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Formulation and Evaluation of Orodispersible Tablet of Omeprazole Using Hibiscus Rosa Sinesis Mucilage as Natural Superdisintegrant

Harish Porwal, Anjali Chourasiya, Narendra Gehlod, Dr Vikas Jain
Mahakal Institute of Pharmaceutical Studies, Ujjain

Abstract: *Orodispersible tablets (ODTs), also known as fast melt, quick melts, fast disintegrating have the unique property of disintegrating in the mouth in seconds without chewing and the need of water. In the present work, orodispersible tablets of Omeprazole were prepared by direct compression method using Hibiscus rosa sinesis mucilage as natural superdisintegrant with a view to enhance patient compliance and to avoid hepatic first pass metabolism and to improve its bioavailability. The prepared batches of tablets were evaluated for hardness, friability, drug content uniformity, wetting time, water-absorption ratio and in- vitro dispersion time. Short-term stability studies on the promising formulation indicated thatthere are no significant changes in drug content and in vitro dispersion time*

Keywords: Orodispersible tablet, Omeprazole , Superdisintegrant, Hibiscus Rosa Sinensis, Bioavailability, solubility

I. INTRODUCTION

Oro-Dispersible Tablet: Oral delivery is current standard in the pharmaceutical industry wherever it is regarded as the safest, most suitable and most economical method of drug delivery. The oral cavity is an attractive site for the administration of drugs because of ease of administration. Oro-dispersible drug delivery system are Novel Drug Delivery techniques that make the tablets disintegrate in the mouth without chewing and water, and immediate release and enhanced bioavailability, with better patient compliance. Recently, the European Pharmacopeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates within a minute or second in the mouth before swallowing. United States Food and Drug Administration (FDA) defined Oro-dispersible tablet as “a solid dosage form containing medicinal substances or active ingredient which disintegrate or dissolve rapidly within seconds when placed upon the tongue.

Oro-dispersible tablets have a quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pregastric absorption when formulated as ODTs may oral bioavailability of drug is enhancedby avoiding the hepatic first pass metabolism. It provides good stability, accurate dosing, easy of manufacturing[6]. Oro- dispersible tablets are made by a direct compression method using super Disintegrate as an important component.1

II. MATERIALS AND METHOD

Omeprazole was obtained as Yarrow chem. pvt. Ltd Microcrystalline Cellulose, Mannitol, Aspartame, Magnesium Stearate, Talc was obtained from loba chemicals.

2.1 METHODS:

Extraction & characterization of mucilage from hibiscus rosa-sinesis:Hibiscus rosa sinensis (China rose) was procured from the college garden (plant and herbs collection) facility. Collected leaves was carefully washed and dried under shade for 24 hrs and then further dried in oven at at 30-40°C. Size was reduced with the help of grinder. Powdered leaves were sieved through sieve no. #22 and then used for further evaluation 2.

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Extraction of mucilage includes 2 steps.

Step 1: Extraction of Mucilage: Powdered leaves of Hibiscus rosa sinensis were used for the extraction of mucilage. 100gm of powdered leaves placed in 1000ml beaker containing 500ml of distilled water and allowed it to boil for at least 3 -4 h with continuous stirring and heating at 60°C of sufficient release of mucilage in water. Concentrated solution was then filtered through muslin cloth in order to separate marc from the filtrate and refrigerated for cooling (3-4°C).

Step 2: Isolation of Mucilage: To the extract of mucilage, acetone was added to the quantity of three times the volume of filtrate for precipitation of mucilage. The precipitated mucilage was washed with acetone and then collected through filtration by muslin cloth. Mucilage was further dried in hot air oven at temperature less than 40°C. The obtained dried mucilage was grinded and passed through sieve No. #80 and finally stored in air tight container.3

Characterization of prepared mucilage powder:

Organoleptic Characterization of Isolated Mucilage: The extracted mucilage was characterized for various parameters like color, odor, taste, texture and fracture etc 56.

Percentage Yield: The percentage yield was calculated in the percentage amount of hibiscus rosa sinesis mucilage sample used before the extraction process and the amount of powder of mucilage obtained after the extraction. The Percentage Yield was calculated by the using following formula.

Percentage yield = weight after extraction / weight before extraction ×100

Determination of Mucilage pH:

The pH of the mucilage was determined by using 1% w/v solution of mucilage inwater and was determined by digital pH meter.

Swelling Index: It was calculated by weighing a butter paper of size 2X2 cm. then butter paper was dipped in a Petridish containing water and re-weighed. After this 10 mg of the powdered sample was kept in a butter paper placing this on Petridish containing 15 ml of water and the swelling index was calculated after 24 h and the final result was calculated using the formulae.

$SI = V2 - V1 / V1 \times 100$

Where,

V1=Initial volume of mucilage before hydration; V2=final Volume of hydrated mucilage

Bulk Density and Tapped Density:

Bulk density of powder mucilage was determined by bulk density apparatus. Density was calculated as weight of the powder divided by the volume acquired by that weighed powder. The SI unit of density is gm/ml. The difference between the bulk density and tapped density is that, in bulk density, bulk volume is used whereas in the tapped density, tapped volume is used which can be obtained by switching on the equipment for 100 times tapings.

Bulk density = mass of powder/bulk volume of powder.

Tapped density = Mass of powder / Tapped volume of powder

Carr's Index: The Carr's index was determined using following formula. Carrs index = Tapped density – Bulk density/Tapped density × 100 Hausners Ratio: The Hausners ratio was calculated using following formula Hausner's Ratio = Tapped density / Bulk density

Angle of Repose:The angle of repose of powder was determined by the funnel method. The accurately Weighed mucilage powder were taken in funnel. A funnel is fitted andis secured with its tip at a height (h) of 2 cm above graph paper which is placed on a horizontal surface. The accurately weighed powder were taken and dropped in funnel. The powder blend was allowed to flow through the funnel freely onto the surface The angle of repose was calculated by measuring the diameter and hight of powder cone and putting the values to the equation.4

$\theta = \tan^{-1}(h/r)$

2.2 Preformulation Studies:

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Solubility of drug : 50mg Omeprazole of was weighed and solubility of this sample was checked in water, methanol and phosphate buffer by using calibration curve method. The drug was found to be soluble in methanol57

Identification of λmax of Omeprazole : 50mg of drug was weighed and was dissolved in 50ml of methanol (1mg/ml). 10ml of this solution was withdrawn and volume was made up to 100ml. Appropriate dilutions were made with methanol to give concentration of 10 µg/ml, scanned in UV range from 200- 400nm and spectrum was recorded.5

Preparation of calibration curve of Omeprazole: Calibration curve of Omeprazole in methanol:

Preparation of stock solution

Accurately weighed 50mg of Omeprazole was transferred into a 50ml volumetricflask & dissolved to obtain a 1000µg/ml stock solution of Omeprazole. From the stock solution, 1ml was taken into a 10ml volumetric flask and volume was made up with methanol to obtain a 100µg/ml of solution6.

Preparation of dilution : From 100µg/ml solution the appropriate aliquote of 0.5ml, 1ml,

1.5ml, 2ml, 2.5ml, were taken into different volumetric flask and diluted up to 10ml to get different concentration range 5-25 µg/ml. The absorbance of each dilution was noted.

Calibration curve of Omeprazole in phosphate buffer pH 6.8:

Preparation of dilution : From 100µg/ml solution the appropriate aliquote of 1.0ml, 2.0ml, 3.0ml, 4.0ml, 5.0ml, were taken into different volumetric flask and diluted up to 10ml with phosphate buffer pH 6.8 to get different concentration range 10 -50 µg/ml. The absorbance of each dilution was noted.7

Calibration curve of Omeprazole in pH 1.2 HCl buffer:]

Preparation of stock solution

Accurately weighed 50mg of Omeprazole was transferred into a 500ml volumetric flask & dissolved in pH 1.2 HCL buffer. Then sonicated for 15 minute and the volume were made up with pH 1.2 HCl buffer to obtain a 100µg/ml stock solution of Omeprazole.

Preparation of dilution

From 100µg/ml solution the appropriate aliquot of 0.5ml, 1ml, 1.5ml, 2ml, 2.5ml, were taken into different volumetric flask and diluted up to 10ml with pH 1.2 HCl buffer to get different concentration range 5-25 µg/ml. The absorbance of each dilution was noted.

Calibration curve of Omeprazole in Distilled water:

Preparation of stock solution

Accurately weighed 50mg of Omeprazole was transferred into a 500ml volumetric flask & dissolved in Distilled water. Then sonicated for 15 minute and the volume were made up with Distilled water to obtain a 100µg/ml stock solutionof Omeprazole.

Preparation of dilution : From 100µg/ml solution the appropriate aliquot of 1ml, 2ml, 3ml, 4ml, 5ml, were taken into different volumetric flask and diluted up to 10ml with Distilled water to get different concentration range 10-50µg/ml. The absorbance of each dilution was noted.

Determination of solubility of Omeprazole in various (Methanol, phosphate pH buffer 6.8 and pH 1.2 HCl buffer, water) mediums:

The solubility of Omeprazole in various medium was determined by shake flask method. In this method 5ml of each solvent was taken into a vial and an excess amount of Omeprazole was added. The vials were sealed properly and stirred continuously. After solubilization of Omeprazole , an extra amount of Omeprazole drug was added to the vials containing drug-solvent mixture and stirred for a period of

6 hours (saturation time). The process was repeated until saturation solubility of Omeprazole, indicated by presence of undissolved drug. The mixtures were then kept at room temperature for 24 hrs. and the solution were filtered through what man's filter paper. Then diluted with respective solvents i.e. Methanol,phosphate pH buffer 6.8 and pH 1.2 HCl buffer, water. The drug concentration was analyzed spectrophotometrically at 300 nm. using UV-visible spectrophotometer (Shimadzu- 1800).8

Drug-excipient interaction study:

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The compatibility of the drug was assessed by drug-excipient interaction study. The drug was mixed with various (Beta-cyclodextrin, Hibiscus Rosa-senesis mucilage , Microcrystalline Cellulose, Mannitol Aspartame Magnesium Sterate Talc) excipients in a 1:1 ratio in glass vials which were properly sealed & labelled and kept undisturbed for 15 days. Physical and chemical observations of all the mixtures were done on initial day and 15th day by TLC.9

Thin layer chromatography: Preparation of TLC Plates Firstly silica gel-G slurry prepared by mixing silica gel-G with distilled water in mortor pestle and triturated continuously to make uniform slurry. Then glass slide was taken and slurry poured uniformly on glass slide and allow to dry TLC plate in hot air oven at 1200C for activation.

Preparation of sample: A sufficient amount of each compound was dissolved in absolute methanol. A capillary tube was used to spot the sample on TLC plates. The diameter of each spot was limited to 0.3 cm. The compounds were spotted at 1 cm intervals from the bottom of the plate. Allow it dried in air.Development of the solvent system:The solvent system was prepared using methanol: water (1:1) was used as mobile phase. The 100 ml of small beaker was used and the solvent system waspoured in it. The glass beaker was lined with filter paper for pre saturation with the solvent system for 15-30 minutes.10 Stationary phase – Pre coated silica gel-G

Mobile phase –

Methanol: choloform (1:4) v/v Hexane: ethylacetate (8:2) v/v Ethyl acetate (5ml)

Toluene:Methanol:Triethylamine (7:3:0.2) v/v

Development of thin layer plate:The previously spotted plates kept in mobile phase. Plates were developed in an ascending manner. When the solvent reached to the mark the plate was removed and the wet plates were dried

Detection of spot: The iodine chamber was prepared and TLC plate was placed in a chamber. Thereafter the plate was removed from chamber and spot was observed.

Calculation of Rf value: Rf value can be calculated by following formula:Rf= Distance travelled by solute / Distance travelled by solvent

Detail of excipients

Table No. 1: Details of Excipients

S.No.	Excipients	Purpose
1	Beta-cyclodextrin	Solubility enhancer
2	Hibiscus Rosa-senesis mucilage	Superdisintegrant
3	Microcrystalline Cellulose	Disintegrant
4	Mannitol	Diluent
5	Aspartame	Sweetnning agent
6	Magnesium Sterate	Lubricant
7	Talc	Glidant

2.3 Formulation and optimization of orodispersible tablet: Experimental design for optimization:

A two factor three level factorial design (32) was used for the formulation optimization of orodispersible tablet of Omeprazole and experimental trials are performed at all 9 possible formulations. In which the amount of β-cyclodextrin (X1) and Hibiscus Rosa- Senesis mucilage (X2) were selected as independent variables (factor) varied at three different level: low(-1), medium(0), and high(+1) levels. The drug release and disintegration time used as dependent variables (response).63

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Table No.6.4: Composition of Orodispersible tablet:

S. No	Name of ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
	Drug (Omeprazole)	20	20	20	20	20	20	20	20	20
1	β-cyclodextrin	30	30	30	40	40	40	50	50	50
2	Hibiscus Rosa-SenesisMucilage	10	12	14	10	12	14	10	12	14
3	Microcrystalline cellulose	124	122	120	114	112	110	104	102	100
4	Mannitol	30	30	30	30	30	30	30	30	30
5	Aspartame	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
6	Magnessium Stearate	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
7	Talc	4	4	4	4	4	4	4	4	4
8	Total	230	230	230	230	230	230	230	230	230

Preparation of orodispersible tablet by direct compression: Orodispersible tablet of Omeprazole were prepared by direct compression method. Weighed all the ingredients accurately according to the table no.4. All the ingredients except Talc, Magnessium sterate were mixed step by step and trituration was continued for 15 minute, and passed through sieve no. #60. Subsequently talc, magnesium stearate mixed at last & again mixed.

The powder was compressed using multistation tablet punching machine (Aidmach Pvt. Ltd.) with 8mm flat punch, B-tooling and corresponding dies

2.4 Evaluation parameter:

Pre-compression Parametres of powder:

Bulk Density:

Bulk density is defined as the total mass of the powder divided by the bulk volume and is expressed as gm/ml. The Weighed blend of powder was taken from each formulation in a measuring cylinder and the initial volume of the powder (Vb) in the measuring cylinder was noted. This was calculated by using the formula64:

$$\text{Bulk density} = \frac{\text{Weight of the sample}}{\text{Bulk volume}}$$

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Tapped Density: It is the ratio of total mass of the powder to the tapped volume of powder. The volume was measured by tapping the powder for 100 times. After that the tapping was done for 100 times and the tapped volume was noted. Tapped density was calculated by using the following formula65:

Tapped density= Weight of the sample
Tapped volume

Carr's index: It helps in measuring the force required to break the friction between the particleand hopper. It is expressed in percentage. The Carr's index of the powder blend was determined by using the formula13:

Carr's index (%) = Tapped density- Bulk density

Tapped density

Angle of repose: It was determined by the funnel method. The Weighed powders were taken in a funnel. A funnel is fitted and is secured with its tip at a height (h) of 2 cm above graph paper which is placed on a horizontal surface. The accurately weighed powder were taken and dropped in funnel. The powder blend was allowed to flowthrough the funnel freely onto the surface. The angle of repose was calculated by measuring the diameter and height of powder cone and putting the values to the following equation14.

$\theta = \tan^{-1}(h/r)$

Where,

h= height of the

cone.r = radius of the cone.

Hausner's ratio: It is used for flow properties of the blend.

If the hausner's ratio is less than 1.25 that indicates the powder has free flowing properties whereas more than 1.25 that indicates the powder has poor flow ability. It was calculated by following formula:15

Hausner's ratio = Tapped density / Bulk density

Evaluation of Inclusion complex:

Solubility Determination:

An excess amount of prepared Omeprazole-β-cyclodextrin inclusion complex at different concentration (1:3, 1:4, 1:5) were separately dissolved in 5ml phosphate buffer pH 6.8 in vials and sealed properly and stirred continuously. The process was repeated until saturation solubility of inclusion complex. The solution was kept for 24 hours at room temperature. Further the solution was filtered. The solution was adequately diluted with phosphate buffer pH 6.8 and analyzed by using UV - visible spectrophotometer at 300 nm 16

Post Compression parameter of orodispersible tablet:

Weight variation : The twenty tablets were selected randomly and their average weight was determined. Tablets were weighed individually and compared with average weight. If more than two tablets deviate from the range, retest 20 tablets and not more than 2 tablets should deviate from 40 tablets.17

Hardness: Hardness of the tablet indicates the ability of tablet to withstand mechanical shocks while packaging, handling and transportation. The hardness of the tablet was determined by Monsanto hardness tester. Placed the tablet on the lower plunger and zero reading was taken from Monsanto tester scale. The range of Monsanto hardness tester is "0 to 20" kg. The screw knob was moved forward until the tablet breaks and the force required breaking the tablet was noted. Thereare three tablets of each formulation batch were tested randomly and the average reading was recorded. It is expressed in kg/cm2 18

Thickness: Thickness of the tablets was calculated by the use of vernier calliper. The scale was set to zero and placed the tablet laterally between the jaws of vernier calliper. Subsequently make certain jaws shall just touch object to be measured. The reading displayed was Record. Take out the sample, clean the jaws and keep the caliper in place. There are three tablet of each formulation batch were checked randomly and standard deviation was measured. It is expressed in mm.19

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Friability: Friability of the tablet was determined using Roche friabilator. Tablets was Weighed before placing in friability apparatus. Place 10 tablets in the friabilator and were subjected to 100 revolutions for 4 minute at 25 rpm and dropping the tablet at the height of 6 inches in each revolution. Taken out the tablet after 100 revolutions completed. A maximum loss of weight not greater than 1.0 % is acceptable for most tablets. Then friability was calculated by the given formula:

Percentage friability = Initial weight - Final weight ×100
Initial weight

Disintegration time: First suspend the assembly in the beaker containing 6.8 pH phosphate buffer at 37±0.5OC. The tablet was placed into each of the six tubes of the disintegrating apparatus and one disc was added to each tube. Run the apparatus until the tablet completely disintegrated. Note down the time taken for the complete disintegration of the tablet without any remitants. Removed the assembly from 6.8 pH phosphate buffer. The tablets were passed the test if all of them have disintegrated.70

The test was repeated on 12 additional tablets, If 1 or 2 tablets failed to disintegrate. Not less than the 16 tablets of the total of 18 tablets pass the test. If the tablets adhered to the disc and the preparation under examination failed to comply, repeated the test and the disc was omitted.20

Drug content: Ten tablets were taken and amount of drug present in each formulation of tablet was determined. The tablet was crushed in a morter -pestle and equivalent to 10 mg of drug was dissolved in phosphate buffer PH 6.8 in a 100ml volumetric flask. Volume was made up to 100ml. The sample was filtered through filter paper. From this solution 1ml were taken in a 10 ml volumetric flask & diluted with phosphate buffer pH 6.8. Further, 1ml were taken were taken and diluted up to 10ml and analyzed for drug content by UV spectrophotometer at 300 nm using phosphate buffer (pH 6.8).21

Wetting time & Water absorption ratio: A piece of tissue paper folded twice was placed in a small petridish containing10 ml of water. A tablet was put on the tissue paper and the time required for the water to diffuse from the wetted absorbent paper throughout the entire tablet wasthen recorded using a stopwatch.

For water absorption ratio: The wetted tablets were the reweighed. The water absorption ratio and R was determined using following equation

R = Wa-Wb/Wb×100

Wa = Weight of the tablet after water absorption Wb = Weight of the tablet before water absorption

In vitro Drug release study: In vitro drug release study was determined by dissolution test apparatus. The water level was maintained in dissolution vessel up-to the specific mark and adjusted or maintained temperature from heater knob. 900 ml of phosphate buffer pH 6.8 was poured in dissolution vessel and adjusted temperature between 37±0.5 C. The shaft was positioned in such a way that its axis is within 2 mm of axis of the vessel and lower edge of blade was 23 -27 mm from the inside of bottom of vessel. The paddles were lowered down. The tablet was put in each vessel and paddle was rotated at 50 rpm for 30 min. Withdrawn 5 ml sample at every 5 minutes interval and replaced by equal volume of fresh dissolution medium. Filtered the samples using what man's filter paper and analyzed for drug release of the samples by UV-visible spectrophotometer at λ max 300 nm. using phosphate buffer pH 6.8 as blank.73

2.5 Stability study:

A selected samples of tablets were subjected to stability . The samples were collected for testing at a time interval of 0 and 4 th week. The stability study were kept at (25±2 O° C) and (40°C ± 2 °C) and relative humidity(75% ± 5%) and were tested at time interval of 0 and 4th week. Samples in both studies were tested for their appearance, retention factor to evaluate the stability of the tablets.22

III. RESULT AND DISCUSSION

Extraction and characterization of Hibiscus Rosa-Senesis mucilage powder:

Extraction of Hibiscus Rosa-Senesis mucilage: The mucilage was extracted from Hibiscus Rosa-Senesis .

Characterization of Hibiscus Rosa- Senesis mucilage powder: The prepared mucilage powder was evaluated as follows:

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Table no.3: Characterization of Hibiscus Rosa Senesis mucilage powder:

S.NO.	Parameters	Result
1	Color	Green
2	Odour	Odorless
3	Taste	Bitter
4	Percentage Yield	12.6%±0.611
5	pH of Mucilage	6.87±0.043
6	Solubility of Mucilage	Soluble in hot water and insoluble inorganic solvents
7	Bulk density	0.47±0.005
8	Tapped density	0.67±0.015
9	Carr's index	11.5±0.208
10	Angle of repose	19.63±0.650
11	Hausner's ratio	1.21±0.017

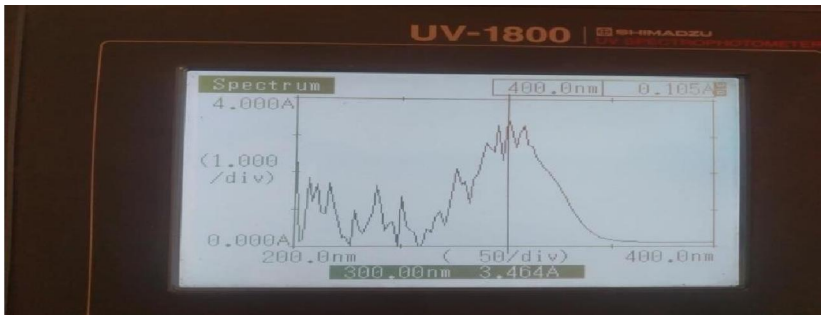

Figure .1: UV spectroscopy of Omeprazole

Preparation of calibration curve of Omeprazole :Calibration curve of Omeprazole in Methanol : The calibration curves of Omeprazole in Methanol were prepared and shown below:

Table no.4: Absorbance data of Omeprazole in Methanol for preparation of calibration curve, at 300 nm

S.No.	Concentration(µg/ml)	Absorbance (mean ± standard deviation)(n=3)
1	5	0.097±0.005
2	10	0.209±0.003
3	15	0.325±0.017
4	20	0.426±0.018
5	25	0.54±0.013

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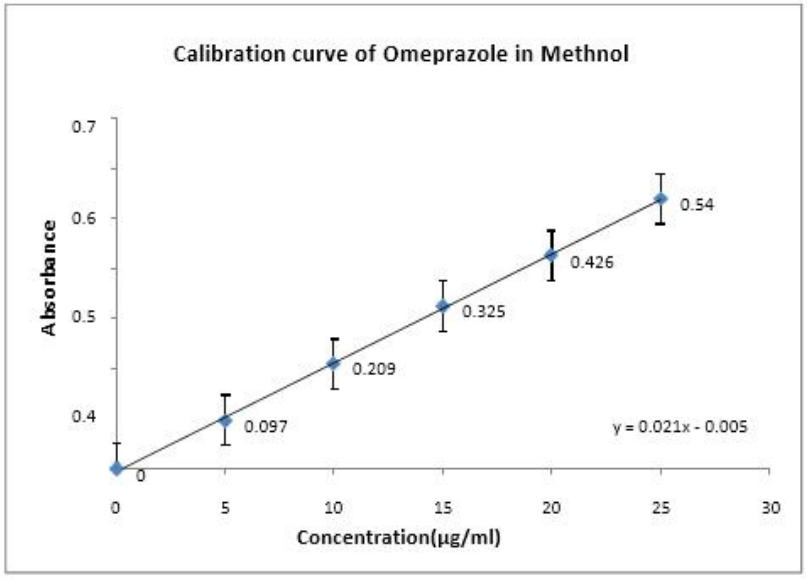

Figure 2: Calibration graph of Omeprazole in Methanol at 300nmOmeprazole Methanol follows the Beer – Lambert's law in the concentration rangeof 5-25 µg/ml.

The calibration curves of Omeprazole in phosphate buffer pH 6.8 were preparedand shown below:

Table no.5: Absorbance data of Omeprazole in phosphate buffer pH 6.8 for preparation of calibration curve, at 300nm

S.No.	Concentration (µg/ml)	Absorbance (mean ± standard deviation) (n=3)
1	10	0.047±0.005
2	20	0.084±0.008
3	30	0.133±0.007
4	40	0.164±0.010
5	50	0.218±0.010

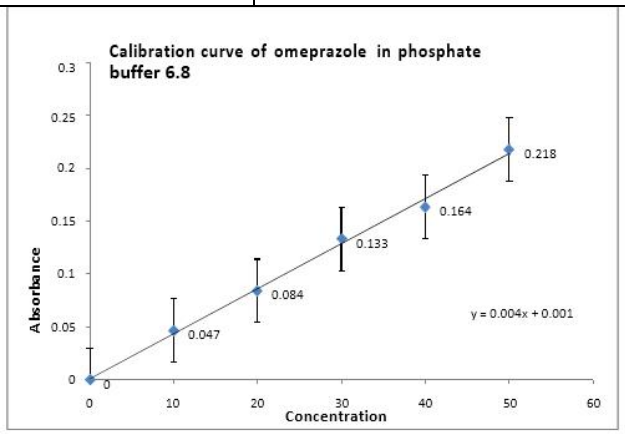

Figure 3: Calibration graph of Omeprazole in phosphate buffer pH 6.8 at 300nm

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Omeprazole in phosphate buffer pH 6.8 follows the Beer–Lambert's law inthe concentration range of 10-50 µg/ml.

Calibration curve of Omeprazole pH 1.2 HCl buffer: The calibration curves of Omeprazole in pH 1.2 HCl buffer were prepared andshown below:

Table no.6: Absorbance data of Omeprazole pH 0.1 HCl buffer forpreparation of calibration curve, at 300nm

S.no.	Concentration (µg/ml)	Absorbance (mean ± standard deviation) (n=3)
1	5	0.076±0.007
2	10	0.144±0.004
3	15	0.232±0.003
4	20	0.318±0.005
5	25	0.384±0.008

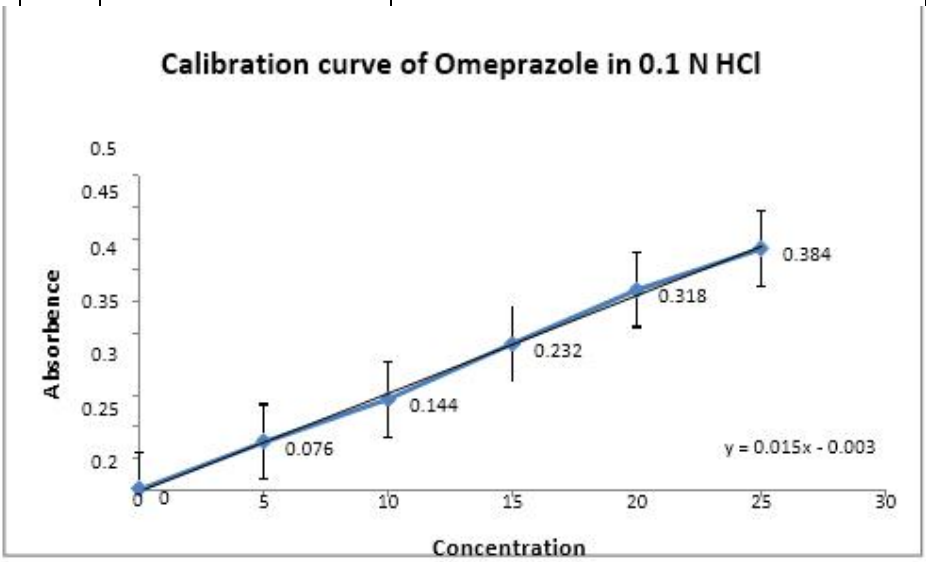

Figure 4: Calibration graph of Omeprazole in pH 1.2 HCl buffer at300nm

Omeprazole in pH 1.2 HCl buffer follows the Beer – Lambert's law in the concentration range of 5-25 µg/ml.

Calibration curve of Omeprazole in water: The calibration curves of Omeprazole water were prepared and shown below:

Table no.7: Absorbance data of Omeprazole in water for preparation ofcalibration curve, at 300 nm

S.no.	Concentration (µg/ml)	Absorbance (mean ± standard deviation) (n=3)
1	10	0.026±0.003
2	20	0.05±0.005
3	30	0.083±0.007
4	40	0.117±0.012
5	50	0.156±0.030

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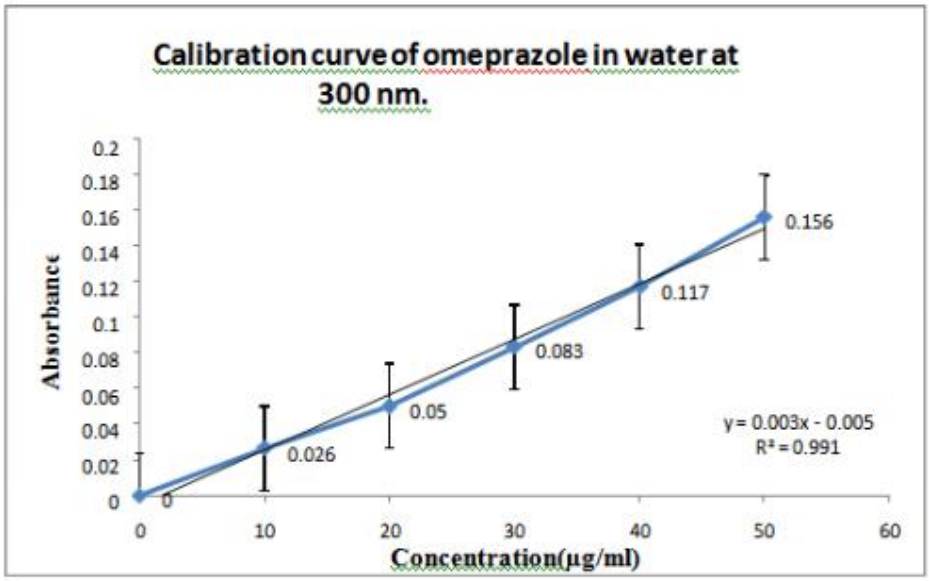

Figure 5: Calibration graph of Omeprazole in water at 300nm

Determination of solubility of Omeprazole in various medium:

The solubility of Omeprazole in various mediums was studied and the results of study were shown in below table:

Table no.8: Solubility data of Omeprazole in different mediums:

S.NO.	Solvent	Solubility (mg/ml) Mean±SD (n=3)	Inference
1	Methanol	30.106±2.186	Sparingly Soluble
2	Phosphate buffer pH6.8	0.184±0.001	Very Slightly Soluble
3	pH 1.2 HCl buffer	0.108±0.007	Very Slightly Soluble
4.	Water	0.578±0.010	Slightly soluble

Determination of solubility of inclusion complex: The solubility of inclusion complexin phosphate buffer pH 6.8 was studied and theresults of study were shown in below table:

Table no.9: Solubility data of inclusion complex:

S.No.	Phosphate buffer pH 6.8	Solubility (mg/ml) Mean±SD (n=3)	Inference
1	Pure drug	0.184±0.001	Very Slightly Soluble

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2	Drug:β-CD (1:3)	0.471±0.004	Slightly Soluble
3	Drug:β-CD (1:4)	0.694±0.008	Slightly Soluble
4	Drug:β-CD (1:5)	0.840±0.012	Slightly Soluble

Drug-excipient interaction study: The drug (Omeprazole) was found to be compatible with various excipients which were selected for formulation of orodispersible tablet. The compatibility was assessed by TLC and the retention factors of all ratios found similar.

Table no.10: Data of drug-excipient interaction study

S.No.	Drug/ Excipient Ratio(1:1)	Physical appearance (initial)	Present Day (Rf)	Physical appearance after 15 days (final)	After15 Days (Rf)
1.	Drug (Omeprazole)	White	0.58	White	0.57
2.	Pure Drug + β-cyclodextrin	White	0.68	White	0.66
3.	Pure Drug + Mucilage	Light green	0.66	Light green	0.64
4.	Pure Drug + MCC	White	0.60	White	0.60
5.	Pure Drug + Mannitol	White	0.63	White	0.64
6.	Pure Drug+ Aspartame	White	0.63	White	0.62
7.	Pure Drug + Magnesium stearate	White	0.68	White	0.69
8.	Pure Drug + Talc	White	0.73	White	0.71
9.	Pure drug + Mixture	Whitish green	0.75	Whitish green	0.74

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Evaluation of orodispersible tablet:

Evaluation of precompression parameters of powder:

Bulk density, Tapped density, Carr's index, Hausner's ratio, Angle of repose

The bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose of selected formulations were performed and shown in table no.7.9. The results show that the all formulations that possess a good flow property.

Table no.11: Evaluation of Precompression Parameters of powder

Formulation	Bulk density (gm/ml) (n=3) Mean±SD	Tapped density (gm/ml) Mean±SD	Carr's index (%) (n=3) Mean±SD	Angle of repose (°) (n=3) Mean±SD	Hausner's ratio (n=3) Mean±SD
F1	0.314±0.004	0.368±0.004	14.635±1.503	25.406±0.374	1.170±0.026
F2	0.299±0.002	0.358±0.003	14.634±1.004	29.333±1.106	1.166±0.015
F3	0.288±0.002	0.345±0.003	16.323±1.047	27.606±0.525	1.186±0.015
F4	0.332±0.003	0.385±0.006	13.907±0.852	26.966±0.450	1.16±0.01
F5	0.307±0.003	0.363±0.002	15.260±1.695	25.59±0.213	1.176±0.020
F6	0.293±0.003	0.355±0.003	17.360±1.663	27.4±0.500	1.206±0.025
F7	0.344±0.003	0.402±0.004	14.414±0.402	26.74±0.767	1.166±0.005
F8	0.326±0.003	0.376±0.003	13.354±1.494	30.6±0.888	1.15±0.02
F9	0.298±0.002	0.330±0.001	9.787±0.459	26.633±0.709	1.103±0.005

Evaluation of post-compression parameters of orodispersible tablet:

The orodispersible tablet of Omeprazole were evaluated like weight variation, hardness, thickness, friability, disintegration time, drug content, wetting time and water absorption ratio. The results of the studies were shown in below table:

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Table no.12: Weight variation, Hardness, Thickness and Friability ofFormulation (F1-F9)

Formulation	Weight variation (mg) (n=3) Mean±SD	Hardness (Kg/cm^2) (n=3) Mean±SD	Thickness (mm) (n=3) Mean±SD	Friability (%) (n=3) Mean±SD
F1	230.16±0.378	2.6±0.264	3.1±0.10	0.460±0.027
F2	229.75±0.312	2.4±0.173	3.1±0.12	0.750±0.047
F3	228±0.938	3.0±0.057	3.2±0.10	0.460±0.045
F4	230±0.301	2.9±0.152	3.3±0.10	0.672±0.045
F5	232±2.13	3.0±0.1	4.06±0.152	0.346±0.043
F6	233±0.28	3.0±0.057	3.4±0.208	0.343±0.043
F7	228.58±0.56	3.0±0.057	3.13±0.057	0.349±0.023
F8	229.83±1.05	3.1±0.1	3.26±0.152	0.361±0.040
F9	228.06±0.17	3.1±0.057	3.73±0.412	0.358±0.040

Table no.13: Disintegration Time, Drug Content, Wetting time & water absorption Ratio of Formulation F1-F9.

Formulation	Disintegration Time (sec) (n=3) Mean±SD	Drug Content (%) (n=3) Mean±SD	Wetting time (sec) (n=3) Mean±SD	Water absorption Ratio (%) (n=3) Mean±SD
F1	42±1.05	91.833±0.233	32.7±0.590	55.97±3.63
F2	38±1.86	93.36±0.356	31.37±0.580	49.01±3.59
F3	37±1.93	95.84±1.362	30.05±0.040	42.18±3.13
F4	35±1.28	92.19±0.583	32.38±0.540	46.75±1.34

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F5	30±1.25	99.25±0.470	29.71±0.546	30.3±1.56
F6	33±1.36	96.85±0.584	31.06±0.015	35.90±0.65
F7	45±1.68	95.76±0.466	33.38±0.580	36.83±0.61
F8	36±1.26	95.60±1.151	34.69±0.534	40.42±0.61
F9	39±1.48	93.73±1.113	35.06±0.015	41.96±0.60

Table no.14: Percentage cumulative drug release data of F1 to F9 formulation of orodispersible tablets:

Time (in min)	% Cumulative drug Release (Mean±SD) (n=3)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	11.4± 3.20	16.9± 3.16	21.8± 4.35	28.8± 2.11	27.4± 2.41	30.2± 3.27	21.1± 3.21	23.9± 3.21	21.8± 2.44
10	214± 1.19	25.3± 1.60	37.2± 2.11	34.2± 2.11	35.1± 2.07	39.9± 3.20	28.8± 2.11	34.4± 4.35	28.1± 3.20
15	34.4± 3.16	40.0± 1.20	46.2± 2.44	44.2± 3.18	46.9± 3.21	44.8± 1.280	41.1± 2.07	43.5± 3.62	33.7± 3.16
20	44.2± 4.37	53.9± 5.52	57.4± 6.41	50.5± 4.81	56.0± 2.07	55.3± 3.22	53.2± 2.45	56.7± 1.95	47± 3.21
25	58.1± 2.07	67.9± 5.25	63.7± 4.34	67.9± 3.20	73.1± 2.14	62.2± 1.96	75.5± 3.21	72.8± 2.07	68.6± 2.11
30	90.9± 3.17	86.0± 1.24	89.5± 3.58	88.1± 3.19	95.8± 2.08	84.6± 3.20	86.7± 1.24	92.3± 4.34	93.7± 2.09

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The percentage cumulative drug release from formulations F1 to F9. The formulation F5was shows the highest release (95.8±2.08) within 30 minutes.

Stability study: Stability studies for one month were performed at different storage condition for optimized orodispersible tablet (F5). The optimized orodispersible tablet were foundto be stable with no change in physical appearance and TLC values (Rf) were found similar at different storage condition at different time interval. It was concluded thatthe formulation is stable at different storage conditions.

Table no.15: Stability data of optimized formulation (F5):

S. No.	Time	Physical appearance	Result	Storage condition	Rf value
1	Initial Day	Light brown	No change in appearance	40°C±2°C/ 75%RH±5%RH	0.71
		Light brown	No change in appearance	Room temperature	0.70
2	After one month	Light brown	No change in appearance	40°C±2°C/ 75%RH±5%RH	0.73
		Light brown	No change in appearance	Room temperature	0.72

IV. SUMMARY AND CONCLUSION

In the present research work an attempt has been made to optimize, formulate and evaluate orodispersible tablet of Omeprazole is proton pump inhibitor drug belongs to BCS class-II (Low Solubility and high permeability). It has poor bioavailability and low solubility.In the present work solubility and bioavailability of drug was enhanced using inclusion complex. The inclusion complex of Drug: β-cyclodextrin was prepared in different ratio by kneading method.The direct compression method was used to formulate and evaluate orodispersible tablet of Omeprazole .The hibiscus rosa sinesis mucilage powder used as the superdisintegrants in the formulation at different concentrations (30,40&50mg) respectively. And inclusion complex of Drug: β-cyclodextrin was used in the formulation MD1-MD9 .As the concentration of superdisintegrant hibiscus rosa sinesis mucilage powder that significant effect on disintegration characteristics as well as drug release. But the higher concentration of mucilage had negative impact on drug release & disintegration time.

Addition of Drug: β-cyclodextrin inclusion complex leads to improved the dissolution characteristics and solubility of drug at optimum concentration (1:5). So, considering the above results it was found that the formulation MD5 was found to be optimized formulation from the data obtained. It is observed from the formulation MD5 which shown disintegration time 30±1.25 sec. and percentage cumulative drug release shown 95.84±2.08 within 30 minute.

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