing, three trials were taken with the mixing time of 5, 10 and 15 min.

Table 10 : Comparative physical parameters of three batches having different mixing time			
B. No.	**Mixing time (minute)**	**% Compressibility**	**Angle of repose (◦)**
FTM_1	5	32.23	36.28
FTM_2	10	33.22	37.36
FTM_3	15	35.13	41.57
Interpretation:- As the mixing time increased the % Compressibility and angle of repose was increased.			

Table: 11 : Comparative evaluation parameters of three batches having different mixing time				
Batch code	**Hardness (n=5) kg/cm^2**	**Thickness (n=5) mm**	**%Friability (n=10)**	**Weight Variation(n=20)**
FTM_1	**4.86 ± 0.15**	**4.75 ± 0.18**	**0.39**	**250±2.12**
FTM_2	5.20 ± 0.89	4.79 ± 0.20	0.41	249±2.22
FTM_3	5.01 ± 0.88	4.85 ± 0.24	0.37	251±2.00
Interpretation:- Batch FTM_1 gives ideal results in various physical parameters				

Table 12 : Comparative dissolution profiles of three batches having different mixing time			
Time (min)	**Cumulative Percentage Release**		
	FTM_1	**FTM_2**	**FTM_3**
0	0	0	0
2	43.55	38.34	34.67
5	52.06	45.21	39.76
10	66.34	57.87	56.65
15	69.88	64.67	60.45
20	72.69	67.98	63.33
25	76.43	71.34	66.79
30	79.25	74.55	70.45
Interpretation:- Batch FTM_1 gives maximum drug release79.25 % in 30 min.			



(Figure 3: Comparative dissolution profiles of three batches having different mixing time)

It is seen that the higher amount of shear i.e. mixing time has a retarding effect on dissolution of drug. There is significant retarding effect was observed in case of 15.0 min. So, 5 min mixing time was kept optimum.

Effect of tablet thickness

Composition of Nimesulide FDT tablets

Composition of Nimesulide tablet to check the effect of tablet thickness on drug release behavior shown in table 13.Different formulations of fast dissolving tablets were prepared by direct compression method. All the powders were passed through sieve no.80 to decrease the particle size. Required quantity of drug and excipient mixed thoroughly and the blend was compressed using Rotary Tablet Machine-12 Station. Each tablet contained 100 mg of Nimesulide and other pharmaceutical ingredients as Listed in table 13.

Table 13 : Formulation of selected batch of Nimesulide fast dissolving Tablet with different thickness of tablet

Ingredients	**FMT_1**	**FMT_2**
Nimesulide	100	100
MCC	92	92
Mannitol	25	25
Mucilage	25	25
Magnesium Stearate	3	3
Talc	5	5
Total weight	**250 mg**	**250 mg**
Tablet thickness (mm)	**5**	**4.6**

Interpretation:-Formulation composition of batch FMT_1 and FTM_2 with different thickness of tablet

Table 14: Comparative evaluation parameters of batches having different tablet thickness

Batch code.	**Hardness (n=5) kg/cm^2**	**Thickness (n=5) mm**	**%Friability (n=10)**	**Weight Variation (n=20)**
FTT_1	4.75	4.76-6.65	0.37	250±2.25
FTT_2	5.24	4.6-5.75	0.45	251±1.54

Interpretation:-Batch FTM_1 gives desired results of various evaluation parameters

Table 15 : Comparative dissolution profiles of batches having different tablet thickness		
Time (min)	**Cumulative Percentage Release**	
	FTT_1	**FTT_2**
0	0	0
2	44.54	34.42
5	48.87	43.67
10	64.34	60.56
15	67.87	63.32
20	70.76	66.33
25	74.44	70.45
30	79.91	72.23
Interpretation:-Batch FTM_1 gives desired drug release of 79.91% in 30 min.		

It is seen that the higher thickness of tablet gives more surface area for dissolution and drug release is higher. Main concern behind this study was to find optimum thickness and also to check the effect of increased and decreased thickness on release behavior, because this parameter may fluctuate during large scale batch. Tablets of batch FTT2 showed retarded drug release because of lowered surface area, Tablets of batch FTT1 showed faster drug release. Batch FTT1 released drug in desired manner. So, 4.76-6.65mm was taken as optimum tablet thickness.

(B) Process parameter related to Mucilage (*PlantagoOvata)*

Effect of solvent for precipitation of mucilage

1. Effect of Acetone for precipitation of mucilage

The seeds (100 g) were soaked for 12 hour in 1 litre distilled water and crushed in blender for 20 minute. The dispersion was boiled for 45 minute and the mass was passed was passed through eight folds of muslin cloth Then the mucilage was precipitated from the filtrate by adding Acetone. The powder was passed through 80 # mesh sieve and weighed to calculate the yield after drying at 45 ^{o} for 6 hour.

2. Effect of ethanol for precipitation of mucilage

The seeds (100 g) were soaked for 12 h in distilled water (1liter) and crushed in blender for 20 min. The dispersion was boiled for 45 min and the mass was passed was passed through eight folds of muslin cloth then the mucilage was precipitated from the filtrate by adding ethanol. The powder was passed through 80 # sieve and weighed to calculate the yield after drying at 45 ^{o} for 6 h. To know the effect of solvent for the precipitation of mucilage, two solvent were taken which are acetone and ethanol.

Table 16 : Effect of solvent for precipitation of mucilage		
Property	**Name of solvent**	
	Acetone	**Ethanol**
Percentage yield	17%	26%
Average particle size	209.17 µm	188.57 µm
Swelling ratio	2.8	3.7
Loss on drying	2.3%	1.7%
P^H	5.9	6.4
Viscosity	7.45 cps	8.08 cps
Bulk density	0.35 gm/ml	0.72 gm/ml
Tapped density	0.60 gm/ml	0.83 gm/ml
Angle of repose	41.34	29.34
Carr's index	41.66%	15.52%
Hausner ratio	1.71	1.15
Interpretation:-Ethanol gives optimum results as compare to Acetone		

It is seen that when the ethanol is the choice of solvent for the precipitation of mucilage, higher the % yield, swelling ratio, Viscosity as compare to Acetone. So Ethanol is a choice of the solvent for the precipitation of mucilage.

Effect of boiling time: The seeds of ishapghola (100 g) were soaked for 12 hour in distilled water (1litre) and crushed in blender for 30, 45 minute. The dispersion was boiled for 45 minute and the mass was passed was passed through eight folds of muslin cloth then the mucilage was precipitated from the filtrate by adding ethanol. The powder was passed through 80 # mesh sieve and weighed to calculate the yield after drying at 45 ^{o} C for 6 hour.

Effect of boiling time for precipitation of mucilage: To see the effect of boiling time, two trials were taken with the boiling time of 15, 30 and 45 min; the physical parameters observed were as follows.

Table 17: Effect of boiling time for precipitation of mucilage

Property	Boiling time		
	15 min	**30min**	**45min**
Percentage yield	26%	22%	21%
Average particle size	188.57 µm	186.57 µm	180.54
Swelling ratio	3.7	3.65	3.45
Loss on drying	23.53	20.64	19.89
P^{H}	6.4	6.2	6.1
Viscosity	8.08 cps	9.66 cps	9.00 cps
Bulk density	0.72 gm/ml	0.87 gm/ml	0.96 gm/ml
Tapped density	0.83 gm/ml	0.61 gm/ml	0.66 gm/ml
Angle of repose	29.34	20.14	27.24
Carr's index	15.52%	40.32%	44.61%
Hausner ratio	1.15	1.67	1.80
Interpretation:-15 minute is the optimum boiling time for the precipitation of mucilage.			

It is seen that when the 30 minute is the boiling time for the precipitation of mucilage, higher the % yield, swelling ratio, Viscosity as compare to 15 minute. After that if we increase the boiling time for precipitation of mucilage there is not significant increase in the % yield, swelling ratio, Viscosity. So 15 minute is the optimum boiling time for the precipitation of mucilage.

CONCLUSION

Attempt was made in the present investigation to improve the dissolution of Nimesulide through the formulation of fast dissolving tablet using natural super disintigrant like *plantagoovata* and mannitol as a pore forming agent by direct compression method. Mucilage *plantagoovata* has significant effect on drug release. Maximum release 79.90% was observed at the mucilage and mannitol concentration 10%. Mean hardness and mean disintegration time of the tablets was found to be 4.00 ± 0.20 Kg/cm^3 and 17 sec respectively. Percentage friability was found 0.39 respectively, which is very nearly to the tablet prepared from the SSG as a super disintegrating agent.

The batch M5 had successfully fulfilled all quality control tests. So formulation of this optimized batch M5 has been taken for process parameters study. The results showed that all optimized parameters were precise. They showed good results cumulatively. On comparing the results with selected batch M5, the physical parameters, micromeritic properties and *in-vitro* drug release study was done as per describe manner So, we can conclude that there were no significant differences in case of boiling time for the precipitation of mucilage. But in case of solvent for the precipitation of mucilage, thickness and mixing time of tablets there were significant different in drug release. This optimized formula and optimized process are ready for scale-up or commercial batch.

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