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Research

Formulation and Evaluation of Mouth Dissolving Tablets of Nebivolol HCL for Treatment of Hypertension

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Abstract

The present study was aimed at the formulation and evaluation of mouth dissolving tablets (MDTs) of Nebivolol HCl for the effective treatment of hypertension, enhancing patient compliance and ensuring rapid onset of action. Nebivolol HCl, a β1-selective adrenergic blocker, suffers from poor aqueous solubility, which limits its bioavailability. To address this, mouth dissolving tablets were formulated using different super disintegrants — Polyplasdone XL, Solutab, and Explotab — in varying concentrations to optimize disintegration time and drug release profile.

A Total of Nine formulations (F1 to F9) were prepared by direct compression method and evaluated for pre-compression and post-compression parameters such as hardness, friability, weight variation, disintegration time, wetting time, and in vitro drug release. Among all the formulations, Formulation F3, containing an optimized concentration of Polyplasdone XL, demonstrated the most desirable results with 99.24% drug release within 30 minutes, fastest disintegration time, and excellent tablet characteristics.

The study concluded that the use of suitable super disintegrants significantly improved the dissolution rate and patient acceptability of Nebivolol HCl MDTs. Formulation F3 was identified as the optimized formulation and holds potential for rapid and effective hypertension management through improved bioavailability and patient compliance.

Keywords: Nebivolol HCl, Mouth Dissolving Tablets, Polyplasdone XL, Solutab, and Explotab.

1. INTRODUCTION

Oral route of administration is considered as the most widely accepted route because of its convenience of self-administration, compactness and easy manufacturing. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water. [1]

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems.[2]

1.1. NEED TO DEVELOP MDT:[3-7]

The need for one of the non-invasive delivery system i.e., Mouth disintegrating tablets persists due to patients' poor acceptance of, and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management.

PATIENT FACTORS:

Mouth disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow tablets and capsules with an 8-oz glass of water. These include the following:

- Paediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients who are unwilling to take solid preparation due to fear of choking.
- Very elderly patients who may not be able to swallow a daily dose of antidepressant.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup
- A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker.
- A schizophrenic patient in an institutional setting who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
- A patient with persistent nausea, who may be journey, or has little or no access to water

1.2. MECHANISM OF ACTION OF MDT IN ORAL MUCOSA:[8-10]

1.3. MECHANISM OF ACTION: The MDT is placed upon patient's tongue or any oromucosal tissue. It instantly get wet by saliva due to presence of hydrophilic polymer and other excipients, then the tablet rapidly hydrates and dissolves to release the medication for oromucosal absorption.

1.4. ADVANTAGES OF MDTS:

Advantages of MDTs include:

- Ease of administration to geriatric, paediatric, mentally disabled, and bed-ridden patients, who have difficulty in swallowing the tablet.
- The MDTs do not need water for swallowing unlike conventional dosage forms. This is very convenient for patients who are travelling or do not have immediate access to water, and thus, provide improved patient compliance.
- Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for paediatric and geriatric patients.
- Bioavailability of drugs is enhanced due to absorption from mouth, pharynx, and oesophagus.
- Pregastric absorption can result in improved bioavailability and because of reduced dosage, improved clinical performance through a reduction of unwanted effects.
- Rapid onset of therapeutic action as tablet is disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- Good mouth feels, especially for paediatric patients as taste-masking technique is used to avoid the bitter taste of drugs.
- Minimum risk of suffocation in airways due to physical obstruction, when MDTs are swallowed, thus they provide improved safety and compliance with their administrations.

- Rapid drug therapy intervention is possible.
- Conventional processing and packaging equipments pleat disintegration in the mouth.

LIST OF MATERIALS

Nebivolol Hcl Procured From Mylan laboratories Ltd., Hyderabad, Provided by SURA LABS, Dilsukhnagar, Hyderabad.

Polyplasdone XL Oxford Laboratories Pvt. Ltd, Mumbai, India

Solutab Oxford Laboratories Pvt. Ltd, Mumbai, India

Explotab Oxford Laboratories Pvt. Ltd, Mumbai, India

Aspartame Oxford Laboratories Pvt. Ltd, Mumbai, India

Talc Oxford Laboratories Pvt. Ltd, Mumbai, India

Mg streate Oxford Laboratories Pvt. Ltd, Mumbai, India

MCC Oxford Laboratories Pvt. Ltd, Mumbai, India

LIST OF EQUIPMENTS

Weighing Balance Sartorius

Tablet Compression Machine (Multi station) Lab Press

Limited, India.

Hardness tester Monsanto, Mumbai, India.

Vernier callipers Mitutoyo, Japan.

Roche Friabilator Labindia, Mumbai, India

Dissolution Apparatus Labindia, Mumbai, India

UV-Visible Spectrophotometer Labindia, Mumbai, India

pH meter Labindia, Mumbai, India

FT-IR Spectrophotometer Bruker, Germany

Tablet disintegration tester Labindia, Mumbai, India

METHODOLOGY

Formulation development:

Drug and different concentrations of super disintegrants (Polyplasdone XL, Solutab, Explotab) and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass motor for 15 min.

- The obtained blend was lubricated with magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 min.
- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 1: Formulation table showing various compositions

INGREDIENTS	FORMULATIONS								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Nebivolol Hcl	5	5	5	5	5	5	5	5	5
Polyplasdone XL	5	10	15	-	-	-	-	-	-
Solutab	-	-	-	5	10	15	-	-	-
Explotab	-	-	-	-	-	-	5	10	15
Aspartame	6	6	6	6	6	6	6	6	6
Talc	4	4	4	4	4	4	4	4	4
Mg streate	3	3	3	3	3	3	3	3	3
MCC	77	72	67	77	72	67	77	72	67
Total Weight	100	100	100	100	100	100	100	100	100

Evaluation of tablets:

Post compression parameters :

a) Thickness

The thickness of the tablets was determined by using Digital micrometer. 10 individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were randomly selected from each batch and individually weighed . The average weight and standard deviation 3 batches were calculated. It passes the test for weight variation test if not more than 2 of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the % shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-friabilator. Accurately weighed six tablets were placed in The Roche friabilator and rotated at 25 RPM for 4 min. Percentage friability was calculated using the following equation.

Friability = ([w_0-w]/w_0) x 100

Where w_0 = weight of tablet at time zero before revolution.

w = weight of the tablet after 100 revolutions

d) Drug content

The content of drug carried out by 5 randomly selected tablets of each formulation. The 5 tablets were grinded to get powder, this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 282 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 min. and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) WETTING TIME:

- **Method:** A piece of tissue paper folded twice was placed in a small Petri dish containing 6ml of water. A water-soluble dye phenolphthalein was added to the Petri dish. The dye solution was used to identify the complete wetting of the tablet surface.
- A tablet was carefully placed on the surface of tissue paper in the Petri dish at room temperature.
- The time required for water to reach the upper surface of the tablets and completely wet them was noted as the wetting time. To check for reproducibility, the measurements were carried out in triplicates (n=3). The wetting time was recorded using a stopwatch.

g) WATER ABSORPTION RATIO (R):

- **Method:** The weight of the tablet before keeping in the Petri dish was noted (W_b) using digital balance. The wetted tablet from the Petri dish was taken and reweighed ($W_{a'}$) using the same. The Water absorption ratio, R, was determined according to the following equation:

$$R = (W_a - W_b) / W_b * 100$$

W_a= Weight of the tablet after absorption

W_b= Weight of the tablet before absorption

h) *IN VITRO* DISPERSION TIME:

- **Method:** *In vitro* dispersion time was determined by placing one tablet in a beaker containing 10 ml of pH 6.8 phosphate buffer at 37±0.5°c and the time required for complete dispersion was determined.
- To check for reproducibility, the measurements were carried out in triplicates (n=3). The dispersion time was recorded using a stopwatch.

i) Dissolution test of Nebivolol Hcl

Drug release from Nebivolol Hcl tablets was determined by using dissolution test USP 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at room temperature of 37˚ C and at a speed of 50 rpm.

5 ml aliquots of dissolution media were withdrawn each time intervals (5, 10, 15, 20 and 30 min) and appropriate dilution by UV Spectrophotometer. The Concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies:

Drug excipients compatibility studies were carried out by mixing the drug with various excipients in different proportions (in 1;1 ratio were to have maximum

likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly. Fourier Transform Infrared Spectroscopy (FTIR) studies were performed on drug, optimized formulation using Bruker FTIR. The samples were analyzed between wave numbers 4000 cm^{-1} and 550 cm^{-1}.

RESULTS AND DISCUSSION:

Preparation of Calibration Curve of Nebivolol Hcl:

The regression coefficient was found to be 0.997 which indicates a linearity with an equation of Y= 0.0551 X-0.0021. Hence Beer-Lambert's law was obeyed.

Table 8.1: Calibration curve data of Nebivolol Hcl in pH 6.8 phosphate buffer

Concentration	Absorbance
0	0
2	0.117
4	0.221
6	0.329
8	0.447
10	0.552

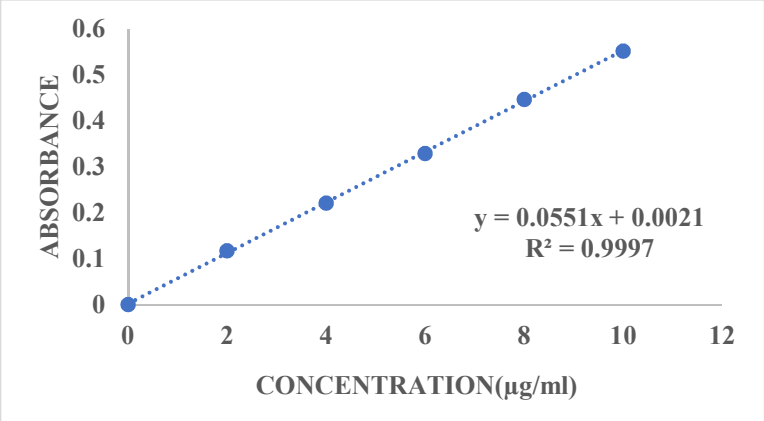

Fig 1: Standard curve of Nebivolol Hcl

EVALUATION OF PRE-COMPRESION PARAMETERS OF POWDER BLEND

Table 2: Evaluation of pre-compression parameters of powder blend

Formulation Code	Angle of Repose	Bulk Density(gm/mL)	Tapped Density (gm/mL)	Carr's Index(%)	Hausner's Ratio
F1	27.06±0.02	0.58±0.06	0.66±0.07	12.12±1.13	1.11
F2	27.06±0.02	0.57±0.09	0.66±0.08	13.63±1.01	1.10
F3	26.57±0.02	0.56±0.05	0.65±0.04	13.84± 0.35	1.08
F4	24.62±0.03	0.58±0.05	0.66±0.07	12.12±1.27	1.07
F5	24.42±0.01	0.58±0.05	0.69±0.02	13.04±1.05	1.10

F6	24.42±0.01	0.61±0.04	0.69±0.06	11.59±1.11	1,10
F7	24.51±0.02	0.62±0.04	0.67±0.04	7.46±1.36	1.07
F8	24.49±0.01	0.58±0.02	0.66±0.08	12.12±1.55	1.17
F9	24.45±0.03	0.58±0.04	0.66±0.02	12.12±0.35	1.08

- For each formulation blend of drug and excipients were prepared and evaluated for various pre compression parameters described earlier in methodology chapter.
- The bulk density of all formulations was found in the range of 0.56±0.05 - 0.62±0.04 and tapped density was in the range of 0.65±0.04 - 0.69±0.06
- The Carr's index and Hausner's ratio was calculated from tapped density and bulk density.

EVALUATIONS OF POST COMPRESSION PARAMETERS OF NEBIVOLOL HCL MOUTH DISSOLVING TABLETS

Table 3: Evaluation of post compression parameters of Nebivolol Hcl Mouth Dissolving tablets

Formulation codes	Average weight(mg)	Hardness (kg/cm^2	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	98.12±0.12	3.5±0.2	0.14±0.04	2.15±0.03	99.6±1.5
F2	97.35±0.35	2.7±0.3	0.35±0.03	2.00±0.01	98.1±2.5
F3	100.22±0.48	3.0±0.2	0.42±0.02	2.19±0.04	97.6±1.5
F4	99.46±0.27	2.5±0.2	0.30±0.04	2.09±0.04	99.3±1.4
F5	98.82±0.33	3.7±0.3	0.39±0.03	2.15±0.03	98.8±1.5
F6	97.64±0.71	3.2±0.2	0.35±0.03	2.05±0.04	99.6±1.5
F7	96.51±0.68	2.6±0.2	0.52±0.04	2.12±0.02	96.3±1.8
F8	98.12±0.15	2.9±0.3	0.47±0.03	2.14±0.02	99.1±3.2
F9	99.08±0.32	2.8±0.2	0.50±0.02	2.90±0.03	98.3±3.24

Table 4: Evaluation of post compression parameters of Nebivolol Hcl Mouth Dissolving Tablets

Formulation	Disintegration time*(seconds)	Wetting time* (seconds)	*In vitro* dispersion time*(sec)	%Water absorption ratio*
F1	26	20	35	97
F2	28	27	29	96
F3	19	17	20	98
F4	28	22	28	96
F5	36	29	36	97
F6	24	31	35	97
F7	23	26	28	96
F8	22	21	24	94
F9	54	28	30	95

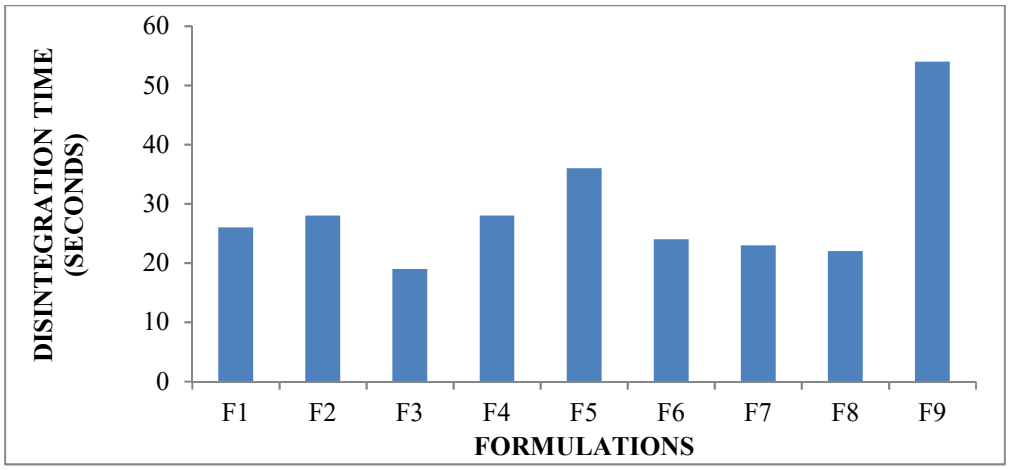

Figure 2: *In vitro* Disintegration time graph

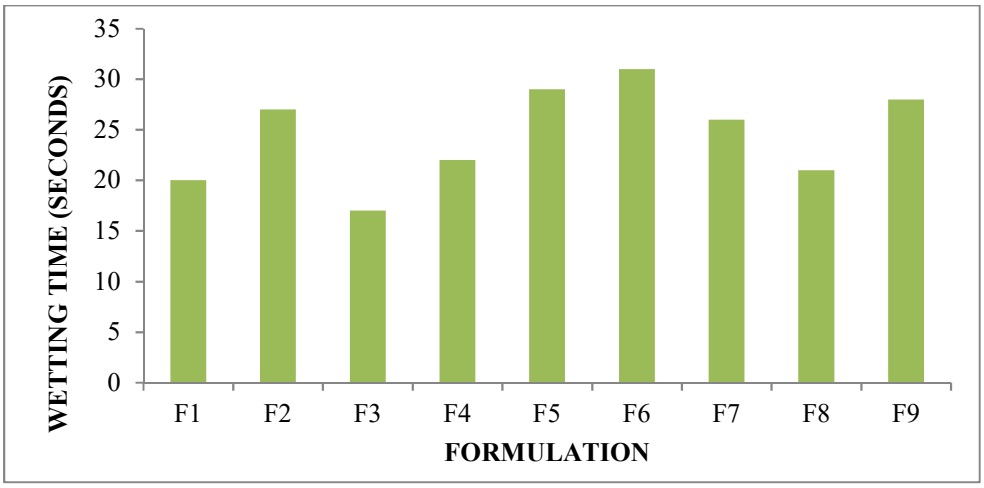

Figure 3: Wetting time graph

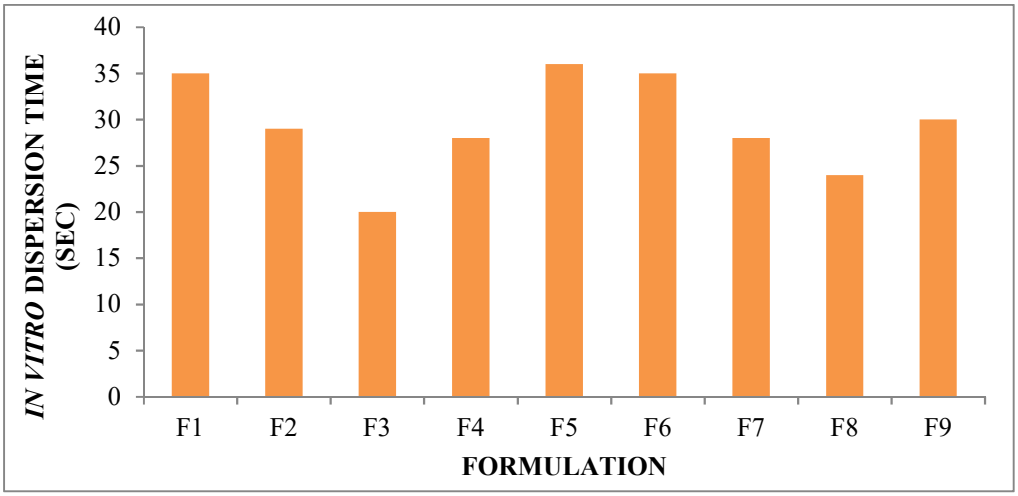

Figure 4: *In vitro* Dispersion Time

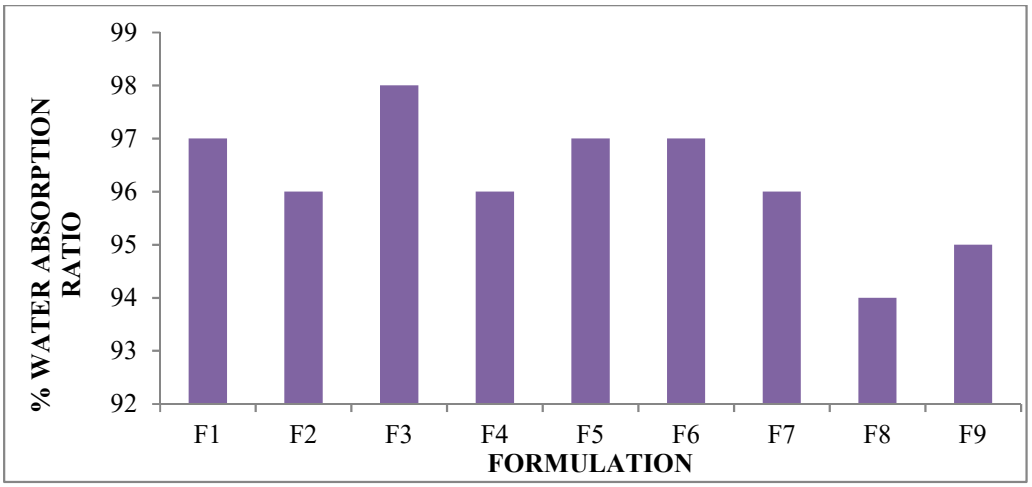

Figure 5: Water absorption ratio graph

***In vitro* disintegration time:** *In vitro* disintegration studies showed from 19 to 54 secs. These results indicate that the F3 formulation which shown less disintegration time than remaining formulations.

Wetting time: Wetting time to the time required to wet completely when kept motionless on the tissue paper in a petridish.

- All the FDT formulations were evaluated for their wetting time as per the procedure described in the methodology section, and the results are shown in table.
- The average wetting time for all the formulations was in the range of **(17 to 31)** seconds.
- It was also observed that formula F3 which had the least wetting time also had the minimum disintegration time showing a strong correlation between disintegration time and wetting time.

***In vitro* dispersion time:** Nebivolol Hcl Mouth Dissolving Tablets F3 formulation dispersed time was 20 secs. It was known that less dispersion time than other formulation.

The *In vitro* dispersion time for all formulation was found to be in a range of **20 to 36** seconds

Water Absorption ratio: All the formulations were evaluated for water absorption ratio according to the procedure described in methodology section and the results are shown in table.

- The maximum water absorption ratio was shown by formulation F3 showed **98 %.**
- Water absorption ratio is proportional to dissolution rate profile as higher the water absorption ratio Higher the dissolution

IN VITRO DRUG RELEASE STUDIES OF NEBIVOLOL HCL

Table 8.5 : Dissolution data of Nebivolol Hcl

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	36.32	42.15	46.86	45.12	41.37	48.95	49.51	31.25	29.13
10	53.56	49.29	59.34	54.64	62.77	57.34	54.69	52.18	52.90
15	61.33	71.03	63.22	66.09	77.74	69.23	73.92	64.31	69.08
20	69.08	79.21	88.65	74.49	84.71	88.11	85.18	72.08	79.95
30	82.57	91.82	99.24	89.51	92.99	98.63	97.21	92.72	94.82

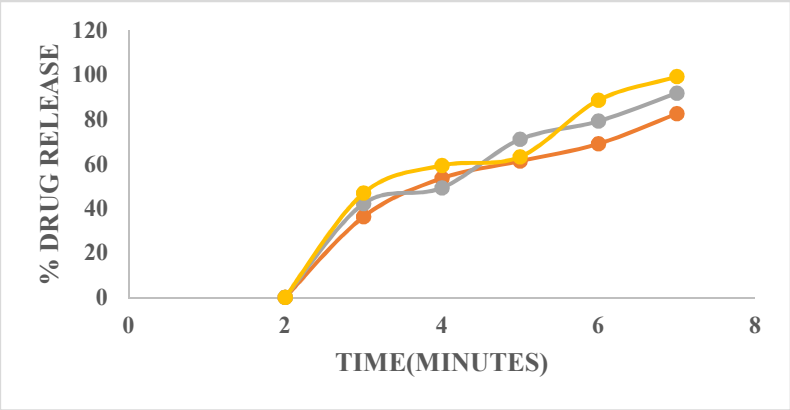

Fig 6: Dissolution profile of formulations F1, F2, F3

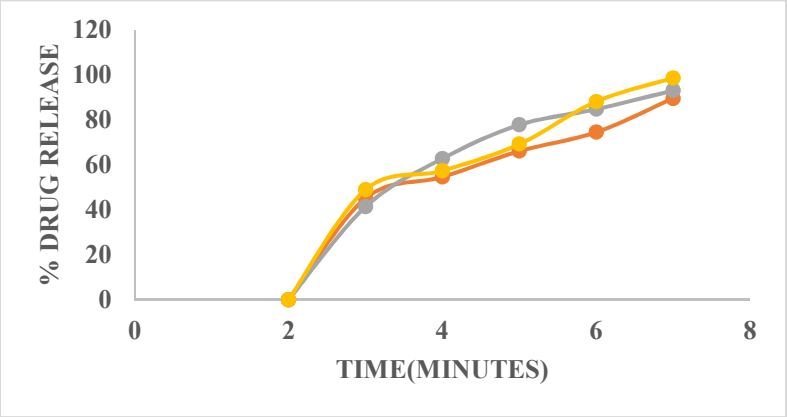

Fig 7: Dissolution profile of formulations F4, F5, F6

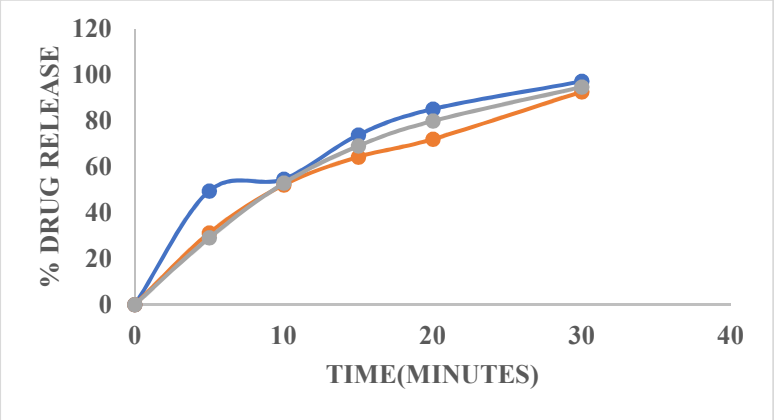

Fig 8: Dissolution profile of formulations F7, F8, F9

The F3 formulation shows 99.24 % drug release in 30 min while using 15mg concentration of Polyplasdone XL and disintegration time is 19 sec. In which increase of concentration of Polyplasdone XL improved dissolution and decreased disintegration so it was optimized formulation. Polyplasdone XL, Solutab and Explotab are three used as super disintegrants. Finally Concluded that F3 formulation was the optimized Formulation.

FTIR RESULTS:

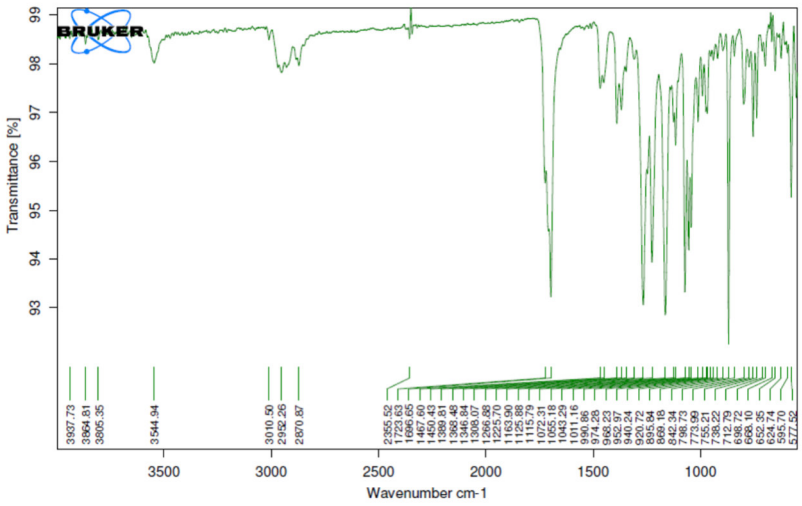

Fig 10: FTIR of Nebivolol Hcl Pure Drug

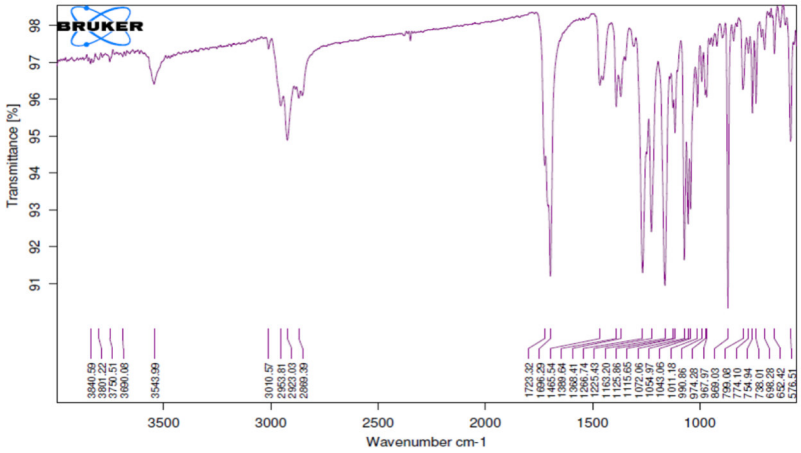

Fig 11: FTIR of Nebivolol Hcl optimized formulation

Nebivolol Hcl was mixed with proportions of excipients showed no colours change providing no drug-excipient interactions

CONCLUSION

The present study successfully demonstrated the formulation and evaluation of mouth dissolving tablets (MDTs) of Nebivolol HCl for the effective management of hypertension. Various super disintegrants such as Polyplasdone XL, Solutab, and Explotab were employed to enhance the disintegration and dissolution characteristics of the tablets. Among the different formulations, the optimized batch showed excellent results in terms of rapid disintegration time, improved drug release profile, and satisfactory physicochemical parameters including hardness, friability, and drug content. The mouth dissolving tablets of Nebivolol HCl thus offer a promising alternative to conventional dosage forms by ensuring faster onset of action, better patient compliance, and ease of administration without the need for water, especially suitable for geriatric and paediatric patients.

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