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PHARMACEUTICAL FORMULATION AND IN-VITRO EVALUATION OF CEPHALOSPORIN –BASED CHEWABLE TABLETS

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ABSTRACT
Antimicrobial agents are among the most commonly used drugs, and are often misused. The in evitable consequence of the widespread use of antimicrobial agents has been the emergence of antibiotic- resistant pathogens and the ever-increasing need for new drugs. Antibiotics are substances produced by various species of microorganisms (bacteria, fungi, and actinomycetes) that suppress the growth of other microorganisms. Some factors alter the action of antibiotics, such as pharmacokinetic factors and route of administration. For therapy to be effective, the drug must reach a level that stops or kills bacteria at the infection site without hurting the patient. To achieve this, we need to consider how the drug moves in the body and other factors related to the patient. Ceftazidime is a 3rd generation broad spectrum β- Lactam cephalosporin class of antibiotic administered orally in pediatric and adult patients.To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ceftazidime and other antibacterial drugs.

KEYWORDS: Cephalosporin, Chewable tablets, Formulation, In-vitro evaluation, Pediatric formulation, Oral antibiotics, Dispersible tablets.

INTRODUCTION

Cephalosporins are a class of β-lactam antibiotics widely used to treat a variety of bacterial infections. While effective, many cephalosporins exhibit poor oral bioavailability due to factors like low solubility and instability in the gastrointestinal, Offers a promising approach to enhance patient compliance, especially among pediatric and geriatric populations.

Chewable tablets are designed to disintegrate quickly in the mouth, facilitating rapid drug Release and absorption. This formulation can be particularly advantageous for patients who have difficulty swallowing traditional tablets or capsules. Moreover, chewable tablets can be formulated to mask the often unpleasant taste of cephalosporins, improving patient adherence to treatment regimens.

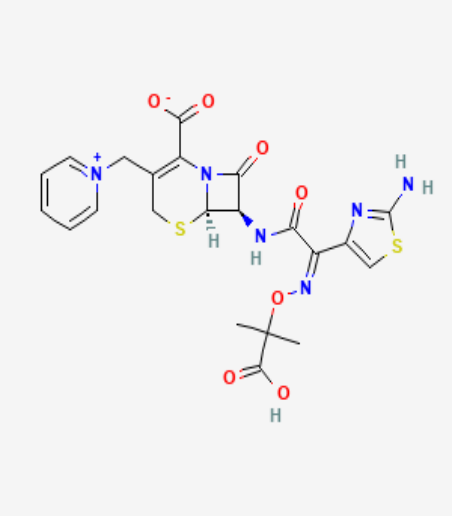
The development of cephalosporin-based chewable tablets involves addressing several key challenges.

- **Taste Masking**: Employing sweetener sand flavoring agents to mask the bitter taste of cephalosporins.
- **Stability**: Ensuring the chemical stability of the antibiotic in the chewable matrix to maintain therapeutic efficacy.
- **Release Profile**: Designing the tablet to release the active ingredient at an appropriate rate to achieve optimal therapeutic levels.
- **Patient Acceptability**: Formulating the tablet to be palatable and easy to chew, thereby enhancing patient compliance.

In vitro evaluation of these formulations typically includes a assessing parameters such as disintegration time, dissolution rate, and stability under various environmental conditions. These evaluations are crucial to ensure that the chewable tablets meet the required pharmacological standards and provide effective treatment outcomes.

Ceftazidime is an orally administered, extended spectrum, semi-synthetic antibiotic of the cephalosporin class.

Category Antibacterial Sub Category: Antibiotic



PHARMACOKINETICS Bioavailability: 50% Protein binding: Approximately 60% Routes of **administration:** Oral Excretion: Renal (unchange) about 50% Mean Elimination.

Half-life: 3 to 4hours
Dosage (Adults):100-400mg

Dosages forms: Chewable tablets

Determination of absorption maxima (λmax) for analysis: For scanning the λmax of drug, standard solution was prepared. about 20 mg of pure drug was weighed and transferred to a 20 ml volumetric flask.10 ml of methanol was added and sonicated to dissolve and made up to mark with methanol. Further diluted 1 ml of resulting solution to 50 ml with methanol, mixed well and filtered through 0.45 Nylon filter. Standard solution was UV scanned between 200-400 nm and absorption maximum was determined spectrophotometrically. Methanol solvent was used as blank

Water by KF(%w/w) and Assay Equipment: Karl Fischer Apparatus, Analytical Balance. Chemicals& reagents: Karl Fischer Reagent, Anhydrous methanol, Purified water.

Procedure: 500 mg of sample was taken and sufficient amount of anhydrous methanol added to the titration vessel and titrated to the electrometric end point with KF reagent. Quickly added 0.5g of test samples mixed and again titrated to the electromeric end point with KF reagent.

Tapped Density: Weighed quantity of drug was taken and transferred in graduated cylinder. The cylinder containing the sample was mechanically tapped by raising the cylinder and allowing it to drop under its own weight using mechanically tapped density tester that provides affixed drop of 14±2 mm at a nominal rate of 300 drops per minute. Cylinder was tapped for 500 times initially and tapped volume (V1) was measured to the nearest graduated units, repeated tapping of additional 750 times was done and tapped volume (V2) was measured. Additional Repeated tapping was performed if the difference between the two successive volumes was less than 2%.

Solubility Analysis

Descriptive term	Part of the solvent required per part of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Practically insoluble	10,000 and over

METHODOLOGY

Preparation by Direct Compression

*All the ingredients were accurately weighed as per formula and dispensed in clean butter paper.
*API, Mannitol, Crospovidone, Hydroxypropyle cellulose Aspartame, Tuttyfruity flavor, FDC red, were sifted through sieve no.30 and dispensed in polybag I.
*Materials of Polybag I was put it in conta blender and mixed for 10 minutes at 8 rpm.
*Magnesium stearate passed through sieve no.40 and added to above blend in blender and mixed for additional 5 minutes.
*Mixture from blender was collected and compression was performed through Tablet Compression Machine.

Test	Results	
	API (d0.9-250.60µm)	API (d0.5-150.50µm)
Bulk density	0.174	0.1695
Tapped Density	0.275	0.2710
Compressibility index	36.72	37.45
Hausner Ratio	1.5804	1.598

RESULT

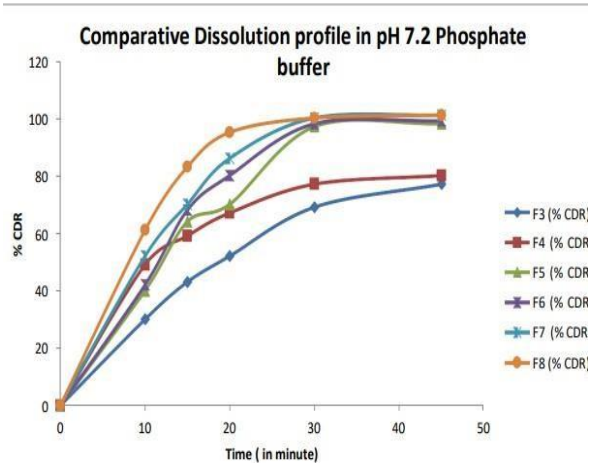
Assay potency or Quantity of API per tablet

(For API having 90=11.3µm)= $Label\ ClaimX\ 100X100$ $\%Assayofdrugx(100-\%Waterby\ KF)$
$Quantity\ of API per\ tablet\ (mg)$=
$200X100X100/100.1X(100-10.8)$ =223.99 mg

Flowp roperties determination of API

S.NO.	INGREDIENTS	(Direct Compression) F1	Direct Compression) F2
1	Ceftazidime	227.5mg	227.52mg
2	Pearlitol(500 DC)	510.48mg	500.48mg
3	Crosspovidone(XL10	70mg	70mg
4	Aspartame	15mg	15mg
5	HPCLH21	---	10 mg
6	Aerosil	30 mg	30 mg
7	StrawberryFlavor	10 mg	10 mg
8	FDC red No40 aluminium lake	1 mg	1 mg
9	Magnesiumsterat	6 m	6 mg
Totalweightoftablet		**870 mg**	**870 mg**

Comparative dissolution profile of various formulations with Innovator in pH 7.5 phosphate buffer medium



CONCLUSION

The aim was to develop a stable chewable tablet of cephalosporins whose in-vitro dissolution profile is similar or to the nearby with that of marketed dosage form, so that a dosage form having same therapeutic efficacy at a low cost can be available in the market. As Drug X has poor dissolution property. Therefore dissolution was improved by using micronised API, binder, disintegrant in the formulation. Preformulation study was performed. In-vitro parameters of formulations were evaluated. As according to USFDA guideline, similarity factor (f2) value should be between50-100inofficialmedium.Therefore Formulation F8 was selected as best formulation as its dissolution profile was found to be similar (On basis of similarity factor f2 value 66) with that of Innovator in official medium (pH 7.2 phosphate buffer medium). Tablets dissolution was performed. Dissolution profile of F8 tablets also was found to be similar with that of innovator. It was optimized and Scale up (F9). Dissolution profile of F9 tablets was also found to be similar in pH 7.2 phosphate buffer medium (Similarity factor f2 value 63). Stability studies of final batch F9 (after packing) were performed and the product was found stable. Thus objective of Formulation, development and evaluation of a stable and bioequivalent chewable tablet was attained.

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