ISSN (Online) : 2454-4159
International Journal of Advanced Research in Science Management and Technology
Volume 2, Issue 7, July 2016

A Research on "Formulation & Evaluation of Mouth Dissolving Tablet of Azithryomycine"

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ABSTRACT- Aftereffect of disintegration time showed that detailing (F9) was the most encouraging definition as the disintegration time and all the physical parameters from this plan were as indicated by particular. A comparative gradation testing was performed between controlled tablets (F11), unflavored tablet (F10) and optimized flavored tablets (F9) and discovered bitterless definition F9 and F10. In-vitro drug discharge study was performed with optimized detailing (F9) in pH 1.2 cushion arrangement which gave 90% medication discharge in 15 min. and 100% in 20min.and contrast and the controlled tablets (F11) which gave 100% discharge in 15 min. in same medium.

KEYWORDS **-** disintegration, comparative gradation testing, tablets (F11), unflavored tablet (F10) and optimized flavored tablets (F9).

I. INTRODUCTION

Tablets and hard gelatine cases constitute a noteworthy segment of the medication conveyance frameworks that are as of now accessible. In any case, numerous patient gatherings, for example, elderly, youngsters, and patients rationally retarted, uncooperative, disgusted, or on diminished fluid admission diets experience issues in gulping these measurement shapes. Numerous elderly persons face challenges in managing customary oral dose shapes in view of hand tremors and dysphasia. Gulping issue is basic in kids as a result of their immature strong and sensory systems. Now and again like movement infection, sudden scenes of unfavorably susceptible assault or hacking, and amid inaccessibility of water, gulping ordinary tablets is troublesome. To satisfy these medicinal needs, formulators have given extensive endeavors for building up a novel kind of dose structure for oral organization known as mouth dissolving tablets (MDT).

MOUTH DISSOLVING TABLET

This is a creative tablet innovation where the measurement structure containing dynamic pharmaceutical fixings breaks down quickly, normally in a matter of seconds, without the requirement for water, giving ideal accommodation to the patient. Trailblazers and innovator organizations have given these tablets different names, for example, orally deteriorating tablets (ODT), mouth dissolving (MD), quick softening, quick dissolving or Orodisperse.

The European Pharmacopeia characterizes Orodisperse as a tablet that can be set in the mouth where it scatters quickly before gulping. Specialists have defined ODT for different classes of medications, which are utilized for treatment as a part of which fast crest plasma focus is required to accomplish craved pharmacological reaction. These incorporate neuroleptics, cardiovascular specialists, analgesics, hostile to hypersensitive and drugs for erectile brokenness.

II. LITERATURE REVIEW

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International Journal of Advanced Research in Science Management and Technology
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Ishikava T.et al(1999) [34] attempt had been made to prepare,using taste masked granules, tablets which can rapidly disintegrate in saliva of drugs with bitter taste. The taste masked granules were prepared using aminoalkul methacrylate copolymers by the extrusion method. None of the drugs dissolved from the granules even at 480min at pH 1.2 in the dissolution test. Howevr the drugs rapidly in the medium at ph 1.2 in the dissolution test. Rapidly disintegrating tablets were prepared using the prepared taste-masked granules, and a mixture of excipients consisting of crystalline cellulose and low substituted hydroxypropyl cellulose. The granules and excipients were mixed well with 1% magnesium stearate, and subsequently compressed at 500-1500 kgf in a single punch tableting machine.

Shriwaiker A.A.et al (2004) [35] Formulated fast disintegrating tablets of Atenolol using three superdisintegrants, Ac-di-sol, Ccrospovidone and Explotab and were evaluated for physical characteristic, in vitro release characteristics, moisture uptake and stability profile. Ac-di-sol proved to be the best among the three and show satisfactory results with 3kg/cm2 hardness and the formulation were found to be stable in release profile.

Terashita K.et al (2002) [36] Tablets were formulated by direct compression method using Acataminophen and was evaluated for their physical properties. It was found that tablets produced by wet granulation and tableting method. Also it show that use of dry type of binder would make posssible to provide a tablet having higher content of medicine with excellent physical properties.

Reddy L. H. et al (1997) [37] reviewed fast dissolving drug delivery system that can be prepared by various technique like direct compression, wet granulation, freeze drying, molding and volatilization. Fast dissolving tablets were prepared using high amount of hydrophilic disintegrating agents, which allows the tablets form to disintegrate quickly in patient's mouth on contact with saliva.

Dandagi P.M. et al (2005) [38] had prepared taste masked ofloxacin mouth disintegrating tablets by addition of sweeteners like aspartame and superdisintegrating like sodium starch glycolate and by mass extrusion technique using taste masking agent like Eudragit E 100 and diluents like micro crystalline cellulose. The tablets were also evaluated for special parameters like wetting time, in-vivo disintegration, mouth feel, in-vitro dispersion time, In-vitro dispersion, In-vitro dissolution study and stability study.

Mishra D.N.et al (2005) [39] attempt had been made to prepare fast disintegrating tablets of veldecoxib using various superdisintegrating following direct compression technique. The tablets were evaluated for hardness, friability, weight variation, disintegrating time & in-vitro dissolution studies. All the formulation showed disintegrating time & in-vitro dissolution studies. All the formulation showed disintegration time of less than 60 sec.

Shishu et al.(2007) [40] formulated rapidly disintegrating tablets of taste masked clhoropheniramine maleate by direct compression method using SSG as super disintegrant. The taste masked granules were preapared using aminoalky1 methacrylate copolymers by the extrusion method. In-vitro release profile obtained at pH 6.8 indicate the perceivable amount of grug will not be released in saliva while high percent release would be obtained at acidic pH1.2 of the stomach. Tablets were evaluated for hardness, friability, wetting time, water absorption ratio, in-vivo disintegration time and in-vitro disintegration time. Taste evaluation performed by both panel testing & spectroscopic method.

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Simone S.et al. (2002) [41] formulated fast dispersible tablets disintegrate either in water, to form a stabilized suspension, of disperse instantaneously in the mouth to be swallowed without the aid of water. A direct compression method was used to prepare these two type of tablets containing coated ibuprofen as a high dosed model drug. The properties of the water dispersible tablet, such as porosity, hardness, disintegration time and increase in viscosity after dispersion, were investigated. Tablets containing 26% glactomannan and 5% crospovidone, disintegrates before the galactomannan start of 95 N. Orodisperisible a short wetting time of 17 sec. and sufficient crushing strength of 40 N.

Avari J. G. et al.(2004) [42] carried out the taste masking of bitter drugs sparfloxacin using cation exchanga resin. The resinate were evaluated for particle size, bulk density, angle of repose and taste. It was found that the rate of dissolution was improved as compared to conventional tablets.

Nol Z. et al. Us Patent No.6605301 (2006) [43] The invention relates to diepersible tablets containing macrolides as active ingridients either on their own or associated with other active ingredients, in addition to a method for the production thereof. The dispersible tablets are charecterised in that the macrolide is chosen from a group that made up of pristinamycin, azithromycin and is present in a basic form in proportion ranging from 20-60% of the total weight of said tablets.

Malke S.et al (2007) [44] Formulated fast dissolving tablets of oxcarbazepin containing pH 102 a diluent and Ac-di-sol as a superdisintegrant by wet granulation process. All the formulations were evaluated for characteristics such as hardness, friability, weight variation, wetting ability, disintegration time and dissolution rate. An effective, pleasant testing and stable formulation containing 12% Ac-di sol and 25% Avicel pH 102 and 8.5% starch as a binder was found to have a good hardness of 4-4.5 kg/cm^{3,} disintegration time of 28 sec. and drug release of NLT 90% within 30 min.

III. PROBLEM DEFINITION

The issue of severe and repulsive taste of medications in pediatric and geriatric definition is a test to the drug specialist in the present situation. On account of mouth dissolving/crumbling tablets the issue of sharp taste of the medication is regularly experience, because of disintegration of the dynamic fixings in the mouth. Notwithstanding it is important to research taste concealing strategy before arrangement of quickly breaking down or mouth dissolving tablets of medications with biting taste.

The strategy utilized here for taste concealing is mass expulsion method utilizing Eudragit 100.Eudragit 100 is insoluble in pH 7.4 or at an impartial pH however solvent in acidic pH. Covering with Eudragit 100 decreases the dissolvability of medication in the spit and veil the severe taste of the medication. When taste conceal granules comes to in the stomach it quickly realese the medication in the stomach, henceforth the bioavailability of the medication is not influenced.

In the present work Azithromycin dihydrate is macrolide anti-infection. It is broadly utilized as a part of the treatment of upper and lower respiratory tract disease, anticipation of scattered Mycobacterium avium complex (MAC) contamination in patients with cutting edge human immunodeficiency infection (HIV) contaminations &uncomplicated skin and skin structure diseases like Folliculitis, Cellutis, and Erysipelas. Despite the fact that it is regularly utilized however the significant issue is its sharpness.

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Oral organization constitutes the favored course to administer Azithromycin dihydrate. Because of the decrease in the gulping capacity with age, elderly patients whine that it is troublesome for them to take some right now utilized measurements shape, for example, tablets and cases. Therefore the tablets that can quickly broke down in the mouth or in the oral cavity were created. Rather than crumbling in water (Dispersible tablet), mouth dissolving/breaking down tablet deteriorate in the oral cavity without drinking water. The crumbled mass can slide down easily in the throat with the assistance of spit. So even individuals who have gulping or biting challenges can bring it easily. In addition these tablets have adequate mechanical trustworthiness to ready to withstand handling without breakage. In the present work, taste kasking of Azithromycin dihydrate was completed by utilizing Eudragit E 100 (mass expulsion technique). These taste conceal granules complex was further defined into the mouth breaking down tablet by direct pressure technique utilizing Crospovidone, Sodium starch glycolate &Ac-di-sol as a superdisintegrant.When it interacts with salivation or gastrointestinal liquid, creating quick disintegration without the development of knots. It additionally gives essential hardness and concoction steadiness to the tablet.

The literature survey revealed that no work has been reported for taste masking of Azithromycin dihydrate using Eudragit E 100.

Therefore the objective of present work was

1) To prepare Drug:Eudragit E 100 taste masked granules.

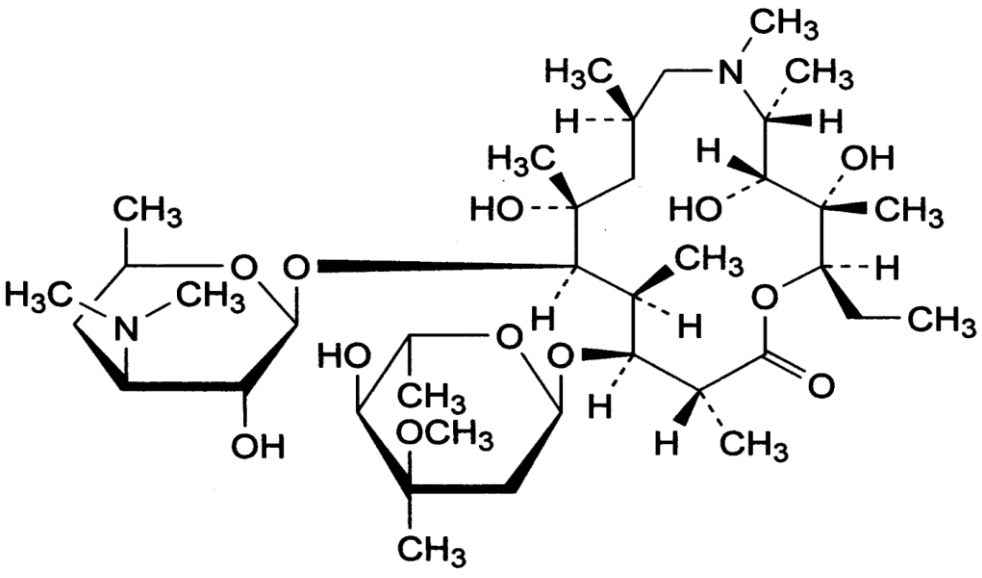
2) To evaluate the Drug:Eudragit E 100 granules for taste masking of Azithromycin dihydrate.

3) To formulate the taste masked granules into mouth disintegrating tablets by direct compression method using various superdisintegrants.

IV. DRUG PROFILE

(A) AZITHROMYCIN DIHYDRATE: [112,113,114,115,116]

Structure:



.2H$_2$O

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(2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl-□-L-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-□-D-*xylo*-hexopyranosyl]oxy]-1-oxa-6- azacyclopentadecan-15-one.

Empirical formula: $C_{38}H_{72}N_2O_{12} \cdot 2H_2O$

Molecular Weight: 785.0

Melting Point: 113-115^{O}C

Description: White or almost white powder.

Category: Antibacterial

Storage: Store in a cool, dry place.

Solubility: It is practically insoluble in water, freely in anhydrous ethanol, and in methylene chloride**.**

(B) EUDRAGIT E 100 [117]

Nonpropritory name

USP: Ammonio methacrylate copolymer; Methacrylic acid copolymer

Synonym: Eastacryl 30D; Eudragit;Kollicoat MAE 30 DP; polymeric methacrylates

Description: It is a cationic polymer based on dimethylaminoethylmethacrylate and other neutral methacrylic acid esters. It is soluble in gastric fluid as well as weakly acidic buffer solution (pH 5). Solvent free granules contain ≥98%dried weight content of Eudragit E. It is used as a film coating material. Here it is used to mask the bitter taste of drug by dispersion coating.

Chemical name: Poly [butyl methacrylate, (2-dimethyl amino ethyl) methacrylate, methyl methacrylate] 1:2:1

Molecular weight: 100000

Functional category: Film former; tablet binder; tablet diluents.

Alkali value: 162-198

Bulk density: 0.390 g/cm^3

Tapped density: 0.424g/cm^3

Solubility: It is soluble/ in Acetone, Alcohol, Dichloromethane, and Ethyl acetate.

Application: Polymethacrylates are primarily used in oral capsule and tablet formulations as a film coating agents.

V. METHODOLOGY

PREPARATION OF DRUG EUDRAGIT E 100 TASTE MASKED GRANULES

1) Method of Preparation.

Taste masked Eudragit E 100 were prepared by using following methods.

A) Mass Extrusion Technique:

Fixed ratio of drug was mixed with different ratio of powdered Eudragit E-100 i.e. they were mixed at 1:1, 1:2, 1:3, 1:4, and 1:5, ratios with the help of mortar and pestle. Then 10% ethanol was added to the mixture of each ratio of drug and Eudragit E-100 in a beaker. Then gel containing the mixture of the drug and Eudragit E 100 was prepared, using this prepared gel the taste-masked granules were prepared by the extrusion method. The prepared gel was manually extruded (pressed out) using a syringe. After extrusion of the gel, ethanol was removed by evaporation overnight and subsequently the solidified gel in the shape of string was crushed into granules using a mortar. A schematic illustration of the method for the preparation of the taste-masked granules is shown in following fig.no.4.

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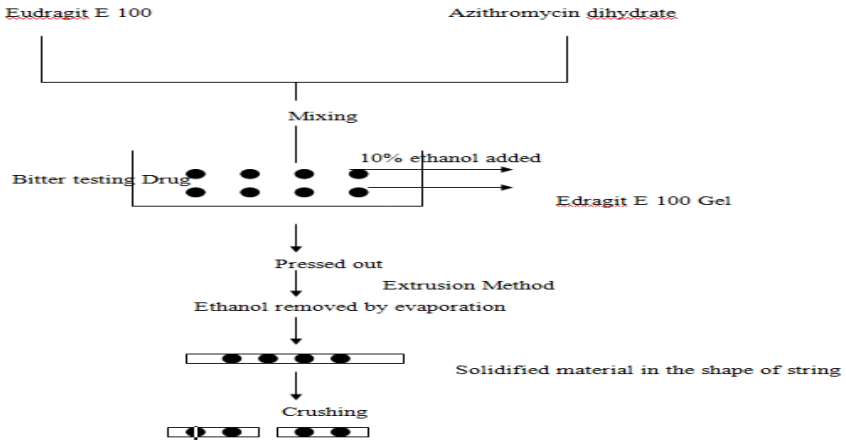

Fig 1: Schematic illustration of preparation of taste masked granules

Formulation Of Mouth Disintegrating Tablet Of Drug: Eudragit E 100 Granules By Disintegrating Additoin Method

1) Formulation

Mouth disintigrating tablets of taste masked Azitrhomycin dihydrate, containing drug:Eudragit E 100 granules (1:5), were prepared using direct compression method after incorporating superdisintegrants such as Crospovidone, Sodium starch glycolate, and Croscarmellose sodium (Ac-Di-Sol) in different concentration. Nine formulations of mouth disintegrating tablets of taste masked Azithromycin were prepared and each formulation contained one of the three disintegrants in different concentration. Unflavored tablets of optimized batch and controlled tablets of pure drug were also prepared for the comparative study. The methods of preparation, amount of Drug:Eudragit E 100 granules equivalent to drug, and other tableting excipients were kept constant to avoid influence of these on the results.

Mouth disintegrating tablets of taste masked Azithromycin dihydrate containing 651.45mg DPC equivalent to 100mg of Azithromycin were prepared by using Avicel pH 102, as directly compressible diluent; Crospovidone, Sodium starch glycolate, Ac-Di-Sol, were tried as superdisintegrants.

DPC and Avicel pH 102 were mixed thoroughly in a glass mortar using a pestle. Superdisintegrants were incorporated in the powder mixture; Aspartame (sweetening agent), Flavor (Mixed fruit flavor), was added to enhance the palatability of tablets & finally magnesium stearate and Talc were added as lubricant. The mixture was weighed (740mg), die cavity of tablet machine set for 740mg, and then mixed blend was compress with 12.4mm flat punch using a Cad mach single punch tablet machine. By keeping weight of the tablet constant all the batches were prepare by direct compression method using single punch tablet machine at a fixed compression force. In the given formulations Avicel PH 102 was used as a directly compressible diluents due to its high swelling index facilitates the rapid disintegration. Aspartame was selected as sweetening agent due to its intense sweetness. So it requires in a very small quantity and it does possess bitter after taste. Flavors are added to enhance the palatability of the preparation. Crospovidone, Sodium Starch glycolate, Ac-di-sol were used, as a super disintegrants due its high swelling index and it requires in very small quantity for rapid disintegration of tablets.

Controlled tablets of Azithromycin Dihydrate were formulated by direct compression method by mixing drug, Avicel PH 102 and mannitol in glass mortar using pestle. Super disintegrants Ac-di-sol (1.5%) and other excipients were added in same concentration as in flavored tablets.

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Preparation of In-vitro Dissolution Fluid:

Phosphate buffer pH 1.2:

a) 0.2M Hydrochloric acid solution: Place 4.25 ml of concentrated hydrochloric acid in 1000 ml. volumetric flask and dilute with water to 1000 ml.

b) 0.2M Potasssium chloride solution: Dissolve 14.911 gm of potassium chloride in water and dilute with water to 1000 ml. Place 50 ml 0.2M Potassium chloride solution in 200 ml volumetric flask add 85 ml 0.2M hydrochloric acid solution then add purified water to volume.

EVALUATION STUDY:

1) Selection of Drug Eudragit E 100 Ratio:

Five batches were prepared containing drug Eudragit E 100 in the ratio of 1:1, 1:2, 1:3, 1:4, and 1:5, in ethanol by the above-mentioned method. After taking the taste of the granules in the different ratio's 1:5 was finalized for further study.

2) Evaluation of Taste of Drug: Eudragit E 100 Granules:

A) Gradation Method: The test of drug Eudragit E 100 granules was checked by panel method. For this purpose, 10 human volunteers were selected. The sample equivalent to normal dose was placed on tongue of volunteers and taste was evaluated after 10 sec. taking the taste of pure drug as standard, the degree of bitterness of drug Eudragit E 100 granules was judged in the scale as given below.

3 – Very bitter

2 – Bitter

1 – Slightly bitter

0 – normal (tasteless)

These volunteers were instructed not to swallow the granules, which were placed on the tongue. They were instructed to thoroughly gargle their mouth with distilled water after the completion of test.

V. RESULT AND DISCUSSION

Formulations chart

Ingradient	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
DPC	651.4	651.4	651.4	651.4	651.4	651.4	651.45	651.4	651.4	651.45	-
Azithromy	-	-	-	-	-	-	-	-	-	-	104.
Avicel 102	55.6	51.9	48.2	55.6	51.9	48.2	55.6	51.9	48.2	50.01	263.
Crospovid	3.7	7.4	11.10	-	-	-	-	-	-	-	-
Sodium	-	-	-	3.7	7.4	11.10	-	-	-	-	-
Ac-Di-Sol	-	-	-	-	-	-	3.7	7.4	11.10	11.10	11.1
Aspartam	15	15	15	15	15	15	15	15	15	15	15
Mannitol	-	-	-	-	-	-	-	-	-	-	331.
Magnesiu	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3	3.7	3.7	3.7
Talc	5.55	5.55	5.55	5.55	5.55	5.55	5.55	5.55	5.55	5.55	5.55
Mixed	5	5	5	5	5	5	5	5	5	-	5

***All quantities are in mg and total weight of tablets is 740mg**

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Evaluation of Taste of Drug-Eudragit E 100 Granules (1:5)

Volunteers	1	2	3	4	5	6	7	8	9	10
Pure Drug	3	3	3	3	3	3	3	3	3	3
Granules	0	0	1	0	0	1	0	0	0	1

3-Very bitter, 2-Bitter,1-slightly bitter, 0-Normal (tasteless)

Evaluation of Taste of flavored, Unflavored MD Tablets and Controlled Tablets

Volunteers	1	2	3	4	5	6	7	8	9	10
Controlled pure drug Tablets(F11)	3	3	3	3	3	3	3	3	3	3
Flavored MD tablets(F9)	0	0	1	0	0	1	0	0	0	1
Unflavored MD tablets (F10)	0	1	0	0	1	0	0	0	0	1

3-Very bitter, 2-Bitter,1-slightly bitter, 0-Normal (tasteless)

Physical Parameters of Tablets of Each Batch

Batch No.	**Weight Variation (Mg)***	**Thickness**	**Hardness Kg/ cm^2**	**Friability (%)**	**Drug Content (%)**
F1	737.33±3.92	5.02±0.032	4.55±0.158	0.58	98.21
F2	736.83±4.07	5.02±0.036	4.80±0.286	0.64	99.53
F3	740.16±3.54	5.02±0.045	4.80±0.249	0.65	98.65
F4	738.83±3.92	5.04±0.034	4.82±0.281	0.63	98.73
F5	740.16±4.99	5.04±0.037	4.77±0.244	0.63	98.34
F6	738.16±4.83	5.05±0.028	4.67±0.159	0.69	97.85
F7	738.83±2.48	5.03±0.033	4.82±0.319	0.61	99.23
F8	740.00±4.33	5.03±0.033	4.80±0.255	0.62	98.79
F9	739.83±1.32	5.03±0.048	4.81±0.282	0.65	98.35
F10	739.50±2.07	5.03±0.028	4.88±0.339	0.64	98.72
F11	739.83±1.32	3.71±0.010	6.65±0.388	0.26	97.84

***Each value represents the mean ± standard deviation (n=6)**

Evaluation of mouth disintegrating tablet of drug Eudragit E 100 granules

Batch no.	**Water absorption ratio**	**In-vitro disintegration time (sec.)**	**Mouth feel (sec.)**
F1	86.67±0.140	38.66±0.57	-
F2	85.59±0.158	35.66±0.57	-
F3	85.82±0.173	31.33±1.52	-
F4	86.44±0.101	33.66±1.52	-
F5	85.59±0.168	30.33±0.57	-
F6	86.53±0.110	28.33±1.52	-
F7	87.59±0.285	27.33±1.52	-
F8	88.10±0.285	24.66±1.52	-
F9	89.13±0.191	16.33±1.52	-
F10	89.66±0.164	16.33±1.52	-
F11	47.06±0.424	85.66±2.08	++

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*Each value represents the mean ± standard deviation (n=3)

In-vitro Dissolution Profile of Formulation F9 (pH 1.2)

Time (min.)	Sample Peak Area	%Drug release
5	1549522	77.14
10	1712604	84.32
15	1885962	91.81
20	2015317	96.99

In-vitro dissolution profile of Formulation F11 (pH 1.2)

Time (min.)	Sample Peak Area	%Drug release
5	1686943	83.99
10	1897541	93.42
15	2010287	97.86

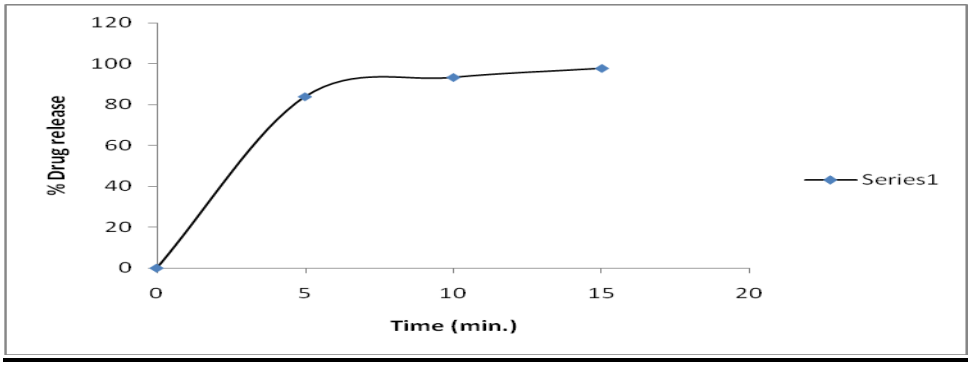

Fig. 4 In-vitro Dissolution Profile of formulation F11 in pH 1.2

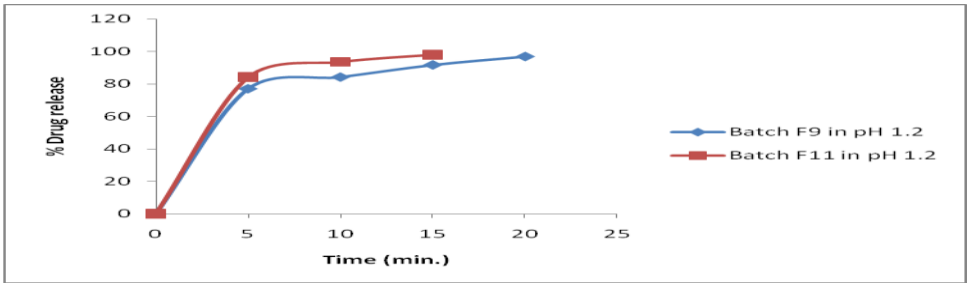

Fig. 5 Compararive In-vitro Dissolution profile of Formulation F9 & F11

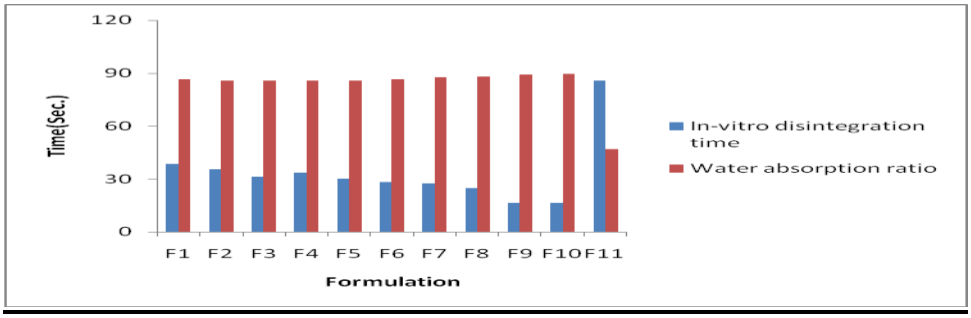

Fig. 6 BAR Graph Comparison of Disintegration with Rank Order F9<F10<F8<F7<F6<F5<F4<F3<F2<F1<F11

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VI. CONCLUSION

The present study was embraced with an intend to detail advancement and assess taste veiled Azithromycin mouth breaking down tablets utilizing distinctive dinner deteriorating specialists. Reformulation study was done at first and results coordinated for the further course of plan. Taking into account reformulation considers diverse bunches of taste covered Azithromycin were readied utilizing chose excipients.

Taste making of Azitrhomycin was performed by mass expulsion procedures utilizing Eudragit E 100 polymer. The Drug Eudragit E 100 complex (DPC) proportion 1:5 was chosen by taste assessment. The DPC was assessed for its bitterless qualities by gradation strategy. Different details of mouth crumbling tablets of taste veiled Azithromycin were created by utilizing different disintegrants viz, Crospovidone, Sodium starch glycolate, Ac-di-sol in various extent by direct pressure strategy. The tablets were assessed for physical portrayal, Mouth feel, Water ingestion proportion, in-vitro disintegration time.

Perception of all detailing for physical portrayal had demonstrated that, every one of them follows the particular of authority pharmacopeias and standard reference. Result of disintegration time showed that definition (F9) was the most encouraging plan as the disintegration time and all the physical parameters from this detailing were as indicated by determination. A comparative gradation testing was performed between controlled tablets (F11), unflavored tablet (F10) and optimized flavored tablets (F9) and discovered bitterless definition F9 and F10. In-vitro drug discharge study was performed with optimized definition (F9) in pH 1.2 support arrangement which gave 90% medication discharge in 15 min. and 100% in 20min.and contrast and the controlled tablets (F11) which gave 100% discharge in 15 min. in same medium.

From the above results it presumed that definition of mouth deteriorating tablets of taste conceal Azithromycin containing superdisintegrant Ac-di-sol (1.5%) i.e. F9 can be taken as an a perfect plan.

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