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FORMULATION OF FAST DISINTEGRATING AMOXICILLIN AND POTASSIUM CLAVULANATE TABLETS: *IN-VITRO* EVALUATION AND STABILITY STUDIES

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ABSTRACT

The present work is aimed to develop a stable formulation of preferred combination of two antibiotics-Amoxicillin and Potassium Clavulunate by using various disintegrants. Amoxicillin and Potassium Clavulunate dispersible tablets were prepared by direct compression method using different disintegrants i.e. Croscarmellose sodium, Crosspovidone, Maize starch and Sodium Starch Glycolate. Aspartame as a sweetener and strawberry flavor were used to increase palatability. The Powder blends were subject to various physical characteristics test such as bulk density, tapped density, Hausner's ratio and Compressibility Index. The prepared tablets were evaluated for hardness, friability, Disintegration time and Wetting time and *In vitro* drug release. Amoxicillin and Potassium Clavulunate dispersible tablets were found to be of good quality fulfilling all the requirements for dispersible tablets. The results indicated that concentration of Crosspovidone, Croscarmellose sodium, Sodium starch glycolate and maize starch significantly affected the release property of the drug. Croscarmellose sodium showed high disintegration time as compared to batches prepared from Maize starch, Sodium starch Glycolate and Crosspovidone. The *In-vitro* dissolution profile of F8 using Crosscarmellose sodium (15%) was found better than all other formulations. The optimized batch tablets were packed in ALU-ALU pack and performed stability studies at 40°C/75%RH. There is no change in the physiochemical properties of the tablet during the stability period. Hence the developed dispersible tablet could be found suitable alternate dosage form.

INTRODUCTION

The aim of the research work is to formulation and evaluation of amoxicillin and potassium clavulunate dispersible tablet. The oral route is the most frequently used route for drug administration. Oral dosage forms are usually for systemic effects resulting from drug absorption through the various mucosa of the gastrointestinal tract. The parenteral route of administration is an important in mandatory condition; otherwise it is probable that at least 90% of all drugs used to produce systemic effects are administered by the oral route. The drugs that are administered orally, solid dosage forms represent the preferred class of product. The reasons for this preference are as follows: Tablets and capsules represent unit dosage forms in which one unit dose of the drug has been accurately placed, whereas in liquid oral dosage forms measurements are typically in error when the drug is administered by the patient. Liquid oral dosage forms are much more expensive to ship and breakage or leakage during shipment is a more serious problem than with solid

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oral dosage forms. Liquids are less portable and require much more space. Drugs are in general less stable in liquid form than in a dry state and expiration dates tend to be shorter. Compared with other routes, the advantages of the oral solid dosage forms are as follows: Simplest, Most compliance, Safety.

The disadvantages include relatively slow onset of action as compared to parenterals, difficult to swallow for kids, terminally ill and geriatric patients and destruction of certain drugs by the enzymes and the secretion of the GIT. e.g.: Insulin. The most popular oral dosage forms are tablets, capsules, suspensions, solutions, emulsions. The other dosage forms that are administered orally are powders, granules, syrups and elixirs. Based on the above advantages, the selected antibiotic drug is developed as tablets for oral administration [1, 2]

Fast Dissolving Drug Delivery System emerged from the desire to provide patient with conventional mean of taking their medication. Difficulty in swallowing is a common problem of all age groups, especially elderly and paediatrics, because of physiological changes associated with these groups of patients other categories that experience problems using conventional oral dosage forms includes are the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack or coughing. Sometimes it may be difficult to swallow conventional products due to unavailability of water [3]. These problems led to the development of novel type of solid oral dosage form called "dispersible Tablets". This tablet disintegrates instantaneously when placed on tongue, releasing the drug that dissolves or disperses in the saliva.

The growing importance of mouth dissolving tablet was underlined recently when European Pharmacopoeia adopted the term "Oro dispersible Tablet" as a tablet that to be placed in the mouth where it disperses rapidly before swallowing. The main criteria for mouth disintegrating (dissolving) tablet is to disintegrate or dissolve rapidly in oral cavity with saliva in 15 to 60 seconds, without need of water and should have pleasant mouth feel. Mouth dissolving tablets are also known as fast dissolving tablet; melt in mouth tablet, rapiment, and porous tablet, dispersible tablet. The uses of amoxicillin and clavulanic acid dispersible tablet are used to treat certain infections caused by bacteria including infections of the ears, lungs, sinus, skin, and urinary tract [4-6].

The aim of the study is to formulate and evaluate of amoxicillin and potassium clavulunate dispersible tablets. The formulations of fast dissolving tablet of amoxicillin and potassium clavulunate is prepared using different disintegrants (Sodium Starch Glycolate, Croscarmellose, Crosspovidone, Maize starch) by direct compression technique. The evaluation of powder blend like Angle of Repose, Bulk Density, Tap density, Hausner ratio, Compressibility index is studied. Tablets are evaluated for various physiochemical properties. The drug and excipients compatibility is studied using FTIR spectral studies. The effect of disintegrants on disintegration power and dissolution of amoxicillin and potassium clavulunate is also studied extensively. Accelerated stability studies are to be carried out for the optimized amoxicillin and potassium clavulunate tablet as per ICH guidelines.

MATERIALS AND METHODS

Materials

Amoxicillin and Potassium Clavulunate was a gift sample from DSM Anti Infectives India Ltd. India. Other materials used in the study such as Maize starch (Universal starch chemicals), MCC and Aspartane (Cabot Sanmar Ltd), Croscarmellose sodium (FMC Biopolymer), Sodium starch glycolate (Vasa pharma chem.), Crosspovidone (ISP), magnesium stearate and Aerosil (Amishi Drugs and Chemicals Ltd), Yellow oxide of Iron (Bharat Pharmaceuticals) were purchased.

Methods

FTIR spectrum analysis

The IR absorption spectra of the pure drug and with different excipients were taken in the range of 4000-400 cm-1 using KBR disc method. Triturate 1-2 mg of the substance to be examined with 300-400 mg, specified quantity of finely powered and dried Potassium bromide .These quantities are usually sufficient to give a disc of 10-15mm diameter and spectrum of suitable intensity by a hydraulic press. The Infrared spectrum of Amoxicillin and Potassium Clavulunate was recorded by using FT-IR spectroscopy and observed for characteristic peaks of drug.

Formulation of tablets

Sixteen formulations were prepared by direct compression method using different disintegrants in various ratios of from F1 to F4 using maize starch as disintegrants in the ratios of 5, 10, 12.5 and 15, and F5 to F8 using CCS as disintegrants in the ratios of 5, 10, 12.5 and 15, and F9 to F12 using Crosspovidone as disintegrants in the ratios of 5, 10, 12.5 and 15, and F13 to F16 using sodium starch glycolate as disintegrants in the ratios of 5, 10, 12.5 and 15. All the formulations and composition was shown in Table No 1.

Evaluation of powder blend

Angle of repose

The frictional force in a loose powder can be measured by the angle of repose. Angle of Repose is the maximum angle between the surface of a pile of powder and horizontal plane. It is usually determined by fixed funnel method and is the measure of the flow ability of powder/granules. A funnel with 10 mm inner diameter of stem was fixed at a height of 2 cm over the platform. About 10 gm of sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. A rough circle was drawn around the

pile base and the radius of the powder cone was measured. Angle of repose was calculated from the average radius using the following formula.

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

Where, θ = Angle of repose; h = Height of the pile;
r = Average radius of the powder cone

Bulk Density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. Usually, bulk density is of great importance when none considered the size of a high-dose drug product or homogeneity of a low-dose formulation. Apparent bulk density (g/ml) of all types of drug were determined by pouring preserved (40-mesh) gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. Bulk density was calculated.

$$\text{Bulk density (g/ml)} = \frac{\text{Weight of sample (gm)}}{\text{Volume occupied by the sample (ml)}}$$

The Bulk Characterization is done in Electrolab-Tap Density Tester.

Tapped Density

Tapped densities of all types of granules were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The cylinder was tapped from height of 2 inches until a constant volume was obtained. In USP TAP DENSITY TESTER, tap density is measured in 500 taps, 750 taps & 1250 taps with drop/time-249 .Volume occupied by the sample after tapping were recorded and tapped density was calculated.

$$\text{Tap density (g/ml)} = \frac{\text{Weight of sample (gm)}}{\text{Volume occupied by the sample (ml)}}$$

Experimentally, the true density of a powder is determined by suspending drug particles in solvents of various densities and in which the compound is insoluble. Wetting and penetration may be enhanced by addition of some quantities of surfactant to the solvent mixture. After centrifuging the suspending molecule the exact tap density is determined

Hausner Ratio

It provides an indication of the degree of densification which could result from vibration of the feed hopper.

$$\text{Hausner ratio} = \frac{\text{Bulk density}}{\text{Tapped density}}$$

Lower Hausner ratio − better flowability
Higher Hausner ratio − poor flowability

Manufacturing of tablets

Dispersible tablet of Amoxicillin and Potassium Clavulunate was formulated using direct compression method. Amoxicillin trihydrate was shifted (Electrolab) through≠ 20 mesh. Potassium Clavulunate and disintegrants were passed through ≠40 mesh. Both blends (Kenwood planetary mixer) were mixed. Mixed blend was sifted through sieve no ≠24 mesh. Remaining amount of aspartame, flavor and talc were shifted through ≠40mesh and colour shifted through ≠60 mesh. Magnesium stearate was sifted through ≠ 60mesh and mixed with the powder blend. Blend was compressed to prepare tablets.

Evaluation of tablets

Shape of the Tablets

Randomly picked tablets from each formulation were examined for the shape of the tablets.

Weight Variation

The test ensures that all the tablets in each batch are of same potency, within reasonable limits. Each tablet in the batch should be uniform in weight and weight variation if any, should be generally within ± 10% for tablets weighing 130 mg or less, ± 7.5% for tablets weighing more than 130 mg and up to 324 mg and ± 5% for tablets weighing 325 mg or more. According to the official test, 20 tablets were weighed individually and collectively. Average weight per tablet was calculated from the collective weight. Then the weights of the individual tablets were compared with the average weight to determine weight variation.

Hardness Test

Tablets require a certain amount of strength, or resistance to friability, to withstand the mechanical shocks of handling in manufacture, packaging, and shipping. The strength of the tablet was determined by Dr. Schleuniger pharmaton apparatus. The force of fracture was recorded.

Friability

Friability test was performed to assess the effect of friction and shock which may often cause tablets to chip, cap or break. It generally reflects poor cohesion of tablet ingredients. Weighed tablets sample was placed in the chamber and the friabilator was operated for 100 revolutions at 25 RPM and the tablets were weighed again. Compressed tablets should not lose more than 1% of their weight.

Thickness

Variation in the tablet thickness may cause problems in counting and packaging in addition to weight variation beyond the permissible limits. Tablet thickness should be controlled within a ± 3% of a standard value. Tablet thickness was measured by Vernier calipers.

Disintegration Test

The disintegration time was determined by using USP Tablet disintegration test apparatus using 900 ml of

distilled water without disk. Time taken by tablets (Sec) for complete disintegration of the tablets until no mass remaining in apparatus was measured.

Uniformity of Dispersion Test

The fineness of dispersion test was done by place 2 tablets in 100 ml of water and stir until completely dispersed. A smooth dispersion is produced, which passes through a sieve no. #25.

Wetting Time

The wetting time and capillarity of oral dispersible tablets were measured by a conventional method. Tablet was placed in a petri dish containing 10 ml water at room temperature and the times for complete wetting of tablets were recorded.

Drug Content Uniformity

The drug content was done by chromatographic method.

Chromatographic Conditions

Column : C18, 250mmX4.0m, 5µm.
Detector : UV detector at 220 nm
Manufacturer Name : schimadzu
Flow rate : 2.0 ml/min
Temperature : Ambient
Buffer preparation : Dissolve 7.8 g of Sodium di-hydrogen orthophosphate in 1000 ml of water with a ortho-phosporic acid to a pH 4.4.

Mobile Phase

A mixture of Buffer &Methanol (950:50) was filtered and degassed.

Standard solution

Weigh accurately 50 mg of Amoxicillin Trihydrate Working Standard and 46.0 mg of Diluted Potassium Clavulunate WS in a 100 ml volumetric flask. Add 60 ml water and sonicate to dissolve. Finally make up volume upto 100 ml with water.

Sample Preparation

Weigh and powdered 20 tablets, transfer powder containing 250mg Amoxicillin in 500 ml volumetric flask. Add 400ml of water and sonicate to dissolve. Make up the volume up to the mark with water. Filter the sample solution through 0.45 µm membrane filter paper.

Procedure

Separately inject 20µl of the standard solution in replicate and calculate RSD of standard area (RSD NMT 2.0%), tailing factor NMT 2.0 and the column efficiency is NLT 1500 theoretical plates, Inject Test solution into the chromatogram and record the chromatograph and measure the response for the major peaks and calculate the result by comparison.

***In vitro* drug release studies**

The *In vitro* dissolution of amoxicillin and potassium clavulanate dispersible tablets prepared by direct compression method using Dissolution test apparatus TDT-06T (Electro lab, Mumbai, India) at the USP type II apparatus at 75rpm. The dissolution studies were conducted in 900 ml of water as a dissolution media at 37°C±0.5ºC. Optimized batches amoxicillin and potassium clavulunate dispersible tablet from F1-F16 were suspended in 900 ml of water was withdrawn at 0, 5, 10, 15, 30, 60, 180, 300,600,900 sec with a pipette and filter through 0.45µm what man filter and then analyzed amoxicillin and potassium clavulunate dispersible tablet content was determined in triplicate by (UV/Vis Spectrophotometer, Shimadzu - 1800) spectrophotometrically at 270 and 205 nm respectively. Fresh medium (5 ml) which was pre warmed at 37°C and was replaced immediately into the dissolution medium after each sampling maintain its constant volume throughout the test.

Stability studies

The stability studies were conducted by storing the tablet in a stability chamber at 25±2ºC/60±5% RH and 40±2ºC/75±5% RH. The tablets are wrapped in ALU-ALU pack and its stored for one month. After one month, tablets were analyzed for its physical properties and dissolution profile.

RESULTS AND DISCUSSION

Drug and excipients interaction was checked out by comparing the FTIR spectra of pure drug amoxicillin trihydrate, diluted potassium clavulunate FTIR spectra of the physical mixture of drug and excipients shown in Figure No 01. IR spectra result indicates that no significant difference in characteristic peak at wave numbers of the drug in presence of the excipients. From the results it can be concluded that drug and excipients are compatible.

The result of the characterization of powder blend was shown in Table No 02. Angle of repose ranged from 25.11 to 29.11 and the compressibility index from 12-17. The LBD and TBD of the prepared granules ranged from0.52 to 0.85 and 0.65 to 0.96 respectively. Hausner's ratio was found to be 1.2 or less than 1.2. The results of angle of Repose indicated good flow property of the granules and the value of the compressibility index further showed support for the flow property.

The results of the disintegration test were shown in Table No 03. Disintegration is the most important characteristic test of dispersible tablet, formulation F8 with Croscarmellose Sodium (CCS) 15% shows an excellent disintegration time of 55 seconds when compared with other formulations.

Table 1. Composition of formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16
Amoxicillin Trihydrate	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3	234.3
Diluted Clavulanic acid	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7	75.7
MCC	149	144	141.5	139	149	144	141.5	139	149	144	141.5	139	149	144	141.5	139
Maize starch	5	10	12.5	15	-	-	-	-	-	-	-	-	-	-	-	-
Crosscarmellose sodium	-	-	-	-	5	10	12.5	15	-	-	-	-	-	-	-	-
Crosspovidone	-	-	-	-	-	-	-	-	5	10	12.5	15	-	-	-	-
SSG	-	-	-	-	-	-	-	-	-	-	-	-	5	10	12.5	15
Aerosil	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Aspartame	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Mag. Stearate	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Yellow oxide of Iron	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

Table 2. Characterization of powder blend of all the formulations

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16
Angle of Repose	26.53± 0.22	25.11± 0.25	25.24± 0.24	27.81± 0.12	28.33± 0.20	29.11± 0.27	25.90± 0.32	26.90 ±0.25	25.51± 0.27	25.48± 0.25	25.72± 0.24	26.31± 0.25	26.21± 0.28	26.75± 0.29	25.25± 0.23	25.50± 0.27
Bulk density (gm/ml)	0.725± 0.32	0.750± 0.36	0.825± 0.33	0.850± 0.32	0.605± 0.13	0.610± 0.35	0.725± 0.36	0.813 ±0.33	0.605± 0.38	0.855± 0.33	0.635± 0.38	0.525± 0.36	0.540± 0.32	0.525± 0.34	0.530± 0.36	0.600± 0.37
Tapped density (gm/ml)	0.954± 0.13	0.925± 0.30	0.960± 0.23	0.861± 0.34	0.825± 0.32	0.850± 0.43	0.850± 0.37	0.925 ±0.35	0.800± 0.38	0.954± 0.32	0.835± 0.36	0.714± 0.36	0.680± 0.38	0.650± 0.32	0.700± 0.30	0.725± 0.35
%Carr's index	15.20± 0.23	16.30± 0.32	15.40± 0.33	16.20± 0.35	16.50± 0.36	17.00± 0.38	14.30± 0.35	15.33 ±0.32	15.71± 0.38	13.25± 0.37	12.75± 0.53	12.52± 0.36	15.21± 0.23	16.75± 0.30	15.21± 0.37	15.75± 0.34
Hausner's Ratio	1.115± 0.12	1.033± 0.15	1.166± 0.16	1.012± 0.13	1.163± 0.18	1.193± 0.17	1.172± 0.12	1.137 ±0.16	1.122± 0.15	1.102± 0.18	1.114± 0.15	1.160± 0.18	1.159± 0.10	1.138± 0.12	1.120± 0.18	1.008± 0.16

Table 3. Evaluation of tablets

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16
Avg Weight (Mg)	503±2	502±3	503±2	502±2	502±2	501±3	500±5	500±4	501±3	503±1	502±3	502±2	502±3	504±3	503±2	504±2
Thickness (mm)	3±0.11	3.2±0.12	3.1±0.13	3.0±0.15	3.2±0.17	3.5±0.12	3.6±0.18	3.7±0.16	3.1±0.15	3.8±0.17	3.5±0.15	3.9±0.18	3.6±0.16	3.2±0.12	3.8±0.11	3.3±0.12
Hardness (Kg/Cm^2)	7±0.23	6±0.12	6.4±0.20	5.0±0.22	5±0.12	5±0.25	5±0.20	5±0.28	7.0±0.12	6.4±0.23	6.5±0.25	7.0±0.28	5.4±0.25	6.5±0.28	6.6±0.27	5.4±0.29
Friability (%)	0.80±0.06	0.70±0.04	0.60±0.05	0.80±0.08	0.52±0.07	0.47±0.06	0.48±0.04	0.36±0.02	0.62±0.06	0.70±0.08	0.90±0.06	0.62±0.06	0.65±0.08	0.82±0.06	0.75±0.02	0.64±0.05
Wetting time (sec)	117±1	123±2	106±3	100±1	99±4	93±2	105±5	92±3	89±4	85±2	79±6	73±4	105±6	95±5	90±6	84±5
DT (Sec)	85±0.32	80±0.23	75±0.35	80±0.32	70±0.53	76±0.32	82±0.34	55±0.36	73±0.38	79±0.36	87±0.38	98±0.39	91±0.38	73±0.23	89±0.30	82±0.33
Uniformity dispersion	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Assay of Amox (%)	96.24	96.50	97.25	96.54	98.98	98.53	98.79	99.00	98.21	98.35	98.50	98.72	96.23	96.52	96.70	97.52
Assay of Clav (%)	96.10	96.20	96.00	96.34	98.78	98.32	98.60	98.87	98.00	98.15	98.30	98.52	96.00	96.42	96.50	97.00

Table 4. Stability study report of the optimized formulation

Conditions	Periods (weeks)	Colour	Avg. wt (mg)	Hardness ($Kg/cm^{2)}$	Friability (%)	DT (Sec.)	Thickness (mm)	Assay amox (%)	Assay Clav (%)
$25^0C±2^0C/60±5\%$ RH	0	White	500±5	5±0.5	0.36±0.05	55±5	3±0.1	99.00	98.87
	4	White	499±4	4.5±0.3	0.30±0.5	55±2	3±0.2	97.78	97.00
$40^oC±2^oC/75±5\%$ RH	0	White	500±5	5±0.5	0.36±0.05	55±6	3±0.1	99.00	98.87
	4	white	498±4	4.5±0.4	0.32±0.05	55±4	3±0.3	96.20	96.31

Figure 1. FTIR Spectrum of Amoxicillin Trihydrate, Diluted Potassium Clavulunate and Optimized formulation

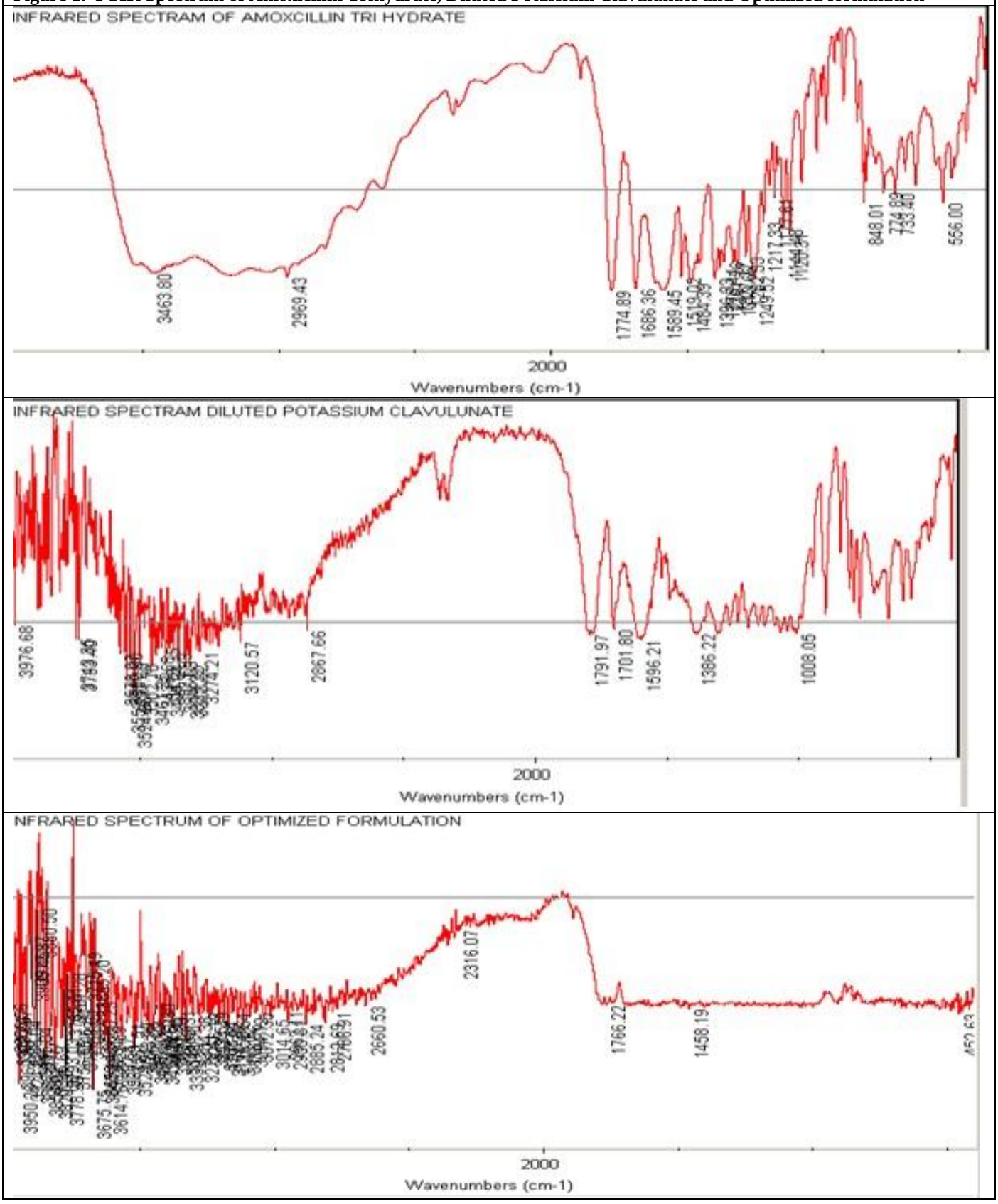


Figure 2. *In vitro* release profile of amoxicillin dehydrate

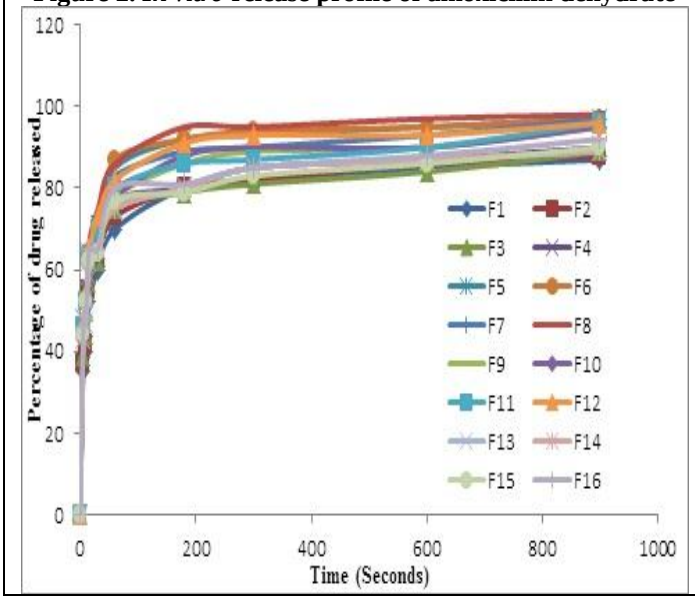
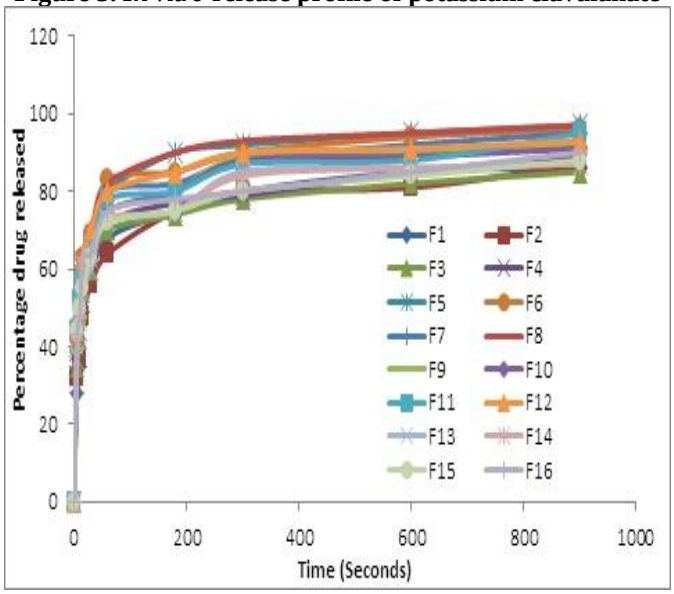


Figure 3. *In vitro* release profile of potassium clavulanate



The results of the evaluation of tablets were shown in Table No 03. The thickness and average weight were found in the range of 3±0.1mm and 502 ±5 mg for all the formulation. In each formulation, weight variation was observed within the I.P limit ±5%. The hardness of different formulations was ranged from 5-7 kg /cm2. All the formulations exhibited less than 1% friability. The results were found to be within the content of uniformity limits (95 to 100.5%). It shows that the drug was uniformly distributed throughout the tablets. The wetting time for all the formulation was found to be between 73 to 123 seconds. All the formulations were passed the dispersibility test.

The results of the *In vitro* dissolution studies were shown in Figure no 02 and 03. *In vitro* dissolution test reveals the release increase from 89% to a maximum of almost 98% for amoxicillin and from 89% to a maximum of almost 97% for potassium clavulunate. The release is in the following order of disintegrantsCroscaramellose sodium >Crosspovidone> Sodium Starch Glycolate> Maize starch. The maximum *In vitro* dissolution was found to be with formulation F8. The formulation with Sodium starch Glycolate 15% shows least *In vitro* dissolution of 89% and the formulation F8 Containing Croscarmellose Sodium were found to be contain maximum *In vitro* dissolution of 98%. It clearly shows that disintegrant (Croscarmellose Sodium 15%) is the best when compared to other disintegrants. The reason may be high porous structure and water wicking mechanism into porous network of tablet hence increases in concentration of Crosscarmellose Sodium accounts for rapid release [7].

The results of the stability studies were shown in Table No 04. The stability of optimized formulation F8 was monitored up to 4 weeks at 40°C ± 2°C and 25°C±2°C temperature. Periodically (Initial and 4 weeks) samples were removed and evaluated by different parameters like Average Weight, Disintegration time (sec), Drug content (%), Hardness (kg/cm2), Friability (%) and Thickness. There were no major changes observed during stability of amoxicillin and potassium clavulunate dispersible tablet ((F8).

CONCLUSION

The amoxicillin and potassium clavulunate dispersible tablets have been developed with direct compression method. The sixteen various compositions of formulations were prepared using Maize Starch, Sodium Starch Glycolate, Crosspovidone, Croscarmellose sodium as a disintegrants. The powder blend were subject to various physical characteristics tests such as bulk density, tapped density, Hausner's ratio, compressibility index and core tablets were evaluated for weight variation, hardness, thickness, disintegration time and the results were found within specification. In-vitro dissolution profile of sixteen formulations was carried out by using four disintegrants like Maize Starch, Sodium starch Glycolate, Crosspovidone and Croscarmellose sodium.

The In-vitro dissolution profile of F8 using Crosscarmellose sodium (15%) was found maximum release when compared to other formulations. The optimized batch tablets were packed in ALU-ALU pack and performed stability studies at 40°C/75% RH. All the results were found to be satisfactory. Sweetening agent i.e Aspartame and flavouring agent i.e strawberry flavour were used to increase palatability of the dispersible tablet. Hence the designed and developed formula of combination of amoxicillin and potassium clavulunate dispersible tablets could be used as alternate dosage form.

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