

Design, Development and Characterization of Omeprazole Loaded PVA-Poloxamer 188 Nanosuspension.

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ABSTRACT: In the present study attempt was made to prepare a nanosuspension of Omeprazole using different stabilizer namely poloxamer 188, tween 80, PVP K30 by nanoprecipitation method with an objective to improve solubility and enhance dissolution of Omeprazole. Prepared nanosuspensions were evaluated for physical appearance, drug excipient compatibility, particle size, PDI, drug content, saturation solubility, in-vitro release study, Transmission electron microscopy (TEM) and zeta potential. Poloxamer 188 produced nanosuspension particle size range between 142 ± 20 - 414 ± 20 nm and PDI of 0.564. DSC and FTIR studies revealed the compatibility of drug with excipients. The batch f₁-f₉ nanosuspension containing Omeprazole and poloxamer 188 prepared by nanoprecipitation method at 1000bar and 30 cycle exhibited promising enhanced saturation solubility ($35.5 \pm 50.6\mu\text{g/ml}$) and increased dissolution ($96.41 \pm 0.35\%$) as compared to pure Omeprazole which may help to improve bioavailability. The present study demonstrated successful preparation of nanosuspension of Omeprazole.

Keywords: Omeprazole, Nanosuspension, Development and Characterization, solubility enhancement.

I. INTRODUCTION:

Ulcer an open sore on an external or internal surface of the body caused by a break in the skin or mucous membrane which fails to heal. Ulcers range from small painful sores in the mouth to bedsores and serious lesions of the stomach or intestine is a break in the inner lining of the stomach the first part of the small intestine, or sometimes the lower oesophagus is called a ulcer. (M.D. Kathryn Watson et al., 2020) Twenty-five million Americans suffer from an ulcer and 1 in 10 will develop an ulcer at some point in their lives. An ulcer is a sore or hole in the lining of the

stomach or duodenum (the first part of the small intestine). Anyone can get an ulcer men, women, and children. The pathophysiological structure shows aggressors like increased acid and pepsin, an impaired defence system of the mucosa (mucus, mucosal circulation and possibly PG's and epidermal growth hormone). Disturbances in the inter digestive and digestive motility brings about most clearly the pathophysiological differences between GU and DU. Therapeutic corrections of the high secretion lead to pathological reactions in other parts of the system.

Omeprazole is used to treat certain conditions where there is too much acid in the stomach. It is used to treat gastric and duodenal ulcers, erosive esophagitis, and gastroesophageal reflux disease (GERD). GERD is a condition where the acid in the stomach washes back up into the esophagus. Omeprazole is a selective and irreversible proton pump inhibitor omeprazole suppresses gastric acid secretion by specific inhibition of hydrogen-potassium adenosine triphosphatase (H⁺, K⁺-ATPase) enzyme system found at the secretory surface of parietal cells. It inhibits the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen. Since the H⁺/K⁺ ATPase enzyme system is regarded as the acid (proton) pump of the gastric mucosa, omeprazole is known as a gastric acid pump inhibitor. Formulation development for the requirement polymer Poloxamer 188. and polyvinyl alcohol (PVA).

Nanosuspension is a submicron colloidal dispersion of drug particles. A pharmaceutical nanosuspension is defined as a very finely colloid, biphasic, dispersed, solid drug particles in aqueous vehicle, size below 1 μm , without any the poor solubility and slow dissolution rate of many drugs are major industrial problem especially for pharmaceutical scientists involved in drug

discovery and drug development.(Geeta Vikram Yadav et al., 2012) It has been reported that about 40% of the compounds being developed by the pharmaceutical industry are poorly water soluble or “insoluble” in water.(Bhabani Shankar Nayak et al., 2018)

II. MATERIALS:

Omeprazole powder was a gift sample from Diamond Drugs Pvt. Ltd., Kolkata, India. The Poloxamer 188 was obtained from SD fine chemicals, Mumbai. And polyvinyl alcohol (PVA) collected from ACS chemicals Ahmadabad and Loba chemicals Pvt. Ltd Mumbai. Other chemicals used for the study were of analytical grade.

III. PREFORMULATION STUDIES:

Preformulation is the branch of pharmaceutical sciences that utilizes biopharmaceutical Preformulation studies in the preliminary investigation of drug and other ingredient before developing any pharmaceutical product development in order to get stable safe and effective dosage forms the following preformulation studies are carried to get the initial information of the drug and excipients.

3.1 Organoleptic Characteristics:

- i. Colour: A small quantity of pure omeprazole is taken in butter paper and viewed in well illuminated place.
- ii. Odour: very less quantity of omeprazole as well as smelled place.
- iii. Taste: very less quantity of omeprazole is used to get taste with the help of tongue as well as smelled place.

3.2 Solubility: The solubility of the drug affects its bioavailability the solubility of drug is expressed in the terms of maximum amount of a solute that dissolve in given amount of solvent. 1ml of each solvent was taken in different test tube at room temperature ($25\pm 2^\circ\text{C}$) and definite amount of drug was dissolve in each solvent. An increment of drug was added to each test tube until undissolved particles are seen at saturation point. Then each solvent was filtered and analysed by UV Spectrophotometer (1800, Shimadzu Japan) and concentration was calculated.

3.3 Melting point: Melting point determination of omeprazole is done by using Melting Point Apparatus. In that method the presealed capillary is filled by the small amount of drug. Then capillary and thermometer were placed in Melting Point Apparatus. Then see capillary for melting the drug.

The temperature were noted when the drug start to melt and the drug till complete melt. The melting point of omeprazole is determined by capillary method using small quantity of omeprazole is taken and placed in apparatus and determined the melting point and matched with standards.

3.4 Partition coefficient: The partition coefficient of Omeprazole was determined by shaking flask method in n-octanol PBS Buffer system 10 mg of drug Omeprazole was added into 50 ml each of n-octanol and water. The mixture was shaken for 24 hours until equilibrium was reached. Phases were separated in a separating funnel and the aqueous phase was filtered through 0.2μ filter, suitably diluted and amount of Omeprazole in aqueous phase was determined by measuring the absorbance using UV spectrophotometer. The partition coefficient (Po/w) of Omeprazole was calculated from the ratio between the concentration of Omeprazole in organic (Coil) and aqueous phase (Caq) using following equation. $Po/w = (Coil/Caq)$ equilibrium.

3.5 UV Spectrophotometric analysis of drug:

3.5.1 Determination of wavelength of maximum absorbance (λ_{max}): The standard solutions of OMP further diluted to get concentration of 10 $\mu\text{g/mL}$. These solutions were scanned in the wavelength region of 200-400 nm and the λ_{max} was observed and recorded Omeprazole respectively.

3.5.2 Preparation of calibration curve: Working standard solutions were prepared for the Omeprazole from the standard solution of 100 $\mu\text{g/mL}$. Different aliquots were taken from standard stock solution and diluted with methanol separately to prepare 2 $\mu\text{g/mL}$, 4 $\mu\text{g/mL}$, 6 $\mu\text{g/mL}$, and 8 $\mu\text{g/mL}$, 10 $\mu\text{g/mL}$ and 12 $\mu\text{g/mL}$ solutions respectively. The absorbance values of Omeprazole the calibration curves were plotted with concentrations against absorbance and regression equation was calculated.

3.6 FTIR Spectroscopy: The Fourier transform infrared spectroscopy (FTIR) spectra was used to obtain the FTIR spectroscopy for the following samples(1) Pure omeprazole powder, (2) Poloxamer 188 alone and (3) physical mixture of omeprazole and the selected stabilizer (poloxamer 188). The samples were grounded and mixed thoroughly with potassium bromide. The spectrum obtained was in between the wave number of (400-4000 cm^{-1}) (Priyanka S. Pagar et al., 2017)

3.7 DSC Study: Thermal analysis was performed using a differential scanning calorimeter equipped with a computerized data. The sample of pure drug, and physical mixture were heated at a scanning rate

of 10°C/min between 30 and 350°C and 40 ml/min of nitrogen flow the differential scanning calorimeter analysis gives an idea about the

interaction of various materials at different temperature. It also allows us to study the possible degradation of the material.

IV. PREPARATION OF NONOSUSPENSION

Table.01: Composition of Omeprazole Nanosuspension in different Batch

Formula Code	Omeprazole (gm)	Poloxamer 188 (gm)	PVA (gm)	Methanol (ml)	Water (ml)
F1	1	0.5	0.5	5	10
F2	1	1	0.5	5	10
F3	1	1.5	0.5	5	10
F4	1	2	0.5	5	10
F5	1	2.5	0.5	5	10
F6	1	3	0.5	5	10
F7	1	3.5	0.5	5	10
F8	1	4	0.5	5	10
F9	1	4.5	0.5	5	10

Preparation of nanosuspension: Nanosuspensions were prepared according

done at 25°C. and the electric field strength was around 30mV the

to nanoprecipitation method. Pure drug Omeprazole and Poloxamer 188 was dissolved in (5 ml) methanol at in room temperature to form uniform organic solution. The prepared organic solution was then injected slowly drop wise with the help of a syringe into an aqueous phase (10 ml) containing stabilizers (PVA) under high speed mechanical agitation of 1000 rpm to get desired nanodispersion. Prepared nanosuspension was then stirred magnetically at 500 rpm at room temperature for 12 h to evaporate organic solvent. Complete evaporation of methanol was determined by spectrophotometric method. The volume was then adjusted with the addition of triple distilled water to recover loss in keeping other parameters constant. The batches were prepared according to the formulation design nanosuspension.

zetasizer nanorange of instruments provides the ability to measure three characteristic of particle or molecules in a liquid medium these three fundamental parameters are particle size, zeta potential and molecular weight. By using the technique technology within the zeta-sizer system there parameters can be measured over a wide range of concentrations. The zeta-sizer system also has the ability to perform Auto-titration measurements and trend measurements including the determination of the. (Sahu s.et al.)

V. EVALUATIONS OF NANOSUSPENSIONS

5.1 Particle size analysis: The mean particle size was determined formulation F-1, F-2, F-3, F-4, F-5, F-6, F-7, F-8 and F-9, using optical microscope. In this method, the size of 250 particles was determined and the average particle size was calculated. Thus, a particle size analyser is being further used for the accurate size determination. (Pankaj Verma et. al)

5.3 Drug content: Drug content of nanosuspension formulation was carried out by taking (weigh equivalent to 1 (g) of drug) in Methanol mixture, shaken well, omeprazole is slightly soluble in Methanol mixture so it was then centrifuged at 8000 rpm for 10 min. The supernatants were taken and diluted with Methanol with PBS 7.4 and kept for 24 hrs than filter the what Mann filter paper mixture and the absorbance was measured at 301 nm. The drug content was calculated using the calibration curve.

5.2 Zeta Potential: Zeta potential for nanosuspension was determined using zetasizer nanoseries 90 (Malvern instruments, UK) sample were diluted appropriately with distilled water. zeta potential measurement were

Obtained Amount of Drug

$$\% \text{ Drug content} = \frac{\text{Obtained Amount of Drug}}{\text{Theoretical Amount of Drug}}$$

5.4 In-vitro release study: Drug release from the developed formulation was studied in PBS (Phosphate-buffered saline) pH 7.4 using dialysis bag (12,000MW) diffusion. The developed formulations were placed in the dialysis bag which was pre-soaked in the PBS overnight and immersed

into 200 ml of PBS; the entire system was kept at $37 \pm 1^\circ\text{C}$ at a stirring rate of 300 rpm. At the predetermined time intervals (1, 2, 3, 4, 5, 6, 7, 8, and 9, hr) 5 ml sample were withdrawn and replaced by fresh buffer. The samples were diluted with PBS and determined by UV spectro photometer at 301 nm (Kathle, pankaj kumar et al.)

5.5 Percentage yield: The percentage yield of different formulations was determined by weighing the prepared nanosuspension after drying. The percentage yield was calculated as follows, (Mannan Abdul, et al.)

$$\text{Percent yield} = \frac{\text{Actual Yield}}{\text{Theoretical Yield}} \times 100\%$$

5.6 Percentage Drug loading and Percentage Drug Entrapment Efficiency:

Efficiency Of Drug Loading of formulation were calculated in terms of % drug loading as per the formula (Kathle, pankaj kumar et al.)

$$\text{EE (\%)} = \frac{(W_{\text{total drug}} - W_{\text{free drug}})}{W_{\text{total drug}}} \times 100\%$$

5.7 Transmission Electron Microscopy (TEM):

One drop of the nanosuspension of promising batch was placed on carbon coated grid (3mm) & was

allowed to dry Sample was loaded in TEM using horizontal sample holder images were taken using appropriate magnification up to 1600. As high as 200 KV acceleration voltages allow the Tecani 20, Holland. (Chotai et al.)

5.8 Stability Study: The success of an efficient formulation was evaluated only through the stability studies. The purpose of the stability studies was to obtain a stable product which its safety and efficacy up to the end of shelf life in this study, The prepared nanosuspension was kept under different temperature conditions like-room temperature 30°C and 65% RH and 40°C in 80% RH the sample were assayed for drug content at regular intervals after 1 month.

5.9 Stastical data analysis: The experimental value are presented in standard error of and explored by one-way ANOVA and posthoc. Values were expressed as the mean \pm standard deviation (SD). Tukey multiple methods by employing graph pad instate 3 software.

VI. RESULTS AND DISCUSSION

6.1 Organoleptic Characteristics: The drug sample was observe for physical appearance and compared with the standard mentioned in India Pharmacopoeia.

Table.02: Organoleptic Characteristics

S. No.	Characteristics	Results
1.	Colour	White
2.	Odour	Odourless
3.	Taste	Tasteless
4.	Appearance	Crystalline powder

6.2 Solubility: A solubility test was performed to determined ability of compounds to dissolve in a solvent and also to determine the size and polarity of unknown compounds and the presence of acidic and basic functional groups. The solubility was found to be $(35.5 \pm 50.6\mu\text{g/ml})$ in buffer solution pH 7.4.

6.3 Melting point omeprazole: Melting point is used here to determine the temperature at which the

solid and liquid forms of a pure substance can exist in equilibrium. The melting point of Omeprazole from table was determined as 156°C

6.4 Partition coefficient: Drug quantity in buffer and organic phase was determined by shake flask method through UV spectroscopic analysis then partition coefficient was calculated. The average of pKa was determined as = 4.06

6.5 UV Spectrophotometric analysis of drug:

6.5.1 Determination of wavelength of maximum absorbance (λ_{max}):

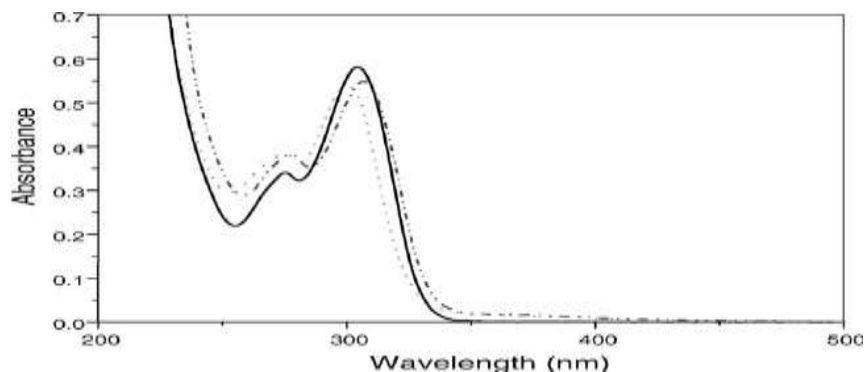
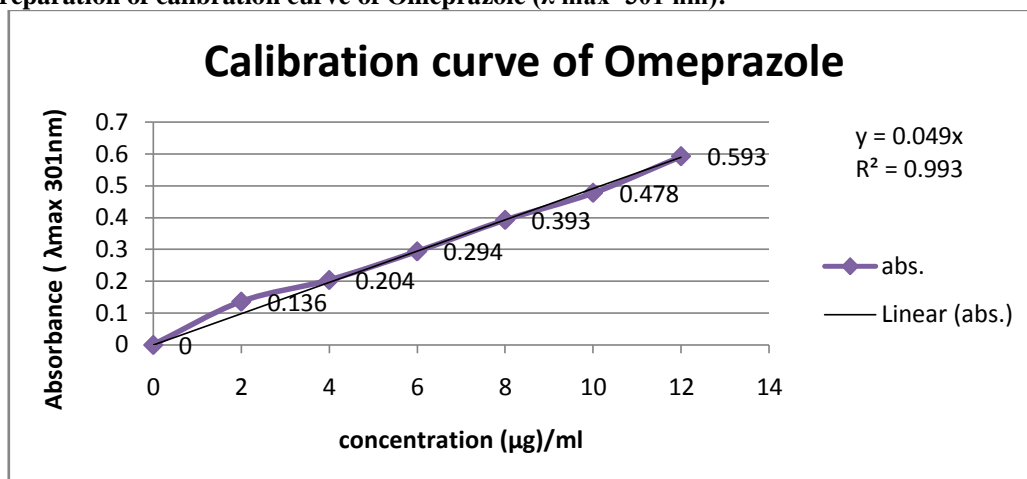


Fig.01 UV Spectra of Omeprazole

6.5.2 Preparation of calibration curve of Omeprazole (λ_{max} =301 nm):



Graph No. 01: Calibration curve of omeprazole

Table.03: Calibration curve of Omeprazole

S.No	Concentration (µg/ml)	Omeprazole Absorbance (λ_{max} =301 nm)
1	0	0
2	2	0.136
3	4	0.204
4	6	0.294
5	8	0.393
6	10	0.478
7	12	0.593

6.6 FTIR Spectroscopy: The Fourier transform infrared spectroscopy (FTIR) spectra was used to obtain the FTIR spectroscopy for the following samples Pure omeprazole powder, Poloxamer 188 alone and physical mixture of omeprazole and the

selected stabilizer (poloxamer 188) The samples were grounded and mixed thoroughly with potassium bromide. The spectrum obtained was in between the wave number of (4000-400 cm^{-1})

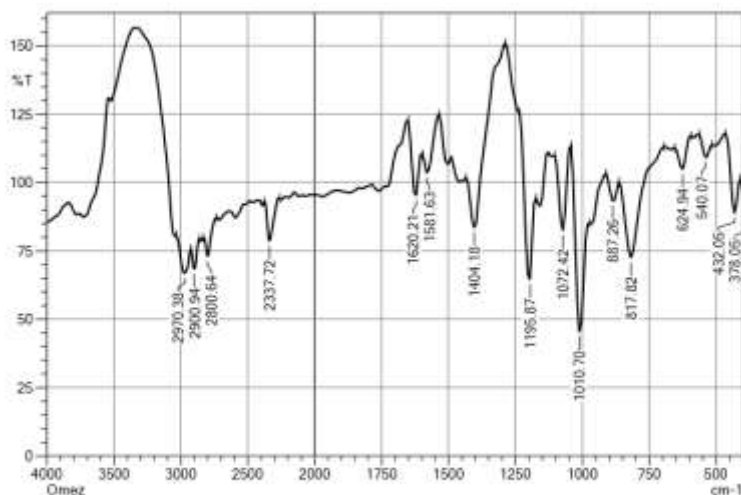


Fig.02: FT-IR of Omeprazole (pure)

Table.04: Characteristics peaks of Omeprazole

S.NO.	Functional group	Frequency range	Observed frequency
1.	-C-H stretch	2950-2840 cm-1	2900.94cm-1
2..	C=C alkenes	1680-1600 cm-1	1620.21cm-1
3.	C=C aromatic	1600-1400 cm-1	1581.63cm-1
4.	C-OH stretch	1200-1020 cm-1	1072.42cm-1
5.	C-Br	750-500 cm-1	540.07 cm-1
6.	C-I	~500 cm-1	432.05 cm-1

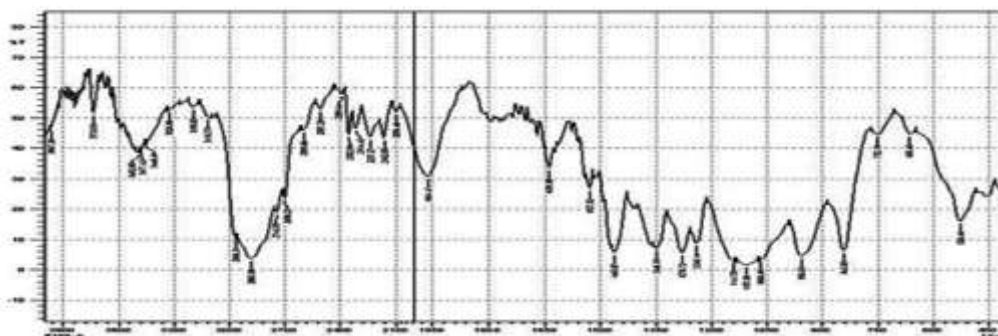


Fig.03: FT-IR pure poloxamer188

Table.05: Characteristics peaks of pure poloxamer188

S.NO.	Functional group	Frequency range	Observed frequency
1	water OH Stretch	3700-3100 cm-1	3843.43 cm-1
2	carboxylic acid OH stretch	3600-2500 cm-1	3421.10 cm-1
3.	CH ₃ bend	1465-1365 cm-1	1342.21 cm-1
4.	C-O-C stretch	1250-1050 cm-1	1100.03 cm-1
5.	C-Br	750-500 cm-1	529.29 cm-1

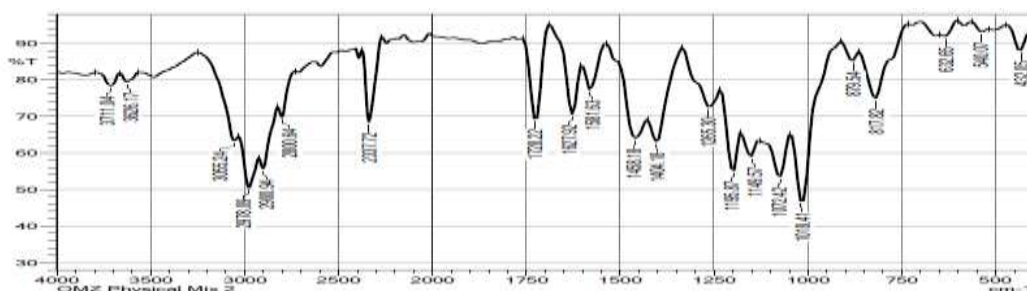


Fig.04: FTIR spectrum of physical mixture of omeprazole and poloxamer 188 at ratio (1:1)

Table.06: Characteristics peaks of mixture of omeprazole and poloxamer 188

S.NO.	Functional group	Frequency range	Observed frequency
1	water OH Stretch	3700-3100	3711.04 cm-1
2	Alcohol OH stretch	3600-3200 cm-1	3504.95 cm-1
3	=C-H stretch	3100-3000 cm-1	3055.24 cm-1
4	carboxylic acid OH stretch	3600-2500 cm-1	2800.64 cm-1
5	C=O aldehyde	1740-1720 cm-1	1728.22 cm-1
6	C=C aromatic	1600-1400 cm-1	1404.18 cm-1
7	CH ₃ bend	1465-1365 cm-1	1320.04 cm-1
8	C-O-C stretch	1250-1050 cm-1	1072.42 cm-1
9	C-Cl	800-600 cm-1	632.65 cm-1
10	C-Br	750-500 cm-1	540.07 cm-1
11	C-F	1400-1000	1018.41
12	C-I	~500	432.05

6.7 DSC study:

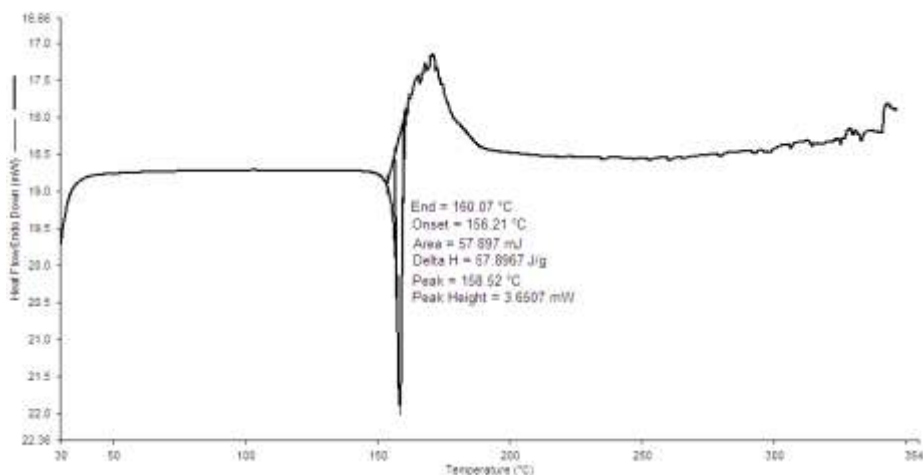


Fig.05: DSC Spectrum of Omeprazole.

DSC of pure Omeprazole showed a characteristic, sharp endothermic peak at 160°C which is associated with the melting point of drug & indicated the crystalline nature of omeprazole.

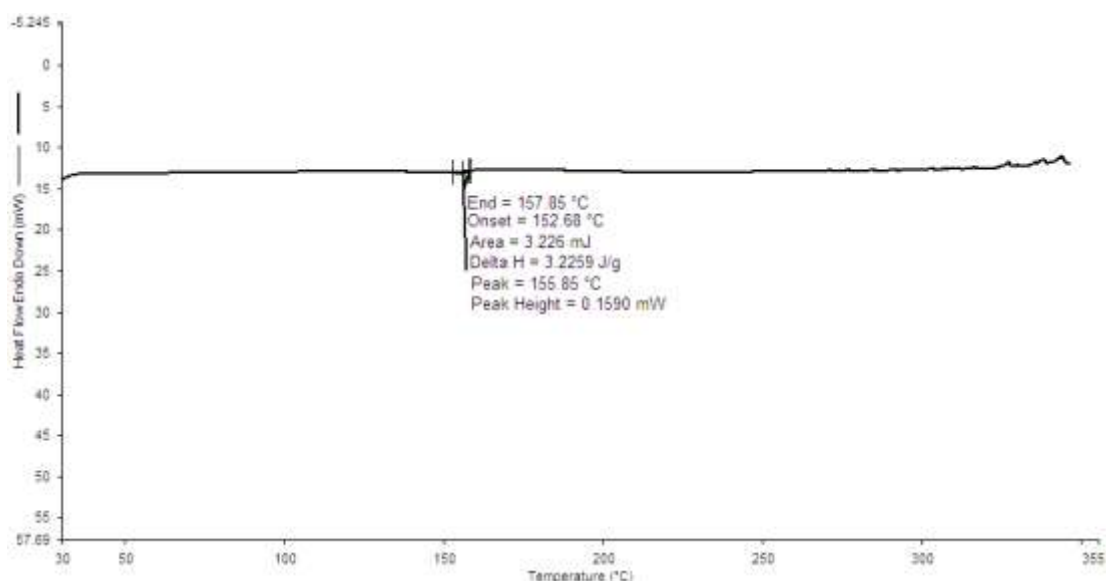


Fig.06: DSC Spectrum of Physical mixture of Omeprazole.

DSC of pure Omeprazole showed a characteristic, sharp endothermic peak at 1600c which is associated with the melting point of drug & indicated the crystalline nature of omeprazole of physical mixture of Omeprazole exhibited endothermic peak at 1570c, which is peak of the drug, indicated that there is no interaction between

the drug & excipients used in the formulation & they are compatible each other.

VII. POST FORMULATION STUDY:

7.1 Particle size analysis: The mean particle size of the nanosuspension was found to be increased with increasing. Poloxamer 188 concentration and was in the range 122 to 418 shown in Table No.07

	Size (d.nm):	% Intensity:	St Dev (d.nm):
Z-Average (d.nm): 368.2	Peak 1: 221.0	72.6	39.62
Pdl: 0.564	Peak 2: 1185	27.4	244.2
Intercept: 0.926	Peak 3: 0.000	0.0	0.000
Result quality: Good			

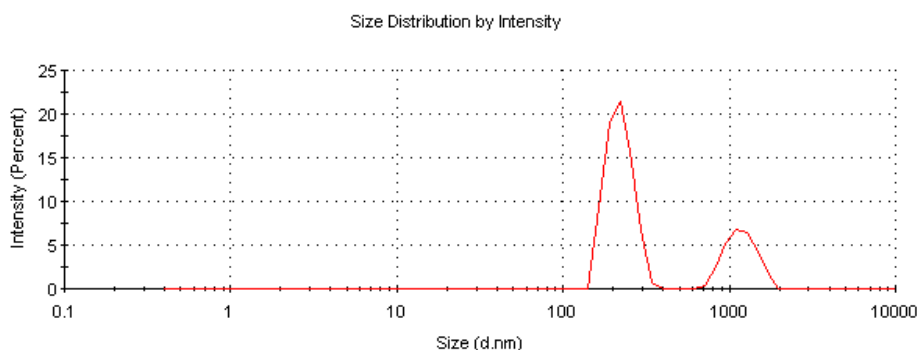


Fig.07: Particle size analysis report of omeprazole nanosuspension (F1)

	Size (d.nm):	% Intensity:	St Dev (d.nm):
Z-Average (d.nm): 196.0	Peak 1: 217.0	97.6	87.27
Pdl: 0.194	Peak 2: 4784	2.4	731.5
Intercept: 0.954	Peak 3: 0.000	0.0	0.000
Result quality : Good			

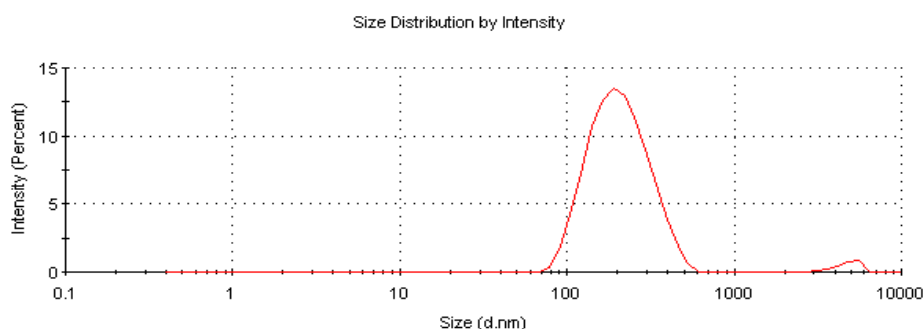


Fig. 08: Particle size analysis report of omeprazole nanosuspension (F9)

7.2 Particle charge (Zeta Potential): The zeta potential is the measure amount of charge on the particle and represents an index of particle stability. It is an important characteristic of nanoparticles which determine the physical stability of the formulation, in vivo distribution and targeting ability of nanoparticles Zeta potential was

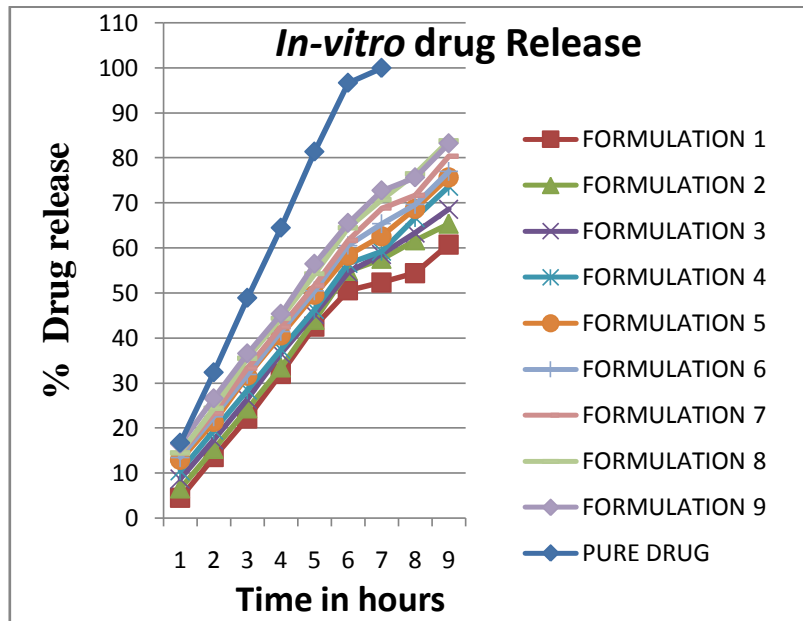
determined as a function of physical stability. The stabilizer was adsorbed on the surfaces of the generated nanoparticles, which gave the zeta potential ranging from 10.4 ± 1 mV to 45.2 ± 1 mV Batch F9 showed the best zeta potential value (45.2 ± 1)

Table.07: Optimized particle data (mean \pm SD, n – 3) for selected Omeprazole batches

Batch	Mean particle size (nm)	Zeta potential (mV)
F1	142 ± 20	10.4 ± 1
F3	179 ± 16	12.2 ± 2
F5	250 ± 12	41.2 ± 1
F7	316 ± 18	43.2 ± 2
F9	414 ± 20	45.2 ± 1

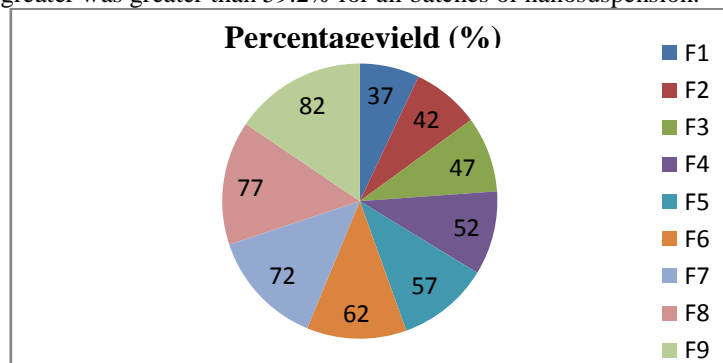
7.3 Drug content: In nanosuspension formulation the drug particles were reduced to nano sized during the formulation process there was not any drug loss step involved, so the formulation was considered as being 100% drug content the drug content was found to be 90 % w/w.

7.4 in-vitro drug release: The in-vitro dissolution study was carried out using dialysis bag phosphate buffer pH 7.4 the release rate for the formulation was found to be slow formulation showed best drug release rate. In vitro dissolution data of optimized formulations during stability showed table (09)



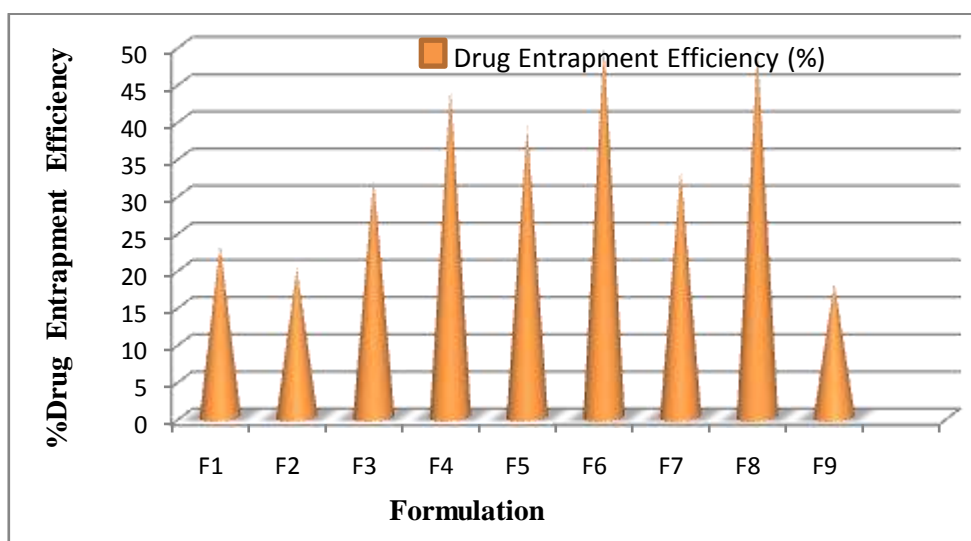
Graph No.02: in-vitro drug release of Nanosuspension Formulation

7.5 Percentage yield: The percentage yield was found in the range of 37% to 82% it was observed that average percentage yield was greater was greater than 59.2% for all batches of nanosuspension.



Graph No.03: Percentage yield

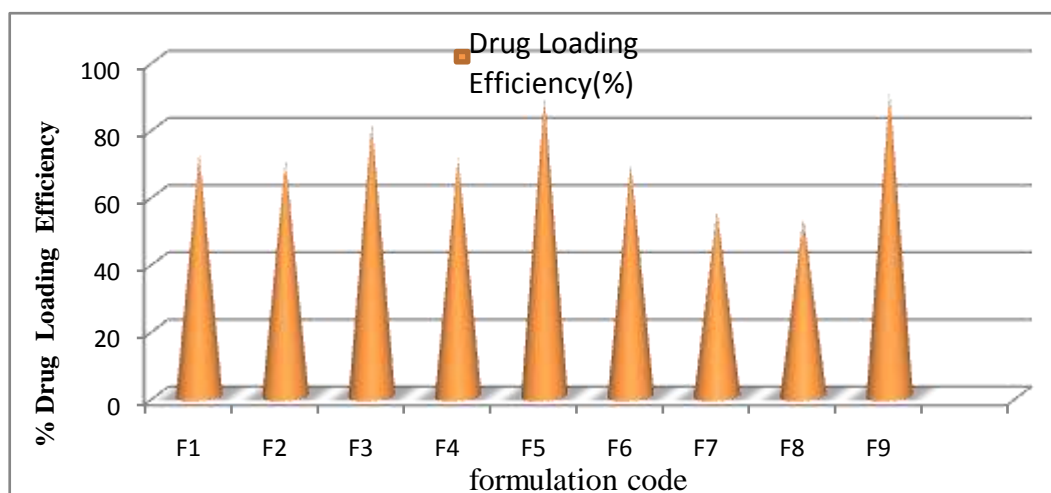
7.6 Percentage Drug loading and Drug Entrapment Efficiency: The selected F9 (according to its higher release and smallest particle size) was subjected for calculation of entrapment efficiency and drug loading it was found to be about 90 ± 0.75



Graph No.04: Drug Entrapment

Table.08: Particle size, Percentage yield, and Percentage Drug loading and Percentage Drug Entrapment Efficiency of nanosuspension.

Formulation Code	Particle Size	% Yield	% Drug Entrapment Efficiency	% Drug Loading Efficiency
F1	121	37	23	72
F2	186	42	20	70
F3	190	47	32	81
F4	236	52	44	71
F5	256	57	39	89
F6	287	62	50	69
F7	319	72	33	55
F8	378	77	49	53
F9	418	82	18	90



Graph No. 05: Drug loading efficiency%

7.7 Transmission electron microscopy (TEM): TEM was used for the study of structure and morphology of formed nanosuspension of the selected formulation F3. The image indicates the size and shape of omeprazole particles further, no sign of drug precipitation was observed inferring

the stable nature of the formed nanosuspension. The diameter of the particles observed in the micrograph is in agreement with the dynamic light scattering results. In TEM images, optimized nanosuspension showed spherical shape of nanoparticles with mean diameter 157.5 nm.

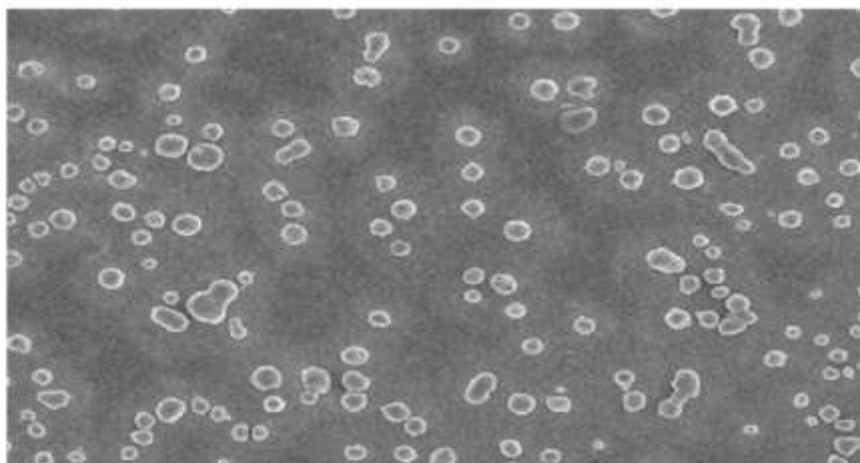
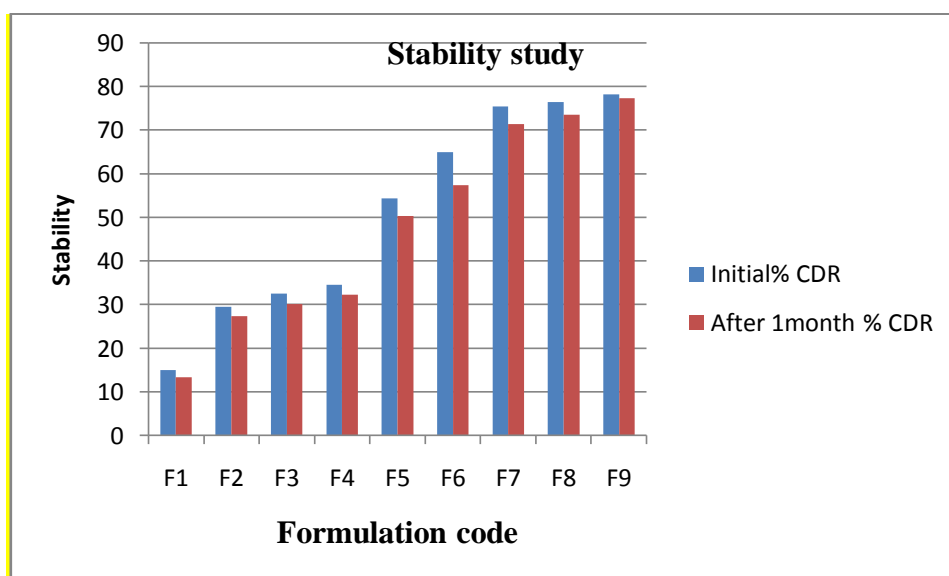


Fig.09: Transmission electron microscopy of Nanosuspension

7.8 Stability Study: The accelerated stability studies were carried out according to ICH guidelines optimized formulation F9 was packed in strip of aluminium foil and this packed formulation was stored in stability chamber maintained at room temperature 30°C and 65% RH and 40°C in 80% RH (zone conditions as per ICH guidelines) for 1 month. The nanosuspension was evaluated before

and after 1 month for change in appearance and in vitro release. After a period of one month the sample were observed for any change on appearance. It was observed that nanosuspension that nanosuspension was devoid of any change in colour or appearance of any kind of spot on it. Was also noted that nanosuspension was free of any kind of microbial or fungal growth or bad odour.



Graph. No: 06: Stability studies

Table .09: in-vitro drug release profile of omeprazole nanosuspension cumulative percentage drug release (%)

S. NO.	TIME (hrs)	1	2	3	4	5	6	7	8	9
1.	F1	4.44	13.44	22.12	32	42.54	50.55	52.33	54.44	60.78
2.	F2	6.55	15.33	24.33	33.43	44	54.88	57.56	61.66	65.35
3.	F3	8.65	17.34	26.33	36.55	45.22	54.56	58.56	63.34	68.56
4.	F4	10.44	19.45	28.39	37.45	46.32	56.55	59.24	66.66	73.67
5.	F5	12.89	21.34	31.55	40.56	49.54	58.34	62.45	68.65	75.67
6.	F6	13.43	22.44	31.83	41.45	50.43	60.54	65.33	69.67	76.98
7.	F7	14.43	23.23	33.23	42.44	51.56	61.65	68.77	71.66	80.33
8.	F8	14.44	24.33	35.44	44.34	54.23	64.45	70.65	76.43	83.77
9.	F9	16.45	26.55	36.54	45.34	56.45	65.54	72.77	75.67	83.23
10.	Pure drug	16.66	32.31	48.87	64.45	81.37	96.67	99.98		

Table 10: initial % CDR and after 1 month % CDR (Stability studies)

Formulation	Initial % CDR	After 1month % CDR
F1	15	13.33
F2	29.54	27.44
F3	32.54	30.11
F4	34.54	32.34
F5	54.45	50.34
F6	65	57.45
F7	75.45	71.44
F8	76.55	73.64
F9	78.23	77.36

7.9 Stastical data analysis: All the result obtained during evaluation was verified with different analysis like one way ANOVA. Standard deriation and probality log scale plotting (for measurement of particle size)

VIII. CONCLUSIONS:

Nanosuspension loaded omeprazole using Poloxamer 188 and Polyvinyl alcohol (PVA) as their polymer was developed by nanoprecipitation method and it was found to be suitable nanosuspension in drug loading capacity and sustained release of omeprazole drug. The nanosuspension obtained was nearly spherical in shape and discrete. It can conclude that Nanoprecipitation method to the preparation of omeprazole loaded nanosuspension offers simple and practical approaches to modify drug release

profile essential for controlled site specific and localized drug action. The pre-formulation studies were performed and showed the satisfactory results which helped in identification of drug (omeprazole). FT-IR identification result indicates the purity of drug. FT-IR spectra of the pure drug and with the excipients were identical and do not show any incompatibility. Thus the excipients were compatible with the drug. All the prepared nanosuspension was found to be nearly spherical circular in shape with little cracks. The drug-polymer ratio was found to influence the particle size and release of drug from omeprazole nanosuspension. Drug content of the formulation 90 % w/w. Formulation F9 showed best result in drug loading of 90 % and drug entrapment 18 %. In-vitro drug release from all the formulation was found to be slow and sustained. Stability studies of formulation omeprazole was done at Thus the

nanosuspension batch, was stable after 2 months of storage at 4°C and 25°C respectively.

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