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Formulation and Evaluation of Amoxicillin Oral Tablets for Suspension for Pediatric Patients

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ABSTRACT:
The formulation and evaluation of amoxicillin oral tablets for suspension aimed at pediatric patients involves the development of an innovative dosage form that ensures ease of administration, accurate dosing, and improved therapeutic efficacy. Amoxicillin, a broad-spectrum antibiotic, is commonly used to treat bacterial infections in children; however, pediatric patients often face difficulties with swallowing conventional tablets. The primary objective of this study was to design and evaluate an oral tablet that can be reconstituted into a suspension for easier administration in younger patients. Various excipients were selected for their suitability in tablet formulation, considering factors like stability, taste-masking, and ease of dispersion in water. The formulation was designed to allow easy reconstitution into a stable suspension. Key factors evaluated included the physical characteristics (hardness, friability, disintegration time), chemical stability (amoxicillin content), and in vitro release profile of the tablets. The suspension's pH, viscosity, and microbial stability were also assessed to ensure safety and efficacy. Results indicated that the optimized formulation of amoxicillin oral tablets for suspension met the required quality standards, demonstrating appropriate reconstitution properties, acceptable taste masking, and stable drug release. The formulation was also shown to be safe for pediatric use, with minimal side effects and high patient compliance. This study demonstrates the potential of reconstitutable tablet formulations as a reliable dosage form for pediatric patients, providing an alternative to liquid suspensions while maintaining the therapeutic benefits of amoxicillin.

Keywords: Amoxicillin, oral tablets, suspension, pediatric patients, formulation, evaluation, reconstitution, dosage form.

I. INTRODUCTION:

The main reason for the development of pharmaceutical suspensions is because of drug poor water solubility. Additionally, suspensions also aim to prevent the bitter taste of the therapeutic ingredients, and increase the oral absorption and bioavailability, as well as the drug stability.

Suspensions are usually made up of micrometric solid particles dispersed into an aqueous or viscous continuous phase, which have been widely used as the pharmaceutical form of choice for compounds with poor aqueous solubility. The biphasic solid dispersion is the core system in which the insoluble solid particles are eventually distributed in the continuous phase. The disperse phase consists of insoluble small particles between 0.5–5 μm, which are stabilized in a dispersion medium with the help of a suspending agent. Suspensions are classified depending upon the particle size, therapeutic action, route of administration, etc.[1]

Nowadays, many suspensions are sold as dry powders that must be 'constituted' before using, by adding predetermined amounts of a vehicle, primarily for reasons of stability.[2] In particular, there are few guidelines for paediatric formulations at the moment, but everyone agrees that the quantity and number of excipients should be reduced to a bare minimum. Thus, the formulation of the stable-in-time suspension remains a major challenge. Since the specific vehicle may be utilized to treat a juvenile patients on a long-term basis, this criterion was given special consideration while selecting excipients for suspensions composition. In addition, the suspension solvent should be water-based, flavor-free, dye-free, and sugar-free. Likewise, preparation should not contain any surfactant or antifoaming agents. However, excipients, such as a thickening agent (mostly carbohydrate-based derivatives and PVP), can be included in the formulation to increase the suspension's physical stability by increasing its viscosity.

Amoxicillin (α-amino-hydroxi benzyl penicillin) is a semisynthetic antibiotic; belonging to β-lactam family. Amoxicillin is effective against many different bacteria including Heamophilus influenza, Neisseria gonorrhea, Escherichia coli,

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Salmonella, Proteus mirabilis, Enterococci, Streptococci, Listeria, Helicobacter pylori and certain strain of Staphylococci. It inhibits cross-linkage between peptidoglycan polymer chains that make up a major component of the cell walls of both gram-positive and gram-negative bacteria. Amoxicillin is used for infections of middle ear, tonsils, upper and lower respiratory tract, urinary tract, skin and stomach in adult and pediatric patients.[3,4,5]

Amoxicillin is commercially available in trihydrate form. Amoxicillin is used as powder for suspension at two strengths of 125 mg and 250 mg in children. An important disadvantage of suspensions is inter-dose variability, often seen when patient forgets shaking the bottle before taking the medication. Phase separation and difficulty of reconstituting suspension are other problems of the dosage form. The therapeutic effect of amoxicillin suspensions may change and decline from the 1st day to the last day of treatment. In addition, patients may avoid carrying the medication with them when away from home, resulting in poor compliance and the failure of therapy.

II. METHODOLOGY:

Construction of Calibration curve:

The Amoxicillin solutions were scanned using single beam UV-Visible spectrophotometer to obtain their respective λmax. The λmax was found to be at 223.1 nm for Amoxicillin. Then required dilutions samples were scanned at their respective wavelengths. From the obtained values calibration curve was plotted by taking concentration on X-axis and absorbance on Y-axis and the calibration data and curve.

Differential scanning calorimetry (DSC)

DSC was carried out to find out the presence of any interaction between the drug and excipients. Pure drug (Amoxicillin) and optimized formulation were subjected to DSC analysis. Samples were taken in the pierced DSC aluminum pan scanned in the temperature range of 0-350 ºC for Amoxicillin pure drug and scanned in the temperature range of 400ºC for optimized formulation at a heating rate of 2ºC/min using differential thermal analyzer (Mettler) with STAR e SW 9.01 software and the resulting thermograms.

Fourier Transform infrared spectroscopy (FTIR)

FT-IR spectrometry was found to be most reliable technique for predicting the possible interaction between the drugs. The spectra was recorded for pure Amoxicillin, microcrystalline cellulose individually and for optimized formulation using FTIR (bruker), model 10048657 Alpha.T., AT-001 opus software. The samples were scanned from 1000 to 3500cm-1 and the obtained.

FORMULATION OF TABLETS:

In the tablet pressing process, the main guideline was to ensure that the appropriate amount of active ingredient was in each tablet. Hence, all the ingredients should be well mixed. If a sufficiently homogenous mixture of the components cannot be obtained with simple blending processes, the ingredients must be granulated prior to compression to assure an even distribution of the active compound in final tablet.Two basic techniques are used to granulate powders for compression into a tablet: wet granulation and dry granulation. Powders that can be mixed well do not require granulation and can be compressed into tablets through dry granulation.

PROCEDURE:

Accurate amount of Amoxicillin and remaining excipients were weighed. All the weighed ingredients were transferred to a mortar and blended to obtain a fine powder. The blended powder was passed through # 44 sieve. Sifting was carried out after addition of each ingredient to ensure uniform mixing. The resultant blend was subjected to direct compression using ELITE 10 station rotary tablet compression machine containing flat punches. A total of 15 formulations were prepared. F1 – F11 are placebo formulations and F12 – F15 (AF12-AF15) contain drug along with other ingredients. All the formulations were subjected to various evaluation tests.

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Table.1 Composition of various formulations:

FORMULA	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	AF12	AF13	AF14	AF15
Amoxicillin	-	-	-	-	-	-	-	-	-	-	-	250	250	250	250
Aerosil	25	25	25	25	25			25	25	25	25	25	25	25	25
Aspartame	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	20	20	20	20	20	20	20
SSG	5	12.5	-	-	-	-	20	5	12.5	15	-	-	-	-	-
Sodium bicarbonate	-	-	-	-	-	-	-	-	-	25	25	35	35	40	40
CCS			20	20	20	20			15	10	10	10	10	-	10
Xanthum gum	12.5	5	-	-	5	5	-	12.5	-	-	15	-	-	-	-
Carbopol	-	-	-	-	-	-	-	-	-	-	20	20	20	20	20
SCMC	79.6	79.6	79.6	-	-	-	-	79.6	-	-	-	-	-	-	-
MCC	-	-	-	-	-	-	122	17.5	67.1	103	103	103	103	88	88
Succinic acid	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.85	2	2	2	2	0.84	2
Lactose	17.5	17.5	17.5	97.1	97.1	122	-	-	-	-	-	-	-	-	-
Flavor	72.5	72.5	-	-	-	-	-	72.5	-	-	-	Q.S	Q.S	Q.S	32

EVALUATION TESTS FOR VARIOUS AMOXICILLLIN FORMULATIONS:

EVALUATION OF BLEND CHARACTERISTICS OFAMOXICILLIN FORMULATIONS:

Powder blend of all formulations was evaluated for various pre-compression parameters like Bulk
Density, Tapped Density, Compressibility index, Hausner's ratio and Angle of repose.

Bulk Density

Powder blend was passed through a standard sieve No.20. A weighed amount of powder blend was transferred into a 100ml measuring cylinder. The volume occupied by the powder blend was noted as bulk volume. From this bulk density was calculated using the formula:

Bulk Density = W/Vb
Where W = Weight of the powder blend
Vb = Bulk Volume of the powder

Tapped Density

Powder blend was passed through a standard sieve No.20. A weighed amount of powder blend was transferred into a 100ml measuring cylinder. The measuring cylinder was fixed on the Bulk density apparatus and timer knob was set for 100 tapings. For reproducible results, the process of tapings may be continued until concurrent volume was achieved. This volume was noted as tapped volume. From this tapped density was calculated using the formula:

Tapped Density = W/ Vt
Where W = Weight of the powder blend
Vt = Tapped Volume of the powder

Compressibility Index

Compressibility index was calculated by measuring bulk density and tapped density and the values were executed in following equation to get compressibility index.

$$\textbf{Compressibility Index} = \frac{\textbf{Tapped Density} - \textbf{Bulk Density}}{\textbf{Tapped Density}} \text{x}100$$

Hausner's Ratio

Hausner's Ratio can be defined as ratio of tapped density to bulk density and it was calculated using the following formula:

$$\textbf{Hausner's Ratio} = \frac{\textbf{Tapped Density}}{\textbf{Bulk Density}} \text{x}100$$

Angle of Repose

Angle of repose of tablet powder blend was determined by funnel method. A glass funnel was fixed at a height of 2 cm over a platform. The powder blend was transferred into a funnel by blocking the orifice of the funnel with the thumb. Then the thumb was removed. When the powder was emptied from the funnel, height of the pile (h) and radius of the base (r) was measured. Then the angle of repose was estimated using the formula:

Tan θ = h/r

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EVALUATION OF FORMULATED AMOXICILLIN TABLETS

The prepared Amoxicillin tablets were subjected to various evaluation tests. The results of all these
post compression characteristics of Amoxicillin formulations.

Weight Variation

Twenty tablets were randomly selected from each batch and weighed individually. Average weight was calculated and individual tablet weight was compared with the average weight. As per USP not more than two of the individual tablet weight should deviate from and none should deviate twice that percentage.

Hardness

This test is performed to measure the force required to break a tablet. Hardness or crushing strength of the formulation was measured using Monsanto hardness tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger was placed in contact with the tablet and a zero reading was taken. The upper plunger was then forced against a spring by twisting a threaded bolt until the tablet fractures. As the spring was compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture was measured

Friability

This test is performed to estimate mechanical weakness of tablets. Ten tablets were weighed and placed in a Roche friabilator and apparatus was rotated at 25 rpm dropping the tablets at a distance of six inches for 4 minutes. After revolutions the tablets were dusted and reweighed. Friability (F) was calculated using the following formula :

F= (1- W/W0) X 100

Estimation of Drug content

20 tablets from batch were crushed in mortar and the powder equivalent to 100mg each of Amoxicillin is shaken with 100ml of 0.1 N Hcl in a100ml volumetric flask and sonicated for 15min and filtered through 0.45µm Whattman filter paper. After necessary dilutions, sample was measured at 223.1nm for Amoxicillin using UV-Visible spectrophotometer and the results.

In vitro drug release study

The in vitro dug release study was performed for the formulation and pure drugs using USP type II dissolution apparatus (paddle type) as shown in figure 6.2. Various parameters for performing dissolution studies were tabulated in table 6.4. 5ml sample solution was withdrawn from the dissolution apparatus at regular time intervals and the sample solution was replaced with fresh dissolution medium to maintain sink conditions. The samples were withdrawn at regular intervals of 5,10,15,20,25 min. The withdrawn sample solutions were filtered through a 0.45µm Whattman filter paper and analysed using UV spectrophotometric method at 223.1nm. The results for drug

Modelling of Dissolution Profiles

In the present study, data of the in vitro release were fitted to different equations and kinetic models to explain the release kinetics of Amoxicillin. The kinetic models used were a Zero order equation, First order.

Zero Order Kinetics

Drug dissolution from pharmaceutical dosage forms that do not disaggregate and release the drug slowly (assuming that area does not change and no equilibrium conditions are obtained) can be represented by the following equation;

Qt = Qo + ko t

First Order Kinetics

The application of this model to drug dissolution studies was first proposed by Gibaldi and Feldman (1967). The following relation can express this model:

Log Qt = Log Qo + ktt/2.303

Comparison of drug release profiles of Pure drug and optimized formulation of Amoxicillin:

The drug release profiles of optimized formulation were compared with that of respective pure drugs. The results of dissolution profiles of Amoxicillin were shown and the graphs of zero order and first order.

Sedimentation volume:

Sedimentation volume was determined by taking a definite volume of the reconstituted sample into a graduated cylinder and then keeping it undisturbed for 7 days. After 7 days, sedimentation volume (F) was calculated from the ratio of the final volume (Vf) of the sediment to the original or initial volume (Vi) of the suspension

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before settling , Sedimentation volumes were determined for both freshly reconstituted samples and also for samples undergone storage tests for 7 days. The sedimentation volume F was calculated using the formula,

F = Vu/Vo
where
Vu is the volume of sediment
Vo is the original height of the sample

Degree of flocculation:
The degree of flocculation is calculated by using the formula,
β= F/F∞

Rheological studies:

The rheological studies were conducted for 10ml of RS at 29°C using Brookfield LV viscometer with spindle CP52. Spindle speed was varied for ascending and descending modes by change of 5 rpm/min. Rheograms is constructed and rheological properties were measured. The various conditions of rheological studies are given in the table 7.10 and the rheogram .

Determination of wetting time:

The wetting time of tablets was measured using a simple procedure. A piece of tissue paper folded twice was placed in a small petri-dish containing 10 ml of distilled water. A tablet having was placed on the filter paper. Time required to develop wet the upper surface of tablet was recorded as wetting time.

Zeta potential and Particle size studies

The optimized tablet was dispersed in 25 ml of water and from this 5ml of solution is taken and subjected to zeta potential and particle size studies with the help of Malvern master sizer 2000.

III. RESULTS AND DISCUSSION:

STANDARD CURVE OF AMOXICILLIN

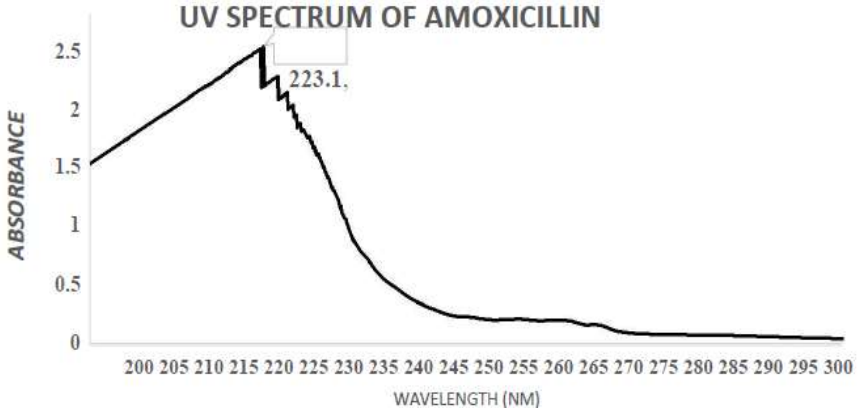

Figure.1 Estimation of standard curve of Amoxicillin

ESTIMATION OF CALIBRATION CURVE

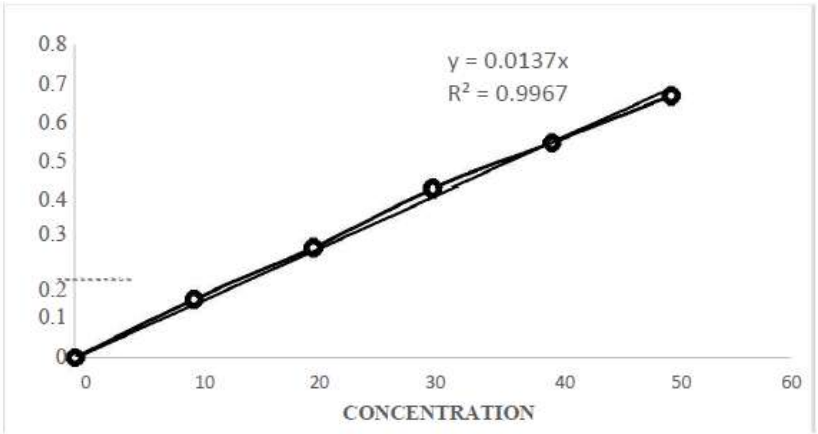

Figure.2 Calibration curve of Amoxicillin using 0.1N HCl

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Discussion: Calibration curve is plotted for both Amoxicillin using UV spectrophotometric method. All the process was analysed and based on obtained concentration and linearity it was found that obtained drug was pure and within the standards specified in IP.

DSC

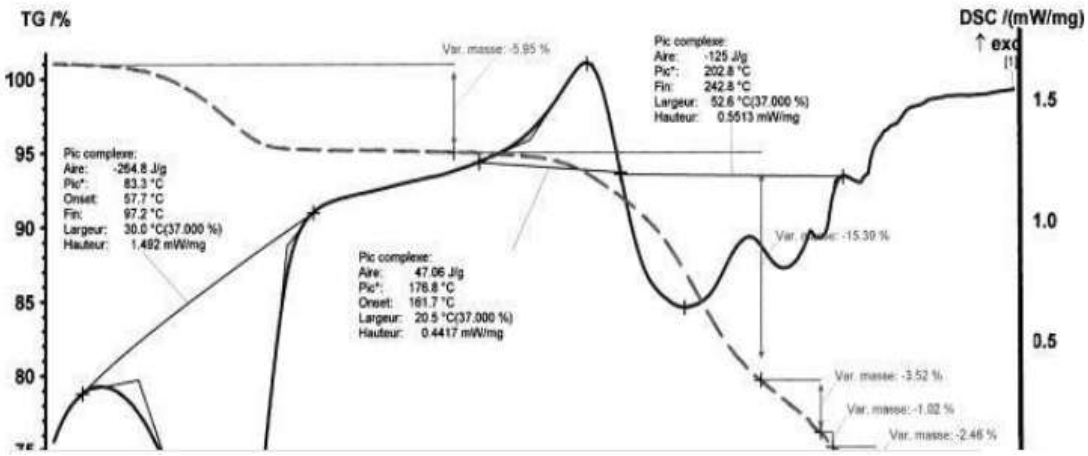

Figure.3 DSC thermogram of pure drug Amoxicillin

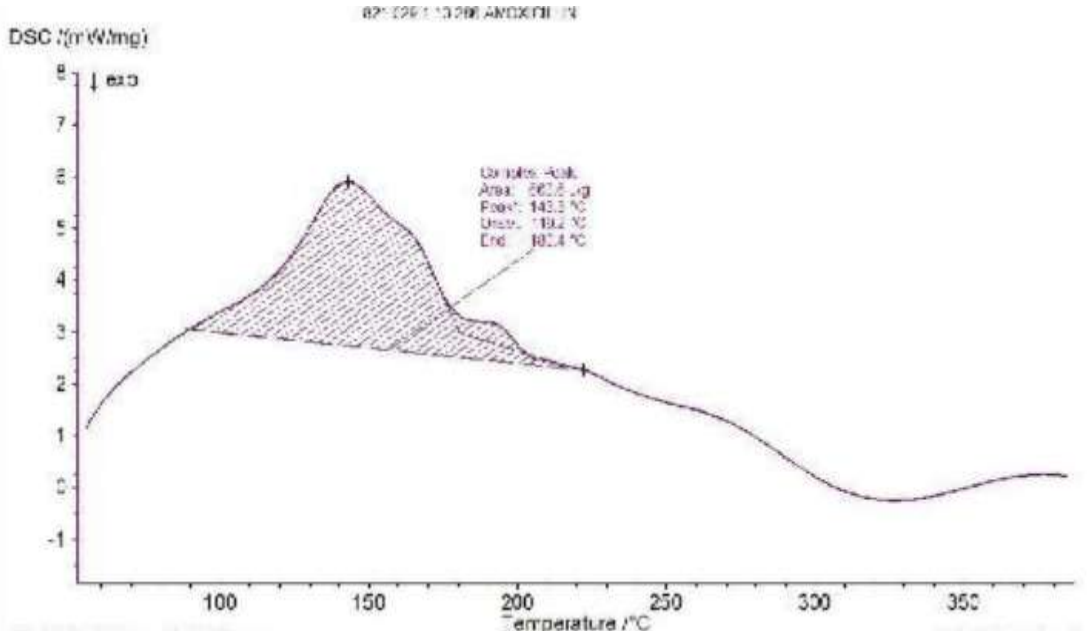

Figure.4 DSC thermogram of optimized formulation of Amoxicillin

Discussion: The DSC thermogram of pure amoxicillin showed broad complex peak at 176.8 ºC and the optimized formulation AF15 of Amoxicillin showed broad complex peak at 143.3ºC which indicates the melting point of Amoxicillin indicating no significant interaction between the drugs and other excipients.

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FTIR

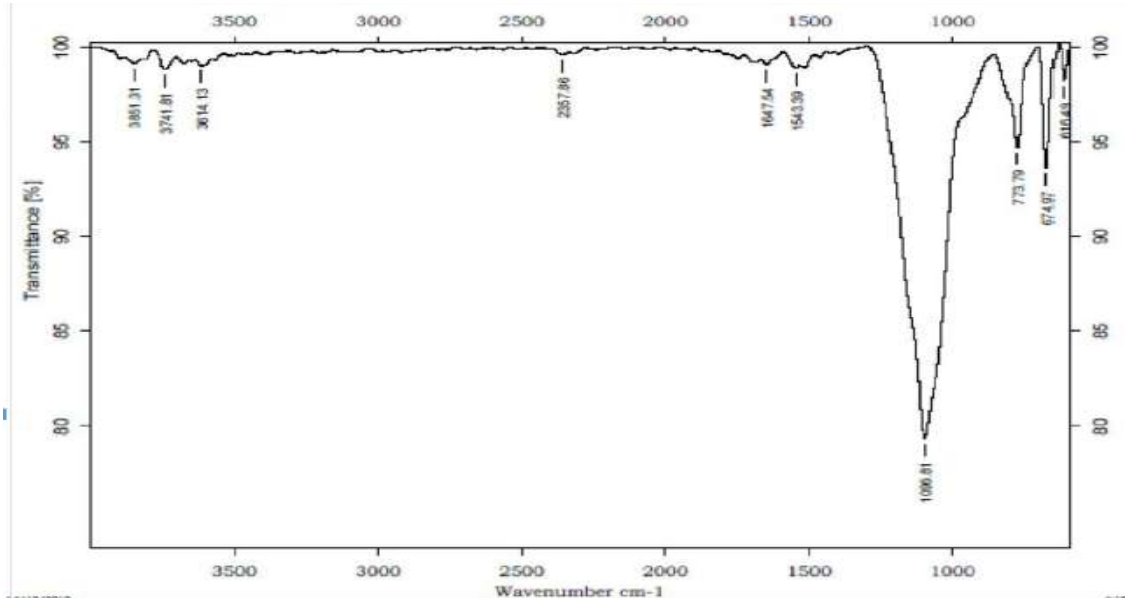

Figure.5 FTIR spectra of Pure drug Amoxicillin

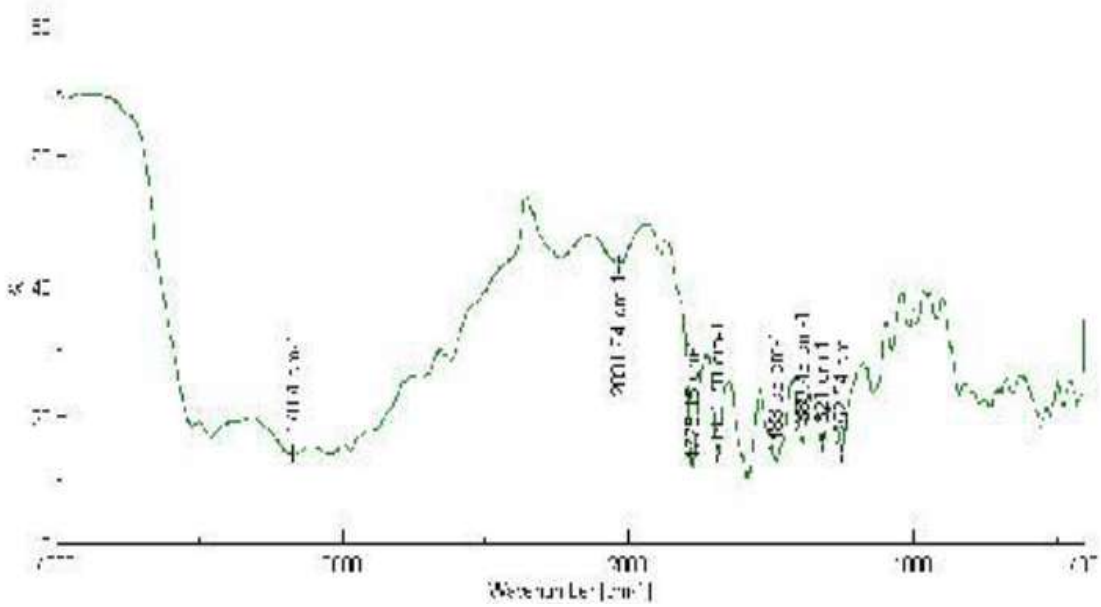

Figure.6 FTIR spectra of Micro crystalline cellulose

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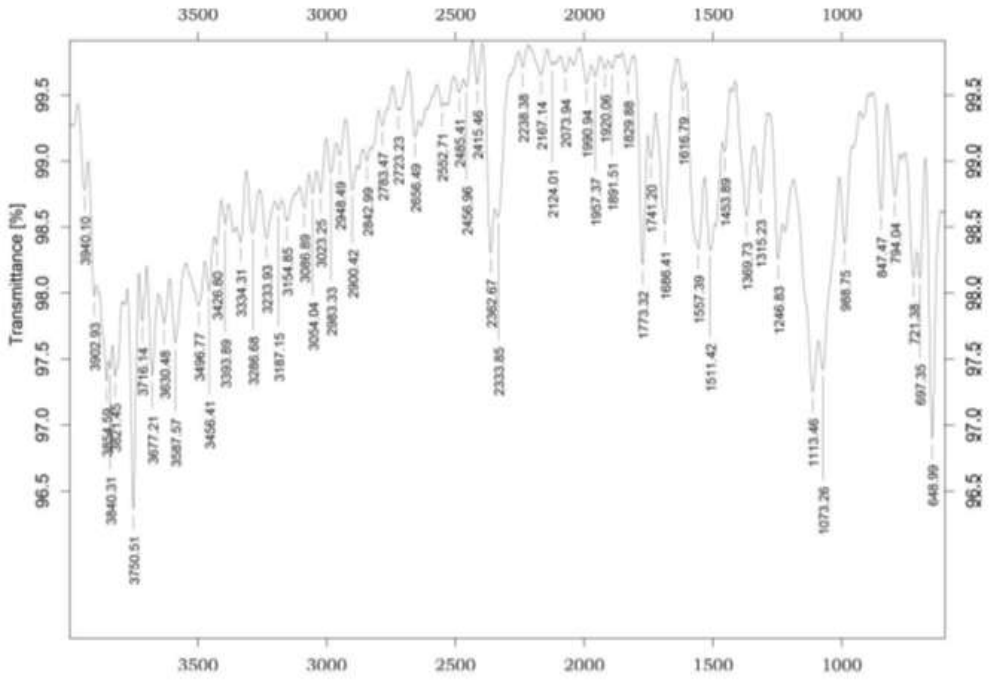

Figure.7 FTIR spectra of optimized formulation of Amoxicillin

Discussion: The IR spectra of pure Amoxicillin showed characteristic bands at The IR spectra of micro crystalline cellulose showed characteristic bands at The IR spectra of optimized formulation of Amoxicillin.

Table.2 Evaluation of Pre-compression characteristics of placebo and Amoxicillin formulations:

Formulation code	Bulkdensity (g/ml)	Tapped density(g/ml)	Carr's index(%)	Hausner's ratio	Angle of repose(º)
F1	0.386	0.712	45.67	1.844	45.90
F2	0.378	0.696	45.60	1.841	46.30
F3	0.417	0.704	33.6	1.688	47.20
F4	0.391	0.695	42.5	1.777	42.1
F5	0.376	0.689	45.4	1.832	43.1
F6	0.479	0.743	35.5	1.551	47.4
F7	0.607	0.761	20.2	1.253	44.5
F8	0.493	0.716	31.1	1.452	48.1
F9	0.592	0.767	22.8	1.295	42.60
F10	0.428	0.701	38.9	1.637	40.2
F11	0.452	0.752	39.89	1.663	43.6
AF12	0.624	0.789	29.13	1.264	42.4
AF13	0.657	0.794	17.25	1.208	35.6
AF14	0.694	0.789	12.04	1.136	32.3
AF15	0.603	0.659	8.19	1.092	28.34

Discussion: The results for formulations showed that Bulk density is ranged between 0.376-0.694g/ml, Tapped density is ranged between 0.689-0.794g/ml, Compressibility index is ranged between 8.19-45.67%, Angle of repose is ranged between 28.34-48.1º, Hausner's ratio is ranged

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between 1.092-1.844. The obtained results indicates that F1 to F6, F8 formulations have poor flow properties and F11, AF12 to AF15 formulations have acceptable flow properties.

Table.3 Evaluation of post compression characteristics of Placebo and Amoxicillin formulations:

Formulation Code	Weightvariation(mg)(n = 20)	Friability(%) (n = 10)	Hardness(Kg/cm^2)(n= 6)
F1	220±0.251	1.06	2.0
F2	220±0.835	0.98	1.6
F3	155±0.532	0.91	1
F4	155±0.216	1.10	0.8
F5	160±0.523	0.96	1.8
F6	160±0.325	1.21	2.6
F7	155±0.412	1.09	2.4
F8	220±0.125	1.12	3.0
F9	450±0.273	0.99	1.3
F10	450±0.312	0.98	2.7
F11	450±0.191	1.05	2.0
AF12	450±0.647	1.21	2.5
AF13	450±0.211	0.97	1.0
AF14	450±0.635	1.03	2.3
AF15	500± 0.216	0.96	2.7

Discussion: Various tests like Weight variation, Hardness, Friability were performed for all the 15 formulations and the results were shown in table. The results for optimized formulation showed that Weight variation was found to be 500± 0.216 2mg. Hardness was found to be sufficient around 2.7 Kg/cm Friability of all formulations was found to be <1% which was within the range specified in IP.

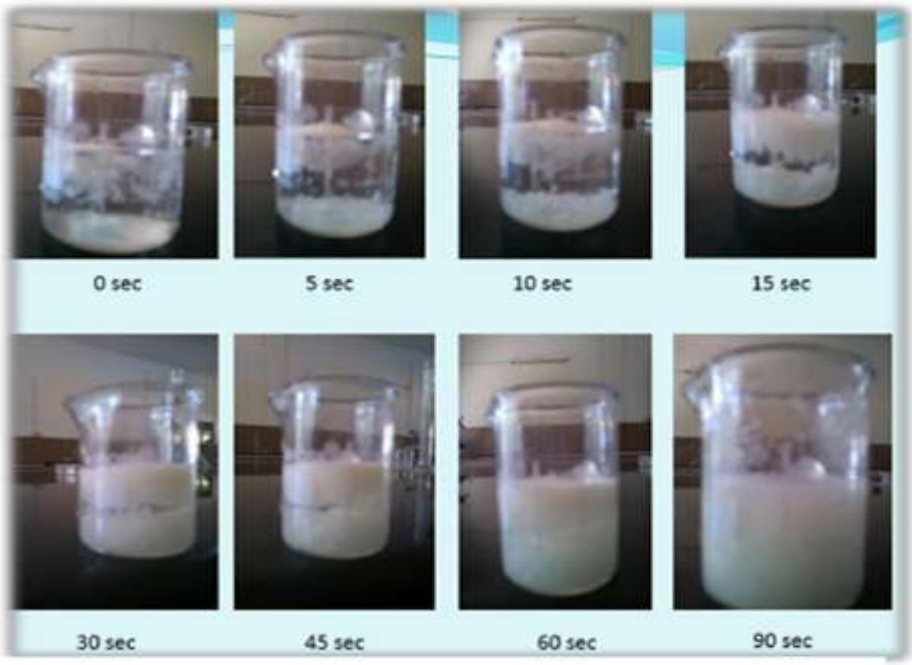

Figure.8 pictorial representation of dispersion of tablets

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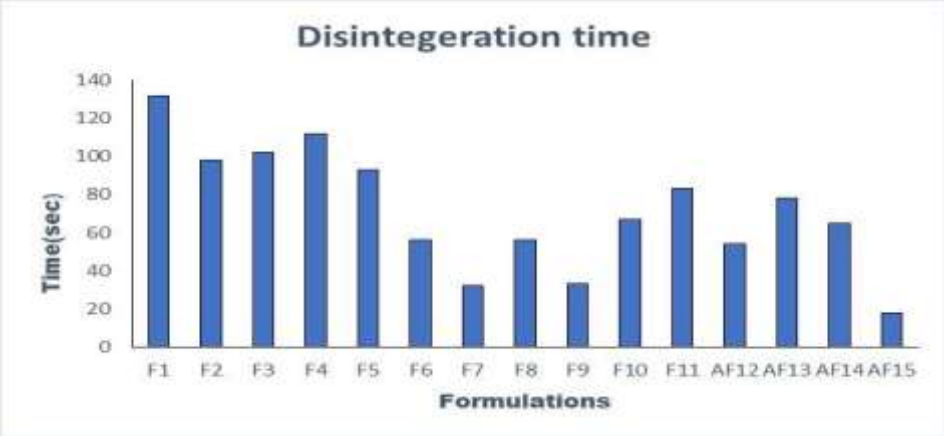

Figure.9:Comparison of disintegration time of various formulations

Discussion: Disintegration test was performed for all the formulations. Tablets from each batch of formulation showed respective disintegration. Disintegration time decreased with increase in the concentration of disintegrants. Disintegration time was given in figure. The rapid disintegration was seen in AF15 formulation containing 15% concentration of Croscarmellose sodium as superdisintegrant rather than the formulations containing Crospovidone and SSG. The immediate disintegration of AF15 formulation is due to the rapid uptake of water from the medium, swelling and burst effect amd the result was shown in table.

Table.4 Observations of all placebo and Amoxicillin formulations

Formulation	Observation				Inference
	Flow property	Physicalparametersof compaction		Dispersability	
		Hardness	Friability		
F1	Passable	Average	Good	Sinkedandno dispersability	Rejected
F2	Poor	Not satisfactory	Good	Stickingandno dispersability.	Rejected
F3	Poor	Not satisfactory	Good	Floatingandno dispersability	Rejected
F4	Passable	Not satisfactory	Good	Nodispersability	Rejected
F5	Passable	Not satisfactory	Good	Nodispersability	Rejected
F6	Poor	Sufficient	Average	Nodispersability	Rejected
F7	Passable	Sufficient	Good	Dispersed	Considered
F8	Poor	Sufficient	Good	Flocculatedand no dispersion	Rejected
F9	Passable	Not satisfactory	Good	Dispersed	Considered
F10	Fair	Sufficient	Good	Nodispersion	Rejected
F11	Passable	Average	Good	Nodispersion andformationof hard cake	Rejected
AF12	Passable	Sufficient	Average	Nodispersion	Rejected
AF13	Good	Not satisfactory	Good	Nodispersion	Rejected
AF14	Good	Average	Good	Nodispersion	Rejected
AF15	Excellent	Sufficient	Good	Dispersed	Considered

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Table.5 Post compression parameters of optimized formulation:

Parameter	Value
Weight variation	500± 0.216 mg
Thickness	7.5mm
Hardness	2.7kg/cm^2
Friability	0.96 %
Disintegration time	15sec
Wetting Time	58.2 sec
Sedimentation volume	0.43
Degree of flocculation	1.326
Viscosity	0.834m.pas
Dispersion time	90sec

Table.6 in vitro drug release data of Amoxicillin formulations

S.No	Time(min)	% Drug release
1	0	0
2	2	33.25±1.21
3	4	54.37±1.05
4	6	76.81±1.53
5	8	88.53±1.12
6	10	98.74±1.03

Discussion: In vitro drug release was performed for the optimized formulations usin USP type II dissolution apparatus (Paddle type) at 50 rpm. The results were shown in table. The release profiles of Amoxicillin formulation is as follows: AF15 showed 98.74% within 10 min. And the pure drug showed showed release up to 96.39% within 45 min. AF15 formulation showed better drug release profile when compared to pure drug, hence AF15 was selected as optimized Amoxicillin.

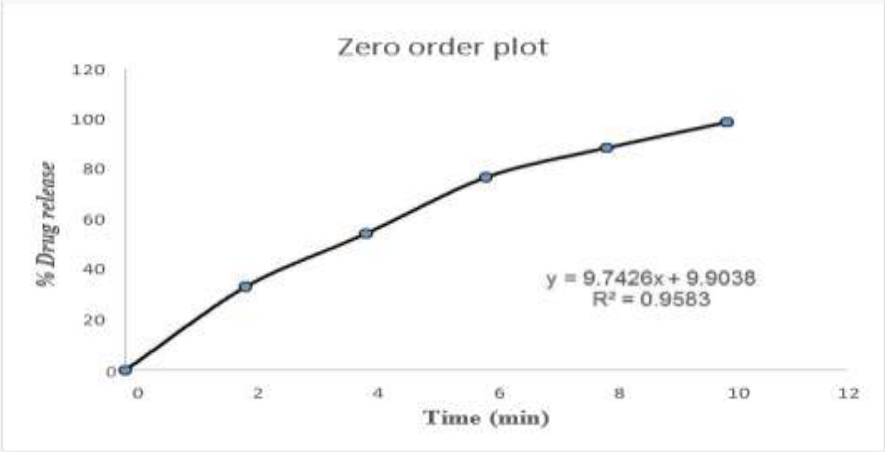

Figure.10Zeroorder plot of Amoxicillin formulation

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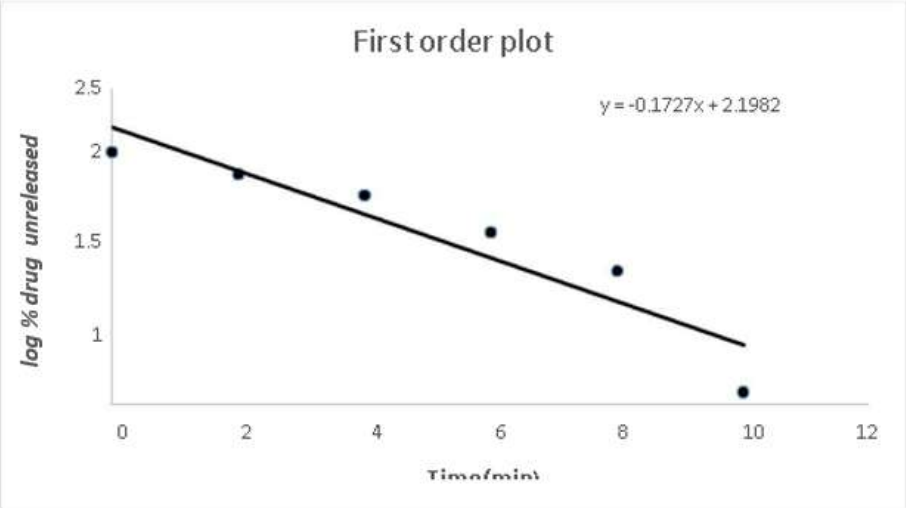

Figure.11 First order plot of Amoxicillin formulation

Table.7Correlation coefficients of the Amoxicillin formulation:

Kinetics	Amoxicillin	
	R^2	K
Zeroorder	0.9583	9.742
First order	0.8739	0.396

Comparative drug release profiles of Pure drug, and optimized formulation of Amoxicillin:

Table.8 In vitro drug release data of pure drug and optimized formulation of Amoxicillin

Time(min)	% Drug released	
	Pure drug	Optimized formulation
0	0	0
2	-	33.25±1.45
4	-	54.37±1.62
6	-	76.81±1.89
8	-	88.53±1.29
10	17.31±1.53	98.74±1.53
15	32.58±1.42	-
20	41.64±1.87	-
25	58.73±1.96	-
30	67.39±1.32	-
35	79.43±1.89	-
40	91.35±1.23	-
45	96.39±1.86	-

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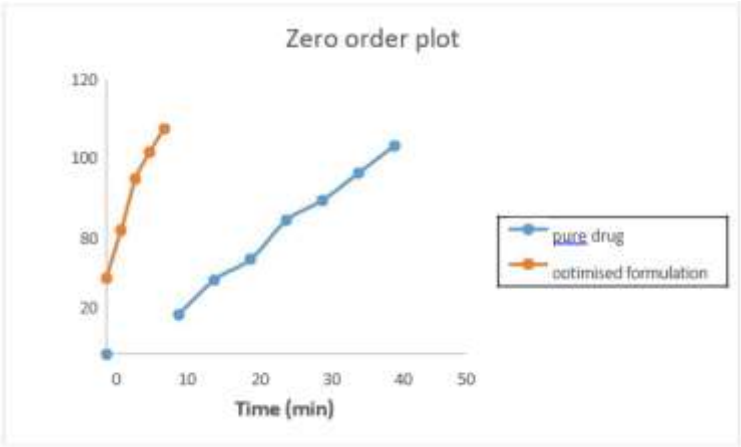

Figure.12 Zero order plot of pure drug and optimized formulation of Amoxicillin

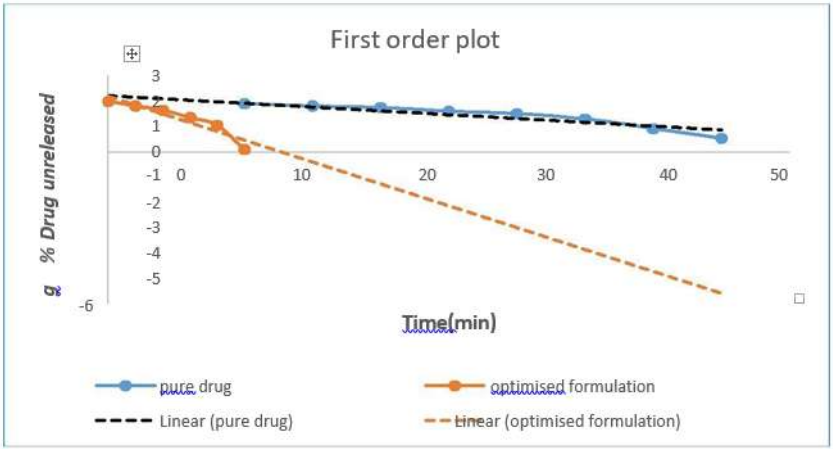

Figure.13Firstorderplotof pure drug and optimized formulation of Amoxicillin

Table.9Drugcontent of Optimized formulation

Name of the drug	Label claim(mg)	Amount of drug estimated (mg)	% of Label claim
Amoxicillin	250	248.69	99.48

Table.10 Sedimentation volume and Degree of flocculation determination for optimized formulation AF15

Time (min)	Initial volume (ml)	Ultimate volume(ml)	Sedimentation volume of flocculated	Sedimentation volume of de flocculated	Degree of flocculation (β)
0	50	50	1	∞	1.326
5	50	46	0.92	0.08	
10	50	42	0.84	0.16	
15	50	39	0.78	0.22	
30	50	36.5	0.73	0.27	
45	50	32	0.64	0.36	
60	50	28.5	0.57	0.43	

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Discussion: The sedimentation volume and the degree of flocculation was calculated for the optimized formulation AF15 was and the results were given in the table. From the data obtained the degree of flocculation was found to be greater than one, hence we concluded that the optimized formulation formed flocculated suspension.

Table.11Rheological studies of optimized formulation of Amoxicillin

S.No	Viscosity (cP)	Speed (RPM)	%Torque (%)	Shear Stress (D/cm^2)	Shear Rate (1/sec)	Temperature (°C)	Time Interval (mm:ss.t)
1	221.74	5.00	11.9	22.17	10.00	29.2	01:00.2
2	161.18	10.00	17.3	32.24	20.00	29.1	01:00.2
3	119.88	15.00	19.3	33.89	30.00	29.1	01:00.2
4	85.71	20.00	18.4	34.29	40.00	29.0	01:00.2
5	67.45	25.00	18.1	35.73	50.00	29.1	01:00.2
6	60.75	25.00	16.3	30.37	50.00	29.1	01:00.2
7	81.52	20.00	17.5	32.61	40.00	29.1	01:00.2
8	100.00	15.00	16.1	30.00	30.00	29.0	01:00.2
9	135.09	10.00	14.5	27.02	20.00	29.0	01:00.2
10	218.01	5.00	11.7	21.80	10.00	28.9	01:00.2

Discussion: The rheological studies were conducted for the optimized formulation AF15, the various conditions for rheological studies are given in the table. and the rheogram obtained for the optimized formulation was shown in the figure. from the figure we concluded that the optimized formulation shows Newtonian flow.

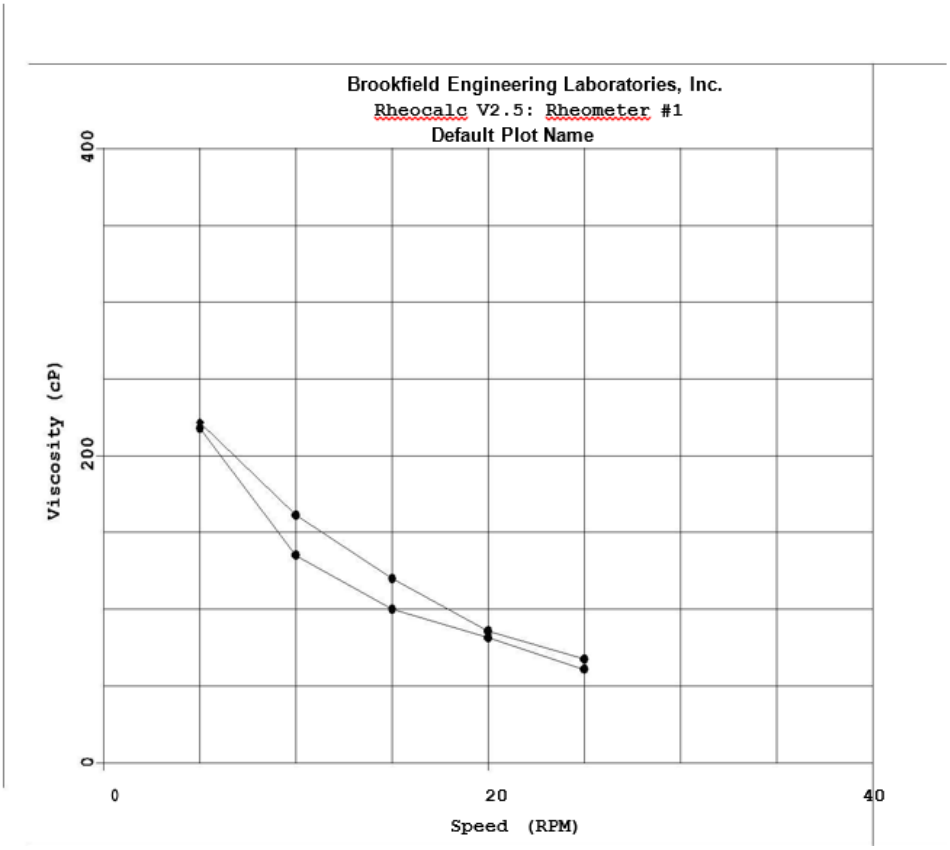

Figure.14 Rheogram of optimized formulation of Amoxicillin

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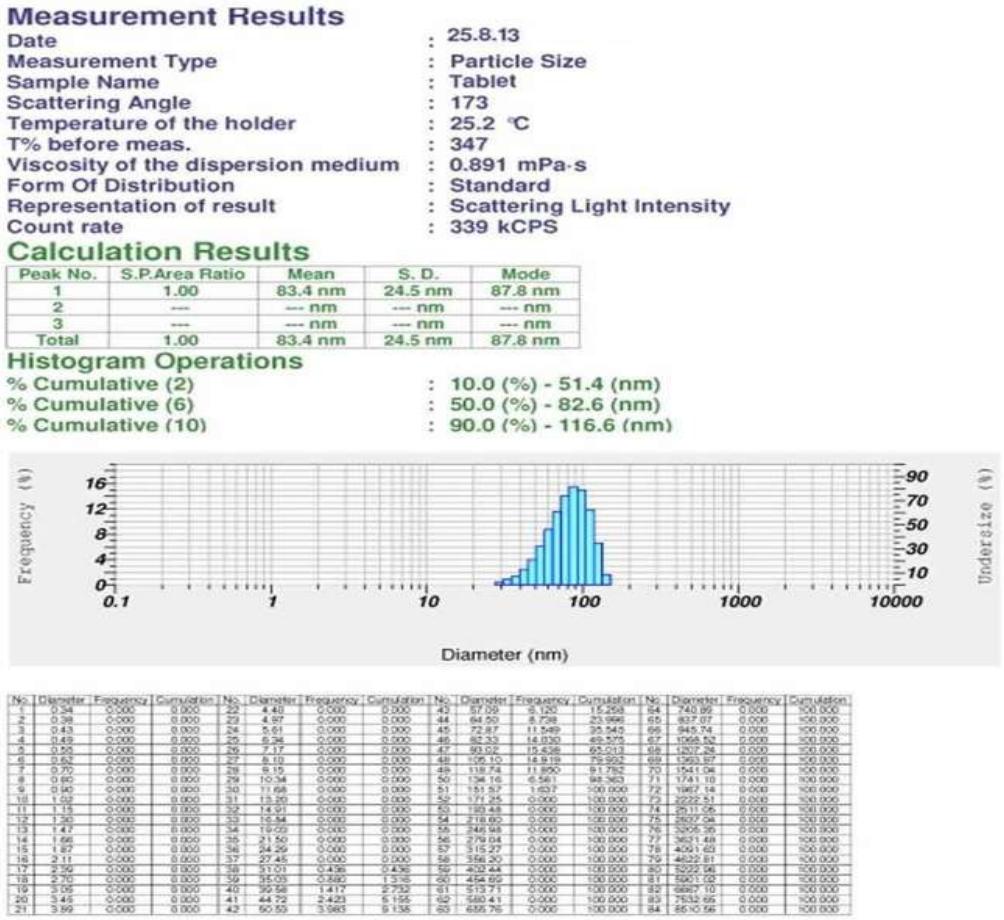
Particle size



Measurement Results

Date : 25.8.13
Measurement Type : Particle Size
Sample Name : Tablet
Scattering Angle : 173
Temperature of the holder : 25.2 °C
T% before meas. : 347
Viscosity of the dispersion medium : 0.891 mPa·s
Form Of Distribution : Standard
Representation of result : Scattering Light Intensity
Count rate : 339 kCPS

Calculation Results

Peak No.	S.P.Area Ratio	Mean	S. D.	Mode
1	1.00	83.4 nm	24.5 nm	87.8 nm
2	---	--- nm	--- nm	--- nm
3	---	--- nm	--- nm	--- nm
Total	1.00	83.4 nm	24.5 nm	87.8 nm

Histogram Operations

% Cumulative (2) : 10.0 (%) - 51.4 (nm)
% Cumulative (6) : 50.0 (%) - 82.6 (nm)
% Cumulative (10) : 90.0 (%) - 116.6 (nm)

Figure.15 particle size analysis optimized formulation Amoxicillin

Discussion: The optimized formulation AF15 was subjected to particle size analysis and the results.

Zeta Potential

Measurement Results

Measurement Results

Date : 25.8.13
Measurement Type : Zeta Potential
Sample Name : Tablet
Temperature of the holder : 25.1 °C
Viscosity of the dispersion medium : 0.893 mPa·s
Conductivity : 6.293 mS/cm
Electrode Voltage : 4.6 V

Calculation Results

Peak No.	Zeta Potential	Electrophoretic Mobility
1	-36.5 mV	-0.000189 cm2/Vs
2	--- mV	--- cm2/Vs
3	--- mV	--- cm2/Vs

Zeta Potential (Mean) : -36.5 mV
Electrophoretic Mobility mean : -0.000189 cm²/Vs

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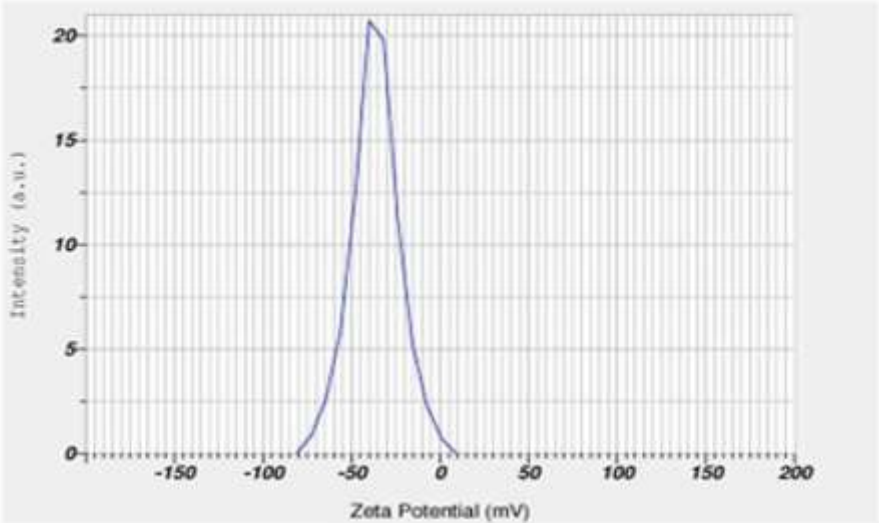

Figure.16 Zeta potential studies for optimized formulation of Amoxicillin

Discussion: The optimized formulation AF15 was subjected to zeta potential studies

IV. CONCLUSION:

- The present study succeeded in formulating tablets for suspensions of amoxicillin, which follows all the required specifications.
- The present study succeeded in obtaining better release profile of optimised formulation compared to pure drug.
- An alternate product to oral powders for suspensions with less cost minimum storage conditions which is affordable by patients is prepared.
- Hence this formulation advantageous in terms of cost effectiveness, decease the bioburden.

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