FORMULATION DEVELOPMENT AND EVALUATION OF MOUTH DISSOLVING TABLET OF NADOLOL

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Abstract: This study aimed to design a mouth dissolving tablet (MDT) of Nadolol It is an Antihypertensive drug that is widely used in hypertension. It is a poorly water-soluble drug (0.14 gm/ml) at pH 1.7 in solubility. Thus, the attempt was made to enhance the water solubility by using the solid dispersion. Drug and disintegrant solid dispersion at a specific amount of mixture. By this method of preparing mouth dissolving tablets for Nadolol which dissolve rapidly in the mouth using Crosspovidone as the disintegrating agent. The solid dispersion technique (Solid dispersion) was used to enhance the solubility of Nadolol. Different Novel & regularly used superdisintegrants such as Croscarmellose sodium, Sodium starch glycolate were used respectively. Tablet prepared by direct compression method. The formulations were evaluated for weight variation, hardness, friability, drug content, wetting time, in-vitro disintegration time and in vitro dissolution studies, etc. the prepared tablets were characterized by Fourier transform infrared spectroscopy, differential scanning calorimetry. The drug release of F3 is 95.30% the formulated tablets were compared to the reference product and the drug release was found to be as per the specifications. Thus, batch F3 was taken as the finalized batch. In Batch F3 all the formulation parameters of the tablets were found to be satisfactory.

Keywords: Nadolol, Solid dispersion, Sodium starch glycolate, croscarmellose sodium. Etc.

INTRODUCTION: Nadolol 5- [3- (tert-butylamino)-2-hydroxypropoxy] -1, 2, 3 ,4- tetrahydronaphthalene-2,3-diol is a poorly water soluble drug used in the treatment of diarrhoea (solubility<1 mg/100 ml). It is commercially available as a hydrochloride salt under the trade name Imodium in order to overcome the problem of poor solubility and hence poor oral bioavailability 1. The aim of this study was to use Nadolol as a model compound to explore another route to tackle this problem, i.e. the use of solid dispersions. They are defined as the dispersion of one or more active ingredients in an inert hydrophilic carrier or matrix at solid state, prepared by the fusion, solvent or solvent- fusion method. These systems provide the possibility of; reducing the particle size of the drugs to (nearly) a molecular level, locally increasing the saturation solubility and/or; of transforming the drug from the crystalline to the (partially) amorphous state.[1, 2]

Mouth dissolving dosage forms has solved some of the problems encountered in administration of drugs to the pediatric and elderly patient, which constitutes a large proportion of the world's population. Hence, patient demand and the availability of various technologies have increased the market share of Mouth dissolving tablets, which in turn prolongs the patent life of a drug. Keeping in view of the advantages of the delivery system, rapidly disintegrating dosage forms have been successfully commercialized, and because of increased patient demand, these dosage forms are expected to become more popular [2, 3].

MATERIAL AND METHODS: Nadolol was procured from Matrix Pharma. Ltd India, Crospovidone were of pharmaceutical greade and Ozone international Mumbai, Lactose procured from Signet Chemical co Ltd, Bandra Kurla Complex, Mumbai, Mannitol from Ozone international Mumbai, Vanillin from New modern chemical co, Mumbai, Aspartame Ozone international Mumbai, Magnesium Stearate from Ozone international Mumbai, Talc from Signet Chemical co Ltd, Bandra Kurla Complex, Mumbai. All solvent used were of analytical greade and were purchased from Merck Ltd. Mumbai (M.H.) India.

Preparation of Solid Dispersion:

1. **Method of preparation inclusion complex**

   The inclusion complex were prepared by using solid dispersion.

2. **Solid dispersion:** Nadolol and HPMC were triturated in ratio 1:1, 1:2, 1:3, and 1:4. w/w with addition of few drop of methanol to form a paste in a separate china dish. The solvent allowed 40^{o}C to evaporate to form a dry solid mass that is further crushed into fine particles and passes through sieve No.60 for further use and held in a desiccator.

3. **Solubility study of various type of prepared paste:** The solvency studies were performed by taking 10 mg drug likeness strong scattering from the each cluster (SD-A, SD-B and SD-C) were broken down in water and PBS (pH6.8) and kept in mechanical shaker for 30 min at 30ºc. Test was taken after 30 min from each volumetric jar and was investigated spectrophotometerically at 129 nm [6]. The solvency studies were performed by taking 10 mg drug likeness actual combination from the each groups (PM-A, PM-B and PM-C) and broke up in water and PBS (pH6.8) kept in mechanical shaker for 30 min at 30ºC. Tests were taken after 30 min from each volumetric flagon and absorbance were estimated by UV-noticeable spectrophotometer [7].

4. **Portrayal of arranged glue:** The medication and the pre-arranged glue were assessed for drug content, meager layer chromatography, FTIR Spectroscopy, In-vitro disintegration examines.

5. **Drug content:** Accurately gauged amount of strong scattering, identical to 10 mg Nadolol was disintegrated in 10 ml of methanol by utilizing mechanical shaker for 30 min. what's more, separated utilizing whatman channel paper and absorbance was estimated at 259 nm by UV-noticeable spectrophotometer [8].

In-vitro disintegration study: Dissolution studies were led utilizing a sort II (paddle) USP disintegration contraption with 900 ml PBS 6.8 pH as disintegration media. The temperature of the medium was kept up with at 37c and RPM set as 50. The medication was measured spectrophotometrically at 129 nm.

Definitions of mouth disintegrate tablets for Nadolol: The tablet arranged by direct pressure method, all the necessary fixing was precisely weighed by electronic equilibrium and gone through strainer no. 40. Blending every one of the fixings in with the worked combination and afterward compacted utilizing a 6 mm level punch on Cemach R&D Tablet press 10 station pressure machine. Tablets hardness was kept up with at 3-3.5 kg/cm2. Tablet weight was kept up with at 6 to 7 mg. All the item and interaction factors like blending time and hardness were kept basically consistent.**Table 1** [6].

TABLE 1: FORMULATION DESIGN OF MOUTH DISSOLVING TABLETS

Sr No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
1	Drug complex (Solid dispersion)	20	20	20	20	20	20	20	20
3	Croscarmellose sodium	3	5	7	9	-	-	-	-
4	Sodium starch glycolate	-	-	-	-	4	8	12	16
5	Mannitol	60	60	60	60	60	60	60	60
5	Lactose	102	100	98	96	101	97	93	89
6	Vanillin	2	2	2	2	2	2	2	2
7	Saccharine Sod.	10	10	10	10	10	10	10	10
8	Magnesium Stearate	2	2	2	2	2	2	2	2
9	Talc	1	1	1	1	1	1	1	1
	Total weight	200	200	200	200	200	200	200	200

Evaluation of Mouth Dissolving tablets: The Formulated mouth dissolving tablet have been evaluated for special parameters like fashionable characteristic, uniformity of weight, hardness, wetting time, Uniformity of

dispersion, Disintegration take a look at, Drug launch look at desk [2 8.]

Well-known characteristic: widespread appearance of tablet, its visual identity length, shape, colour of the tablet changed into evaluated.

Uniformity of Weight: 20 pills of each batch had been collected randomly during compression and weight of individual capsules turned into performed.

Hardness or Friability: For every formulation the hardness and friability of 6 tablets put on decided using Monsanto hardness tester and the Roche Friabilator.[9]

Drug Content: the quantity of active component turned into determined via the technique described within the drug content material. By means of crushing the ten capsules and taking powder equal to 8 mg Loperamide. Then this powder dissolved in 100ml 0.1N HCl appropriate dilution of the ensuing solution changed into organized and absorbances of the ensuing answer were taken UV Spectrophotometrically. % drug content has been calculated.

Wetting time: 5 round tissue papers of 10 cm diameter are placed in a Petri dish with a ten cm diameter. 10 millimeters of water-containing methyl red, a water-soluble dye, is brought to Petri dish. A tablet is carefully placed at the floor of the tissue paper. The time required for water to attain upper surface of the tablet is referred to as a wetting time[10].

Disintegration check: equipment for Disintegration of pills and drugs in step with Indian pharmacopoeia 1996 used for the willpower of disintegration check for dispersible capsules. The beakers containing the 900ml distilled water at 25 ±1˚C and function the apparatus for 3 min. and do away with the assembly from the liquid. The tablets pass the take a look at if they all have disintegrated. Dispersible pills ought to crumble within three minutes whilst examined by way of the disintegration test in keeping with Indian Pharmacopoeia 1996.

Uniformity of Dispersion: This test is applicable most effective to Dispersible tablets. Location 2 tablets in 100 ml of water and stir lightly till completely dispersed. A smooth dispersion is acquired which passes thru a sieve display screen with a nominal mesh aperture of 710 µm (sieve size 22). Drug launch examine in simulated salivary fluid pH 6.8 & 0.1 N HCl: The drug launch method for mouth dissolving capsules is similar to the approach to the technique taken for conventional pills, and is practically equal. the discharge look at finished in USP type 2 dissolution equipment containing 900ml 6.8 pH phosphate buffer and 0.1 N HCl at 50 rpm and 37^{o}C temperature. The drug launch pattern 5ml withdrawal by using appropriate time c programming language and clean dissolution medium were added within the every withdrawal. Then appropriate dilution of the samples has been organized and absorbances of the resulting answer had been taken spectrophotometrically [11].

Stability study: Stability study was conducted by storing the tablets at 40±2^{o}/75±5% Relative humidity for three months. The content, hardness, weight variation and release behavior from dissolving tablets were tested after three month (ICH guidelines).

RESULTS AND DISCUSSIONS:

In the present study, an attempt was made to formulate a mouth dissolving tablet of anti-hypertensive drug having a comparable dissolution profile to that of Reference Listed Drug. The direct Compression method was selected for the formulation of the mouth dissolving tablet. In the pre-formulation studies, API characterization and drug-excipient compatibility studies were carried out. The API status has shown compliance with drug features. The superdisintegrant and other excipients were selected based on the satisfying results produced during drug- excipients compatibility studies to develop the final formulation. Before compression powder blend was studied for pre-compression parameters like bulk density, tapped density, compressibility index, and Hausner's ratio shows powder blend has good flow properties. After compression, tablets were studied for post-compression parameters such as hardness, friability, weight variation, thickness, content uniformity, and dissolution study. Stability studies indicated that there appeared no much difference in the physical appearance, drug content, hardness, friability, and In-vitro drug release studies when the optimized formulation was stored at 40 °C/75 % RH for 90 days. It was also observed that Direct Compression was the best suitable method used for producing mouth dissolving tablets of Nadolol.

- In-vitro dissolution studies pure Nadolol and different ratio of final solid dispersion according to drug contents (10mg drug containing) using type-II (paddle) USP dissolution apparatus with 900 ml Phosphate buffer solution ph 6.8 at 37 ± 0.5 and rpm 50. In tablet batch F1, F2 & F3 contain Kyron -T314, having Direct Compression method, Batch F1 & F2 all physical parameters are satisfactory but disintegration time and dissolution were not satisfactory.

Mouth dissolving tablets of Nadolol were prepared by superdisintegrants addition method and evaluated for various evaluation parameters of the tablets. Total nine formulations were designed (table 1). The hardness of tablets from all formulations was in between 1.76 to 3.56 kg/cm^2. All the formulations showed friability below 0.91%. All the tablets were found to pass the uniformity of weight (table 2). Content of Nadolol from all formulation was found in range of 94.09% to 97.15% (table 2) All the formulations tablets disintegrate in 20 to 90 Sec. respectively (table 2). The wetting time was measured and found in range of 41.66 to 71.00 S (table 2).

Drug excipients compatibility study:

Drug excipients compatibility study was performed as per the method described in the experimental part. Visual observation of the samples was performed for discoloration, liquefaction, and odor. Data relieved that the drug candidate was stable with the selected excipient at a reported ratio at 25^{0c}/60%RH 40^{0}C/75%RH for 15 days and 4 weeks.

Results of drug excipients compatibility studies (Assay Results)

Drug: Excipients	Assay Observation

	Initial	**25^{0C}/60% RH**		**RH 40^{0C}/75%R H**	
		15 Days	**1 M**	**15 day**	**1 M**
Nadolol + Mannitol	98.98 ± 1.12	98.95 ± 1.15	98.93 ± 1.11	98.93 ± 1.19	98.94 ± 1.19
Nadolol + Lactose	99.01 ± 0.94	99.0 ± 0.94	99.01 ± 0.97	99.01 ± 0.98	99.0 ± 0.99
Nadolol +Crospovidone	98.96 ± 1.07	98.92 ± 1.07	98.94 ± 1.09	98.93 ± 1.10	98.93 ± 1.01
Nadolol + Vanillin	98.89 ± 1.01	98.88 ± 1.07	98.87 ± 1.09	98.95 ± 1.15	98.82 ± 1.10
Nadolol + Aspartame	98.98 ± 1.01	98.98 ± 1.12	98.95 ± 1.15	98.85 ± 1.27	98.89 ± 0.99
Nadolol + Magnesium Stearate	98.90 ± 1.21	98.89 ± 1.22	98.90 ± 1.25	98.89 ± 0.99	98.99 ± 0.97
Nadolol + Talc	99.01 ± 0.91	98.99 ± 0.93	99.01 ± 0.95	98.99 ± 0.97	98.85 ± 1.25

All values are expressed as mean ± SD, n = 4

TABLE 2: EVALUATION OF MOUTH DISSOLVING TABLETS

Sr.no	**Parameter**	**Evaluation Result**				
		F1	**F2**	**F3**	**F4**	**F5**
	Precompression parameters					
1	Unlubricated blend LOD (% w/w)	2.27	2.15	2.30	1.85	2.26
2	lubricated blend LOD (% w/w)	1.20	1.18	2.65	2.35	2.89
3	Tapped Density	0.62	0.64	0.54	0.55	0.42
4	Bulk Density	0.40	0.43	0.40	0.45	0.36
5	Compressibility Index	36.2	32.0%	25.0%	18.2%	13.0%
6	Hausner's Ratio	1.55	1.48	1.35	1.22	1.16
	Compressed Tablet Parameters					
7	Appearance	White	White	White	White	White
8	Average weight (mg)	58.9-61.1	59.4-60.5	58.8-60.9	59.7-60.3	58.5-60.8
9	Thickness (mm)	2.47-2.53	2.5-3.06	5.59-3.24	2.43-3.49	2.48-3.41
10	Diameter (mm)	86.4-88.5	4.80- 5.20	5.0- 5.20	4.90-5.20	4.80-5.20
11	Hardness (N)	50N	31-40	30-35	22-28	29-34
12	Disintegration Time	1min 20sec-1min 50 sec	1min10 sec-1min15sec	49 sec-55sec	80sec-98sec	98sec-1.10min
13	Dispersion time in beaker	2 min 35 sec	2min50sec	65sec	80sec	81sec
14	Friability (100 rotation)	0.10%	0.27%	0.10%	0.25	0.11%
15	Friability (750 rotation)	0.43%	fail	0.58%	0.75	0.65
16	% Drug content	83.80	85.83	93.80	81.80	85.90

Sr.no	Parameter			
		F6	**F7**	**F8**
1	Unlubricated blend LOD (% w/w)	2.15	2.30	1.85
2	lubricated blend LOD (% w/w)	1.18	2.65	2.35
3	Tapped Density	0.64	0.54	0.55
4	Bulk Density	0.43	0.40	0.45
5	Compressibility Index	31.0%	26.0%	19.2%
6	Hausner's Ratio	1.48	1.35	1.22
	Compressed Tablet Parameters			
7	Appearance	White	White	White
8	Average weight (mg)	58.5-60.9	58.9-60.7	59.7-61.3
9	Thickness (mm)	2.5-3.06	5.59-3.24	2.43-3.49
10	Diameter (mm)	4.90- 5.20	5.0- 5.10	4.80-5.50
11	Hardness (N)	31-40	30-35	22-28
12	Disintegration Time	2min10 sec-1min15sec	1.30 min sec-2.20min	1.30 min sec-2 min
13	Dispersion time in beaker	2min50sec	85sec	90sec
14	Friability (100 rotation)	0.27%	0.10%	0.25
15	Friability (750 rotation)	0.80	0.98%	0.65
16	% Drug content	82.30	85.87	83.20

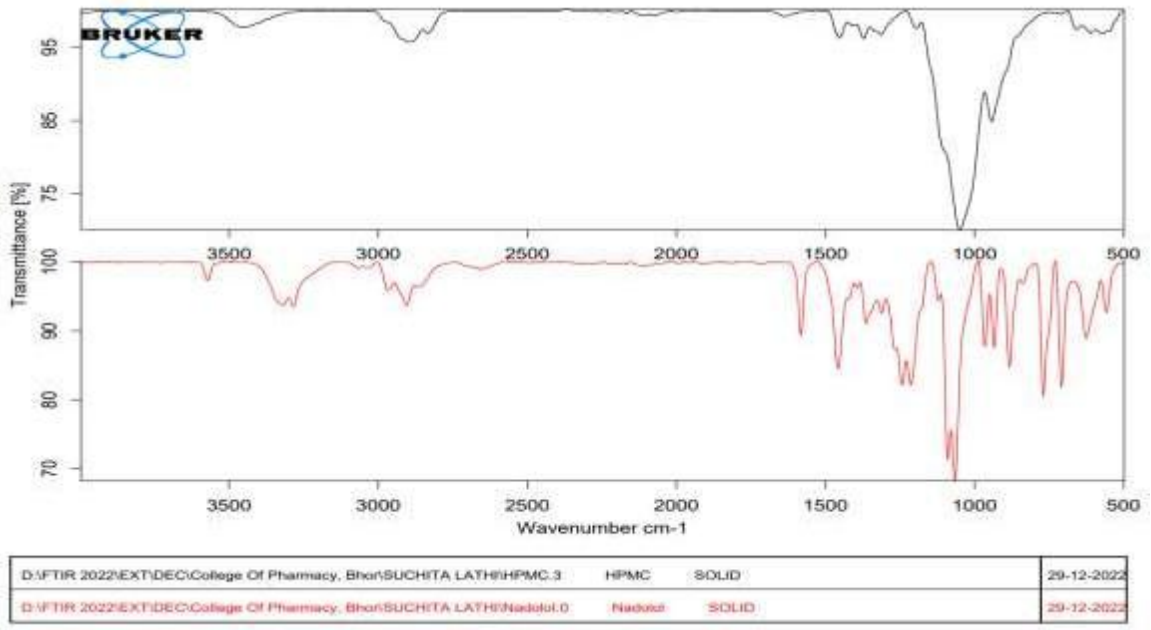


Fig. 1: FTIR Spectra Of Physical Mixture Of Nadolol Solid Dispersion

FTIR spectra are shown in Figure No the characteristic peaks of Nadolol N-H stretch at 3665.32-3643.22cm^{-1}, C-H stretch at 2713.94-2511.74 cm^{-1}, C=C stretch at 2145.23-1998.56 cm^{-1} and C-N stretch at 1643.85-1414.57 cm^{-1}. It was found that formulation F9 is compatible, there is no change in any ingredients.

In- vitro drug release profile of batch, F1-F5 was carried out and compared with the release profile of reference product

DSC Study

The DSC curve of pure drug and drug with carrier was carried out by METTLER TOLEDO diffractometer. DSC spectra of pure Nadolol, physical mixture and solid dispersion obtained.

Interpretation

The DSC of Nadolol API shows a sharp endothermic peak at 142.64^{0}C. Indicated purity of drug Nadolol.

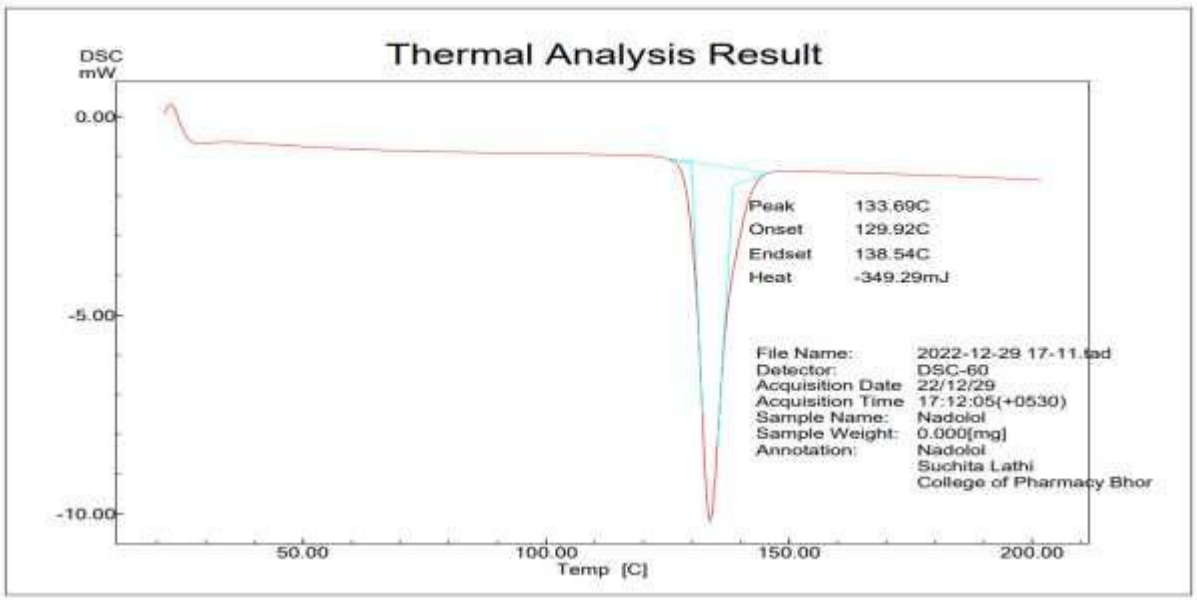


Figure: DSC of Nadolol solid dispersion

Interpretation

Endothermic peak form. Peak of API and formulation. Indicated that no incompatibility.

DSC at solid dispersion showed two peak one peak at 142.64^{0}C.

1st peak of Nadolol solid dispersion indicated no incompatibility between drug and polymer.

Table 3: In-vitro drug release of Batch F1-F5.

Time (minutes)	Reference Product	F1	F2	F3	F4	F5
0	0	0	0	0	0	0
1	6.96	7.15	8.79	9.16	6.46	7.05
2	19.01	18.20	19.85	21.20	14.20	18.45
4	24.24	28.86	32.28	36.86	23.86	26.81
6	35.24	40.78	43.84	49.78	32.78	39.46
8	48.03	55.96	56.25	63.96	45.96	50.76
10	59.9	70.62	70.62	78.62	57.62	72.22
12	69.10	78.14	80.69	87.86	69.14	78.14
14	82.25	83.75	85.83	93.71	81.75	86.89
16	82.30	83.80	85.83	93.80	81.80	85.90

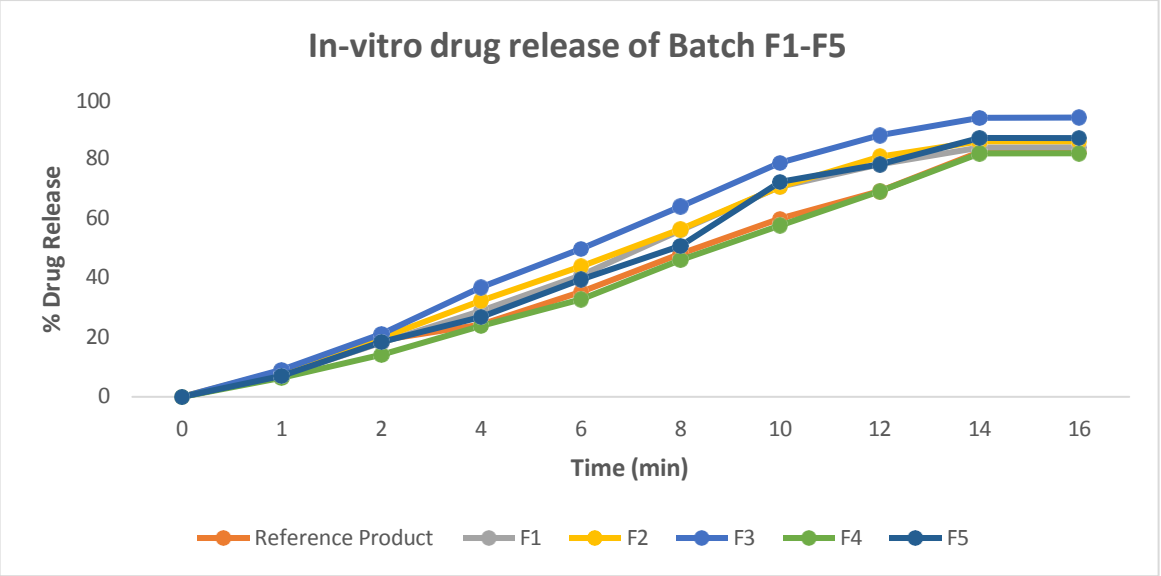


Figure 3: In-vitro drug release of Batch F1-F5.

Observation:

- In tablet batch F1, F3 & F5 contain Croscarmellose sodium & batch F2 & F4 contains Sodium starch glycolate, having Direct Compression method, Batch F1, F2, F4 & F5 all physical parameters are satisfactory but disintegration time and dissolution were not satisfactory.
- In tablet batch F3 there is an increase in the quantity of the superdisintegrant Croscarmellose to so, it improves disintegration time as compared to batch F1, F2, F4 & F5. All physical parameters were satisfactory.

Conclusion:

From the above observation, it was concluded that the percentage drug release of drug is less Except F3 so need to increase the percentage of drug release so further batches are given.

FORMULATION F5 TO F9: In- vitro drug release profile of batch, F6-F9 was carried out and compared with the release profile of the reference product.

Table 4: In-vitro drug release of batch F6-F9

Time (minutes)	Reference Product	F6	F7	F8
0	0	0	0	0
1	6.96	8.06	8.79	8.98
2	19.01	17.20	19.75	21.20
4	24.24	27.96	32.78	36.84
6	35.24	40.72	47.84	48.70

8	48.03	55.86	58.25	63.66
10	59.9	70.36	71.62	76.58
12	69.10	78.35	79.64	80.53
14	82.25	85.86	83.20	84.90
16	82.30	85.87	83.20	84.90

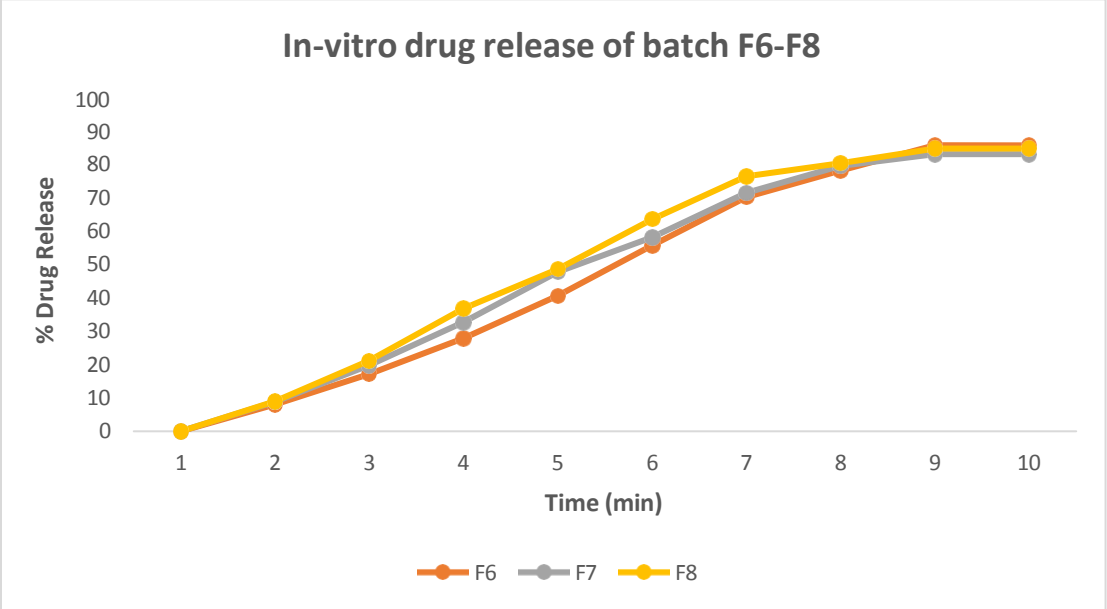


Figure 4: In-vitro drug release of batch F6-F9

Observation:

- In F6, F8 in this batch there is the use of change in the quantity of Sodium starch glycolate. In tablet batch F7 & F9 contain Sodium starch glycolate, having a Direct Compression method. Batch F7 contain Croscarmellose sodium & Batch F9 contain both Croscarmellose sodium & Sodium starch glycolate all physical parameters are satisfactory disintegration time also satisfactory but, percentage drug release was less.

Conclusion:

- In Batch F3 all the formulation parameters of the tablets were found to be satisfactory
- The drug release profile of the formulated tablets was compared to the reference product and the drug release was found to be as per the specifications.
- Thus, batch F3 was taken as the finalized batch.

Wetting Time:

The formulations F1, F2, F3 and F4 were prepared with **Croscarmellose sodium** which shows wetting time. 49.36, 46.47, 42.23 and 43.23 sec respectively. The results suggest that as the content of Croscarmellose sodium is increased wetting i.e., decreases wetting time. The ranking order is Fl >F2>F4>F3.

The formulations F5, F6, F7 and F8 were prepared with **Sodium starch glycolate** which shows wetting time 38.69, 35.12, and 28.47 sec respectively. The result suggests that as the content of **Sodium starch glycolate** increased wetting time decreases. The wetting time follows the order F2>F4>F6>F8.

Statistically, the data were analyzed by one-way ANOVA at $p < 005$. It was found that the data at any point of time are significant at $p < 005$. Tablet wetting initial.

Reproducible batch data:

- **Table 5: Physical parameters of batch F3**

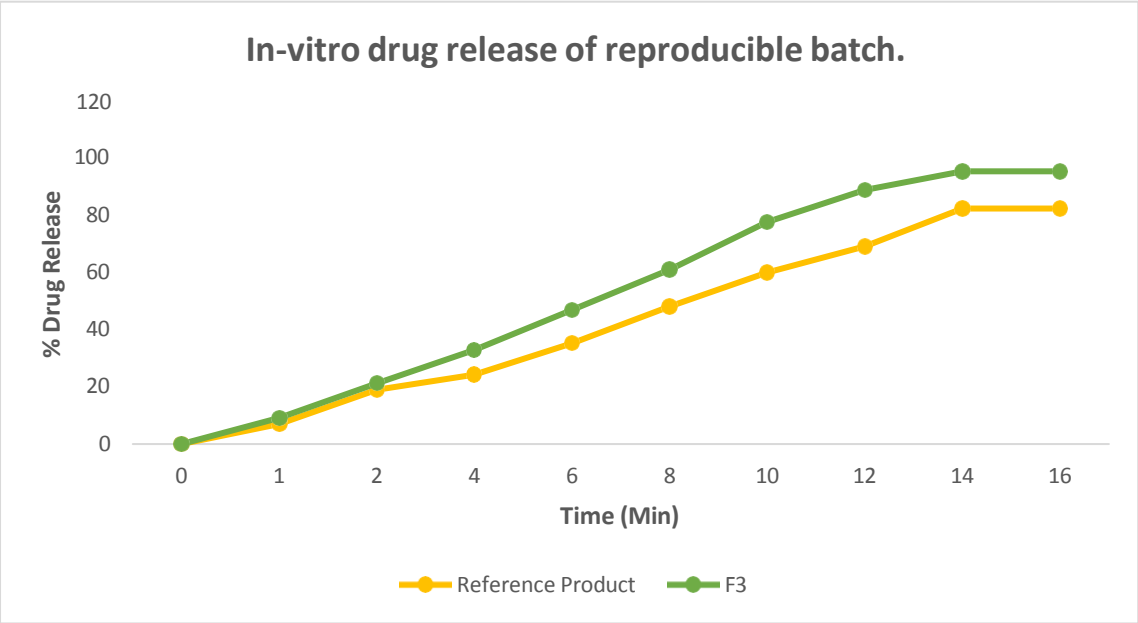
Sr.no	Parameter	Evaluation Result
	Precompression parameter	
1	Unlubricated blend LOD (% w/w)	2.22
2	lubricated blend LOD (% w/w)	2.20
3	Tapped Density	0.56
4	Bulk Density	0.36
5	Compressibility Index	25.0%
6	Hausner's Ratio	1.55
	Compressed Tablet Parameters	
7	Appearance	White
8	Average weight (mg)	59.5-60.5
9	Thickness (mm)	2.48-2.53
10	Diameter (mm)	4.98- 5.10
11	Hardness (N)	30-32
12	Disintegration Time	40 sec- 60 sec
13	Dispersion time in the beaker	40 sec
14	Friability (100 rotation)	0.18%
15	Friability (750 rotation)	0.47%
16	% Drug content	95.3

- The in-vitro drug release profile of batch F3 was carried out and compared with the release profile of the reference product.

- **Table 6: In-vitro drug release of reproducible batch.**

Time (minutes)	Reference Product	F3
0	0	0
1	6.96	9.16
2	19.01	21.20
4	24.24	32.86

6	35.24	46.78
8	48.03	60.96
10	59.9	77.62
12	69.10	88.80
14	82.25	95.30
16	82.30	95.30



- **Figure 5: In-vitro drug release of the reproducible batch.**

CONCLUSION: The Nadolol strong dispersion prepared by solvent evaporation method and after this mouth dissolving tablet was prepared by using this solid dispersion. Solid dispersion is the satisfactory drug transport device, for enhancing solubility and dissolution rate of poorly water-soluble drug. BCS elegance-II drug are greater suitable drug candidate for formulated into solid dispersion and MDT. Solid dispersion prepared by means of solvent evaporation technique shows suitable drug content material and in-vitro drug release. The compatibility of drug and polymer decide by feet-IR and DSC have a look at. The result of IR and DSC shows drug and polymer are well suited each other. Final results of the look at concluded that HPMC are employed as polymer for oral drug transport gadget. Strong dispersion of Nadolol boom solubility and dissolution rate of drug. The solubility of Nadolol in solid dispersion drug transport appreciably accelerated. Further that MDT tablet was formulated by using solid dispersion and further study is carry on this MDT tablet. The Drug- excipients compatibility studies showed that the excipients used in the final formulation have no interaction with the drug. The excipients were compatible with API. Evaluation of physicochemical parameters like hardness, friability, dissolution, and assay indicated that the tablet was mechanically stable and complied with necessary Pharmacopoeial specifications, and comparable to the referred product. In Batch F3 all the formulation parameters of the tablets were found to be satisfactory. The drug release of F3 is 95.30% the formulated tablets were compared to the reference product and the drug release was found to be as per the specifications. Thus batch F3 was taken as the finalized batch.

The formulation further needs to be evaluated for bioequivalence study in healthy human volunteers. Finally, it is concluded that the process adopted for manufacturing provides a product that meets all the predetermined specifications and quality characteristics. The process would imbibe reproducibility and robustness in the formulation.

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