Summer Training at
Abbott Health Care Pvt. Ltd.
(20th April 2012-15th June 2012)

Doctor's Preference of Brands of Clavulanic Acid Combinations in Oral Therapy

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Under the Guidance of
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This is to certify that **Mr. Saurabh Sharma**, pursuing **M.B.A.** from **Institute of Health Management Research** has successfully completed his Summer Training from ***Abbott Healthcare Pvt. Ltd.***

His Summer Training project was focused on "To Study the Doctor's preference of brands of Clavulanic acid combinations in Oral therapy" **under the guidance of Mr. Abhishek Dhadich.**

The period of his summer training was from **April 20th, 2012 to June l0th,2012.**

The work was a part of an on-going project and was confidential in nature and cannot be shared with the institute.

Warm Regards,

For Abbott Healthcare Pvt.Ltd, Mumbai

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Chapter-1
THE INDIAN PHARMACEUTICAL INDUSTRY OVERVIEW

The Indian Pharmaceutical Industry currently tops the chart amongst India's science based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian pharmaceutical industry is estimated to be worth $4.5 billion, growing at about 8 to 9 percent annually. It ranks very high amongst all the third world countries, in terms of technology, quality and the vast range of medicines that are manufactured. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made in Indian Pharmaceutical Industry.

The Indian pharmaceutical sector is highly fragmented with more than 20,000 units. It has expanded drastically in the last two decades. The Pharmaceutical and Chemical Industry in India is an extremely fragmented market with severe price competition and government price control. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. Thera are approximately 250 large units and about 8000 small scale units, which form the core of the pharmaceutical in industry in India (including 5 public sector units).

Current scenario

India's pharmaceutical market grew at 15.7 percent during December 2011. Globally, India ranks third in terms of manufacturing pharma products by volume. The Indian pharmaceutical industry is expected to grow at a rate of 9.9% till 2010 and after that 9.5% till 2015. The Indian pharmaceutical market is expected to touch US$74 billion sales by 2020 from US$11 billion. The market has the further potential to reach US$70 billion by 2020 in an aggressive growth scenario.

Moreover, the increasing population of the higher-income group in the country will open a potential US$8 billion market for multinational companies selling costly drugs by 2015. Besides, the domestic pharma market is estimated to touch US$ 20 billion by 2015, making India a lucrative destination for clinical trials for global giants.

Further estimates the healthcare market in India to reach US$ 31.59 billion by 2020.

Diagnostics Outsoourcing/Clinical Trials

According to the estimates, the Indian diagnostics and lab test services in view of its growth potential, is expected to reach RS. 159.89 billion by FY2013. The Indian market for both therapeutic and diagnostic antibodieis expected to grow exponentially in the coming years. Findings suggest that more than 60% of the total antibodies market is currently dominated by diagnostic antibodies.

Some of the major Indian pharmaceutical firms, including Sun Pharma, Cadila Healthcare and Piramal life sciences, had applied for conducting clinical trials on at least 12 new drugs in 2010, indicating a growing interest in new drug discovery research.

Generics

India tops the world in exporting generic medicines worth US$ 11 billion and currently, the Indian pharmaceutical industry is one of the world's largest and most developed.

Moreover, the Indian generic drug market to grow at a CAGR of around per cent between 2010-11 and 2012-13. Union Minister for Commerce and industry and Minister for Trade and Industry, Singapore, have signed a 'Special Scheme for Registration of Generic Medicinal Products from India' in May 2010, which seeks to fast-track the registration process for Indian generic medicines in Singapore.

Advantage India

The Indian Pharmaceutical Industry, particularly, has been the front runner in a wide range of specialties involving complex drugs' manufacture, development and technology. With advantage of being a highly organized sector, the pharmaceutical companies in India are growing at a rate of $4.5 billion, registering further growth of 8-9% annually.

More than 20000 registered units are fragmented across the country and reports say that 250 leading Indian pharmaceutical companies control 70%of the market share with stark price competition and government price regulations.

Competent workforce: India has a pool of personnel with high managerial and technical competence as also skilled workforce. It has an educated work force and English is commonly used. Professional services are easily available.

Cost-effective chemical synthesis: Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

Legal and Financial Framework: India has 53 years old democracy and hence has a solid legal framework and strong financial markets. There is already an established industry and business community.

Information and Technology: It has a good network of world class educational instituitions and established strengths in Information technology.

Globilisation: The country is committed to a free market economy and globalization. Above all it has a 70 million middle class market, which is continuously growing.

Consolidation: For the first time in many years, the international pharmaceutical industry is finding great opportunities in Indi. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry has started taking place in India.

Indian multinational companies like Dr. Reddy's Lab, Cipla, Ranbaxy, Sun Pharma etc have created awareness about the Indian market prospects in the international pharmaceutical market. Approvals given by Foods and Drugs Administration (FDA) and ANDA (Abbreviated New Drug Application)/DMF (Drug Master File) have played an important role in making India a cost-effective and high quality product manufacturer. Furthermore, the changes that took place in the patent law, change of process patent to product patent, have helped in reducing the risk of loss for intellectual property.

Rank	Company	Revenue (Rs. Crore)
1.	Ranbaxy Laboratories	4198.96
2.	Dr. Reddy's Laboratories	4162.65
3.	Cipla	3763.72
4.	Sun Pharmaceuticals	2463.59
5.	Lupin Ltd.	2215.52
6.	Aurbindo Pharma	2081.19
7.	Glaxosmithkline	1773.41
8.	Cadila Healthcare	1613
9.	Aventis	983.80
10.	Ipca Laboratories	980.44

Table1.1 Top 10 Pharmaceutical Companies in India (2010)

Chapter-2
INTRODUCTION OF ORGANIZATION

Abbott, is a company that focuses on turning science into caring – ABBOTT, A Promise for Life. For more than a century, Abbott Laboratories has been working to advance health care for people around the world. Founded in 1888 by a young Chicago physician, Dr Wallace Calvin Abbott, Abbott Laboratories has evolved into a diversified health care company that discovers, develops, manufactures and markets innovative products and services. Products and services of Abbott span the continuum of care from prevention and diagnosis, to treatment and cure. Abbott today is a global, diversified health care company devoted to the discovery, development, manufacture and marketing of pharmaceutical, diagnostic, nutritional and hospital products. The company now employs approximately 65,000 people and markets its products in 130 countries worldwide.

Abbott extends this commitment with a strong presence in India as it has grown and evolved its operations in India over many decades. Our products encircle life from newborns to ageing adults. Abbott has built expertise and leadership in primary care therapeutic areas like Gastroenterology and Pain care. Our specialty areas include Neuroscience, Metabolic and Hospital Care.

Abbott serves the needs of Indian consumers with products backed by science and R&D. They have locally developed brands like Digene, Cremaffin, Epilex, Zolfresh and Obimet. Abbott has also brought global products including Brufen, Prothiaden, Ganaton, Sevorane, Thyronorm and Leptos to Indian consumers. Abbott's pioneering products like Survanta help infants.

Abbott India, today has strong brand equity and commands esteem in the market place. To reach the customer, Abbott India has a network of 18 distribution points, which cater to 11,000 stockists and 70,000 retailers. Behind Abbott India's success, is a team of competent, committed people, driven by the principles of Value Based Management, and aided by strong alliances and partnerships.

Abbott India Limited provides healthcare solutions through its four business units:

1. Primary Care, which markets products in the areas of Pain Management, Gastroenterology, with well-known brands like Brufen, Digene, Cremaffin.

2. Specialty Care – Metabolic & Urology provides solutions in the areas of Thyroid, Obesity, Diabetes and Benign Prostratic Hyperplasia.

3. Specialty Care - Neuroscience has a varied portfolio, with specialty products in the Neurology and Psychiatric segments.

4. Hospital Care, offers products in the field of anesthesiology and neonatology namely Forane, Sevorane and Survanta.

The company has over 1000 employees and a state-of-the-art formulation plant at Verna

in Goa. The manufacturing locations are designed to produce quality, high volume formulations using cost efficient processes. The plant has well equipped laboratories and trained personnel to ensure international standards of quality at each step of the manufacturing process.

The company has in-house development and medical teams to undertake product and clinical development tailored to the needs of the Indian market.

Abbott provides quality health care worldwide by creating healthcare solutions, which directly affects the life of the common man.

Vision

To be the world's premier health care company

Dedication

To employees, customers, shareholders, suppliers and the public

Strategy

Value Based Management is integral philosophy, directed towards maximizing long-term cash flow and shareholder value through:

- Focus on the Company's core profitable segments to build up our position as one of the leading pharmaceutical companies
- Investments in information technology to improve planning and control of operation
- Increased investments in Human Resources Training & Development to upgrade and broaden the skill base of the organization in consonance with changing needs
- Build flexible cost-efficient manufacturing base through a balanced mix of in house and contract manufacturing.

Our Work Culture

Abbott India is an equal opportunity employer and provides a congenial and professional work environment for all its employees, with great emphasis on teamwork. We stimulate innovation, encourage calculated risk taking and accept mistakes as a part of the learning process.

Encourage experiential learning, and believe in clear delegation of authority and acceptance of personal accountability. We value the involvement of our colleagues in bringing the best to our organization in a spirit of understanding, trust and appreciation of cultural differences. They are open to discussing alternative views and build on constructive feedback.

Our Basic Principle

Respect people: Our people are our strength

A Promise for Life

Turning Science into Caring

They are here for the serving people in their pursuit of healthy lives. This has been the way of Abbott for more than a century – passionately and thoughtfully translating science into lasting contributions to health.

Their products encircle life, from newborns to aging adults, from nutrition and diagnostics through medical care and pharmaceutical therapy.

Caring is central to the work we do and defines our responsibility to those we serve:

Abbott's advance leading-edge science and technologies that hold the potential for significant improvements to health and to the practice of health care.

Value our diversity – that of our products, technologies, markets and people – and believe that diverse perspectives combined with shared goals inspire new ideas and better ways of addressing changing health needs.

Focus on exceptional performance – a hallmark of Abbott people worldwide – demanding of ourselves and each other because our work impacts people's lives.

They strive to earn the trust of those we serve by committing to the highest standards of quality, excellence in personal relationships, and behaviour characterized by honesty, fairness and integrity.

They sustain success – for our business and the people we serve – by staying true to key tenets upon which our company was founded over a century ago: innovative care and a desire to make a meaningful difference in all that we do.

The promise of Abbott is in the promise that our work holds for health and life.

Chapter-3
BACKGROUND OF PROJECT

Introduction

Situational analysis was done during entire project, the project was undertaken in order to know the brands preferred by doctors of various Clavulanic Acid combinations and to find out the reasons behind selecting a particular brand. An attempt was made to know about different brands of Clavulanic Acid available in the market.

Introduction of Combinations

Clavulanic Acid

Obtained from *Streptomuces clavuligerus*, it has a p-lactam ring but no antibacterial activity of its own. It inhibits a wide variety (class II to class V) of B-lactamases (but not class I cephalosporinase) produced by both gram-positive and gram-negative bacteria.

Mechanism of action: Clavulanic acid is a'progressive, inhibitor : binding with β-lactamase is reversible initiallv. but becomes covalent later-inhibition increasing with time. Called a 'suicide, inhibitor, it gets inactivated after binding to the enzyme. It permeates the outerlayers of the cellwall of gram-negative bacteria and inhibits the periplasmically located β-lactamase.

Pharmacokinetics: Clavulanic acid is well absorbed after oral administration. Peak plasma concentration of Clavulanic acid 125 mg single dose is 2.2mcg/ml. It is distributed completely after oral administration. Protein binding of clavulanic acid is about 30 %.The plasma half life of clavulanic acid is one hour About 60 % of clavulanic acid is excreted unchanged in urine. The clavulanic acid component in the drug combination protects β-Lactam antibiotics from degradation by β-lactamse enzymes and effectively extends the antibiotic spectrum to include many bacteris that are normally resistant to β-lactam antibiotics.

β -lactam antibiotics

Mechanism of Action: All β-lactam antibiotics interfere with the synthesis of the bacterial cell wall peptidoglycan. After attachment to binding sites on the bacterium (penicillin-binding

proteins), they inhibit the trnaspeptidation enzyme that cross-links the peptide chains attached to backbone of peptidoglycan. The final bactericidal event is the inactivation of the inhibitor of the autolytic enzymes in the cell wall; this leads to the lysis of the bacterium Some organisms have defective autolytic enzymes and are inhibited but not lysed and they are refrred to as 'tolerant'.

Amoxycillin :This penicillinase-susceptible penicillin is closely related to ampicillin
. The drug is absorbed more rapidly and completely from the GI tract than is ampicillin.
The antimicrobial spectrum of amoxicillin is essentially identical to that of ampicillin, except that amoxicillin is less effective for shigellosis.
Peak plasma concentrations of amoxicillin (AMOXIL, others) are twice those of ampicillin after oral administration of the same dose. Food does not interfere with absorption. Perhaps because of its more complete absorption, the incidence of diarrhea with amoxicillin is less than that with ampicillin. The incidence of other adverse effects is similar. While the t1/2 of amoxicillin is similar to that for ampicillin, effective concentrations of orally administered amoxicillin are detectable in the plasma for twice as long as with ampicillin because of its more complete absorption. About 20% of amoxicillin is protein-bound in plasma. Most of the antibiotic is excreted in an active form in the urine.

Cefixime: It is an orally active third generation cephalosporin highly active against Enterobacteriaceae, *H. influenzae* and is resistant to many β-lactamases. However, it is not active on *Staph. aureus* ,most pneumococci and Pseudomonns. It is longer acting (t1/2 3 hr) and has been used in dose of 200-400 mg BD for respiratory, urinany and biliary infections. Stool changes and diarrhoea are the most prominent side effects.

Cefpodoxime proxetil: It is the orally actir-eester prodrug of 3rd generation cephalosporin cefpodoxime. In addition to being highly active against Enterobacteriaceae and streptococci, it inhibits *Staph. aureus*. It is used mainly for resprratory, urinary, skin and soft tissue infections.

Cefuroxime: is resistant to gram-negative β-lactamases: has high activity against organisms producing these enzymes including PPNG and ampicillin-resistant *H. influenzae* while retaining significant activity on gram-positive cocci and certain anaerobes. It is well tolerated by i.m. route and attains relatively higher CSF levels, but has been superseded by 3rd generation

cephalosporins in the treatment of meningitis. It has been employed for single dose i.m. therapy of gonorrhoea due to PPNG.

Cefadroxil: A close congener of cephalexin; has good tissue penetration-exerts more sustained action at the site of infection; can be given 12 hourly despite a t1/z of 1 hr. It is excreted unchanged in urine, but dose need be reduced onlv if creatinine clearance is < 50 ml/min. The anfibacterial activity of cefadroxil and indications are similar to those of cephalexin.

Project Title

Doctor's preference of brands of Clavulanic Acid combinations in oral therapy: A study.

Objectives

- To find out what are the reasons of selection of Clavulanic Acid combinations by the doctor's.
- To find out which brands of Clavulanic Acid Combinations are preferred by doctors in oral therapy
- To find out what are the factors that influence doctors to choose a particular brnad.

Research Methodology

Type of research

Primary Market Research

Sample Size

115 Doctors

Area of Specialization	No. of Doctor's
Physicians	25
Gynaecologists	25
Paediatricians	25
ENT Specialists	15

Orthopaediacinas	15
Dentists	10

Sampling Method

Convenient Sampling

Duration

24th April to 1st June 2012

Study area

Bhilwara, Bikaner and Jaipur Cities of Rajasthan.

Data Collection

Tool: Semi Structured Questionaire

Method: Survey Method (Face to Face interview)

Chapter-4
DATA ANALYSIS AND INTERPRETATION

Reasons Behind the selection of Clavulanic acid Combinations

S. No.	Reason Behind the Selection of Calvulanic Acid Combinations	No. of Doctors
1	Good efficacy, safety and effectiveness	42
2	Enhanced spectrum of activity	20
3	Enhanced effectiveness of β-lactam antibiotics	28
4	less resistance of bacteria	15

Table4.1- Reasons behind the selection of Clavulanic Acid combinations

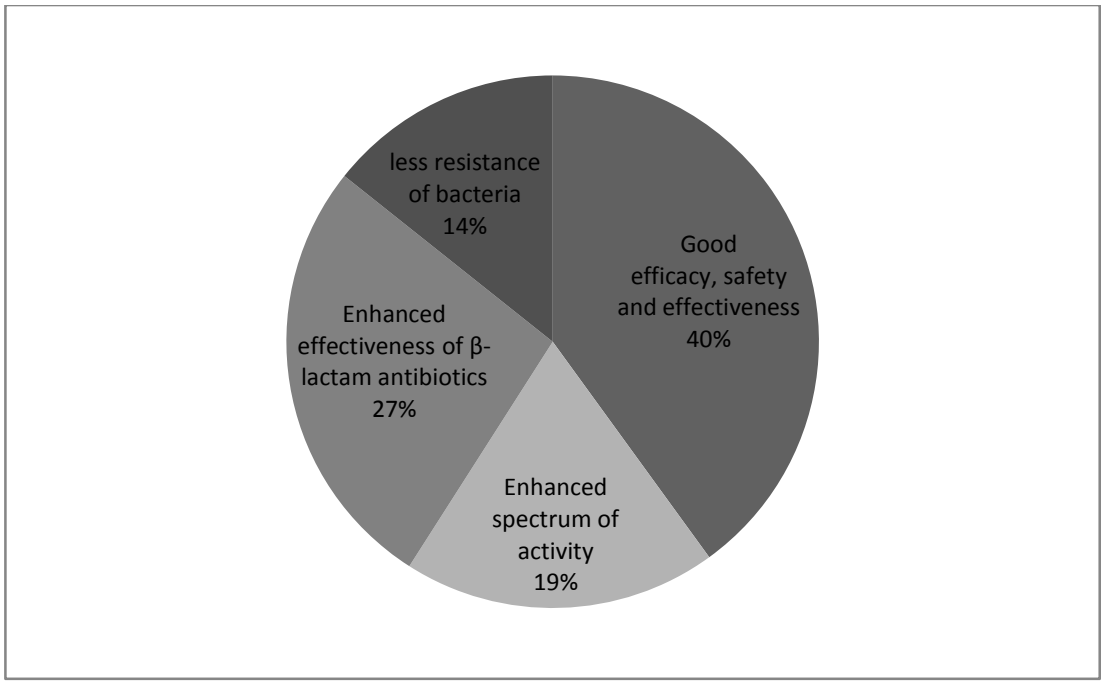

Figure 4.1- Reasons behind the selection of Clavulanic Acid combinations

Inference – Good efficacy, safety and effectiveness is the major reason behind the selection of Clavulanic acid combinations.

Preference of Brands of Amoxicillin and Clavulanic acid combinations (adult dose)

S. No.	Name of the Brand	No. of Doctors
1	Augmentin	29
2	Advent	17
3	Novaclav	15
4	Clavum	12
5	Tresmox	9
6	No Preference	8

Table 4.2Preference of Brands of Amoxicillin and Clavulanic acid combinations (adult dose)

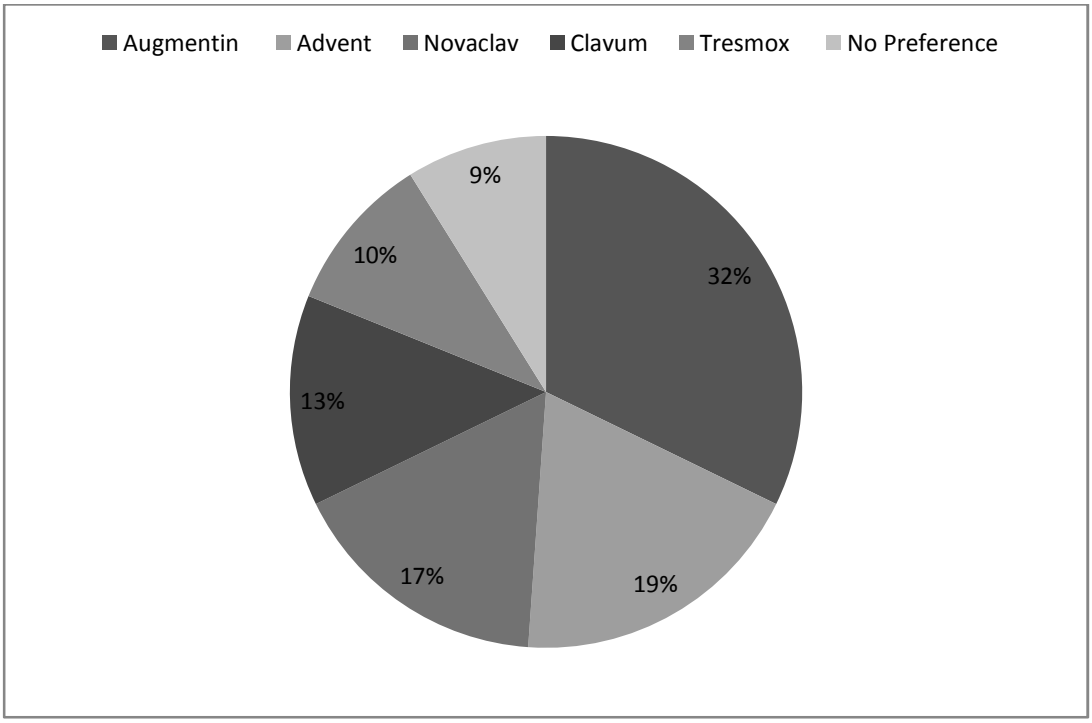

Fig. 4.2 P Preference of Brands of Amoxicillin and Clavulanic acid combinations (adult dose)

Inference-Augmenntin is the most preferred brand of Amoxicillin and Clavulanic acid combinations (adult dose)

Preference of Brands of Amoxicillin and Clavulanic Acid Combination (paediatric)

S. No.	Name of the Brand	No. of Doctors
1	Augmentin Syrup	7
2	Advent Syrup	6
3	Clamp Kid tab	3
4	Nuclav Syrup	4
5	Clavum Dry Syrup	2
6	No pfererence	3

Table 4.3Preference of Brands of Amoxicillin and Clavulanic Acid Combinations (paediatirc)

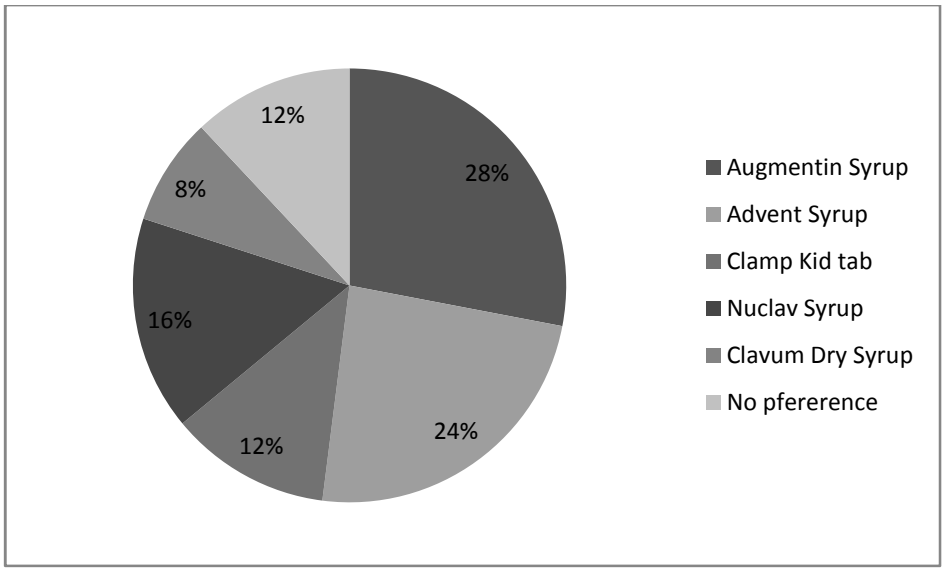

Figure 4.3 Preference of Brands of Amoxicillin and Clavulanic Acid Combinations (paediatirc)

Inference: Augmentin Syrup is the most preferred brand of Amoxicillin and Clavulanic acid preparations by the doctors.

Prefernece of Brands of Cefixime and Clavulanic acid Combination

S. No.	Name of the Brand	No. of Doctors
1	Omnatax CV	34
3	Omnix CV	18
2	Zifi CV	19
4	Zofix CV	10
5	No preference	9

Table 4.4 Prefernece of Brands of Cefixime and Clavulanic acid Combination

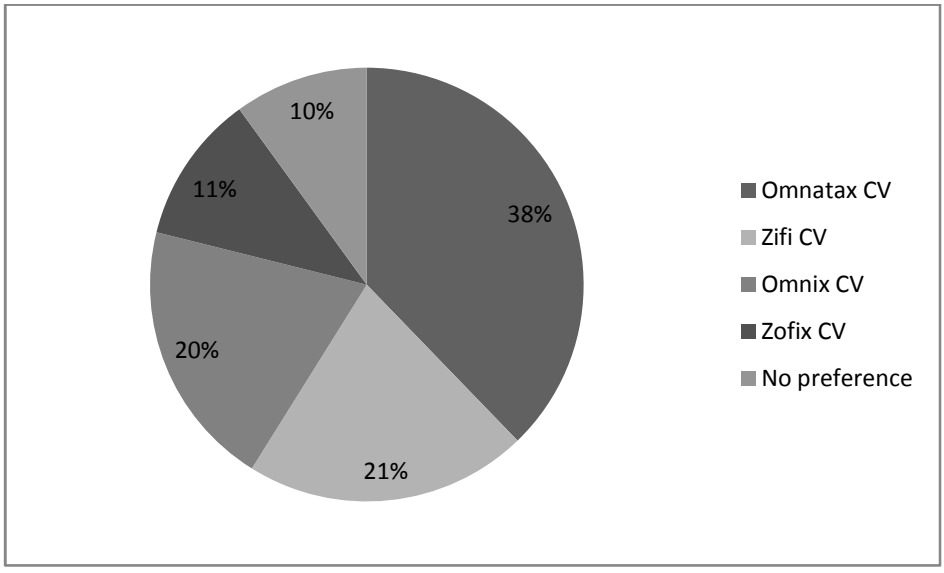

Fig.4.4 Prefernece of Brands of Cefixime and Clavulanic acid Combination

Inference: Omnatax CV is the most preferred brand of Cefixime and Clavulanic Acid combination.

Brand Preference of Cefuroxime and Clavulanic Acid Combination

S. No.	Name of the Brand	No. of Doctors
1	Altacef CV	36
2	Ceroxim XP	22
3	Zefu CV	15
4	No preference	8

Table 4.5 Brand Preference of Cefuroxime and Clavulanic Acid Combination

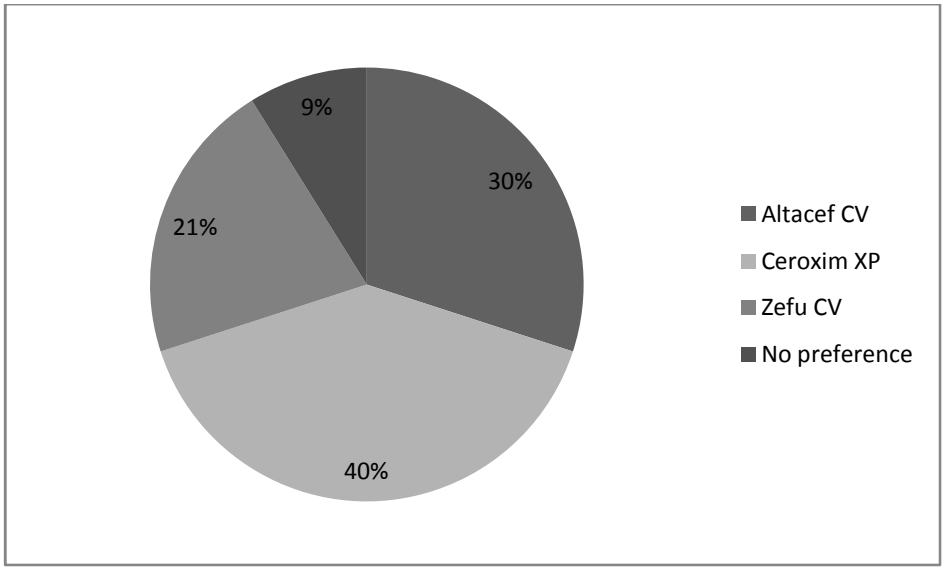

Fig.4.5 Brand Preference of Cefuroxime and Clavulanic Acid Combination

Inference: Altacef CV is the most Preferred brand of Cefuroxime Clavulanic Acid combination.

Preference of Brand of Cefpodoxime and Clavulanic Acid Combination

S. No.	Name of the Brand	No. of Doctors
1	Pecef Duo	29
2	Cepodem xp	17
3	Zedocef CV	18
4	Cefchamp	20
5	No Preference	6

Table 4.6 Preference of Brand of Cefpodoxime and Clavulanic Acid Combination

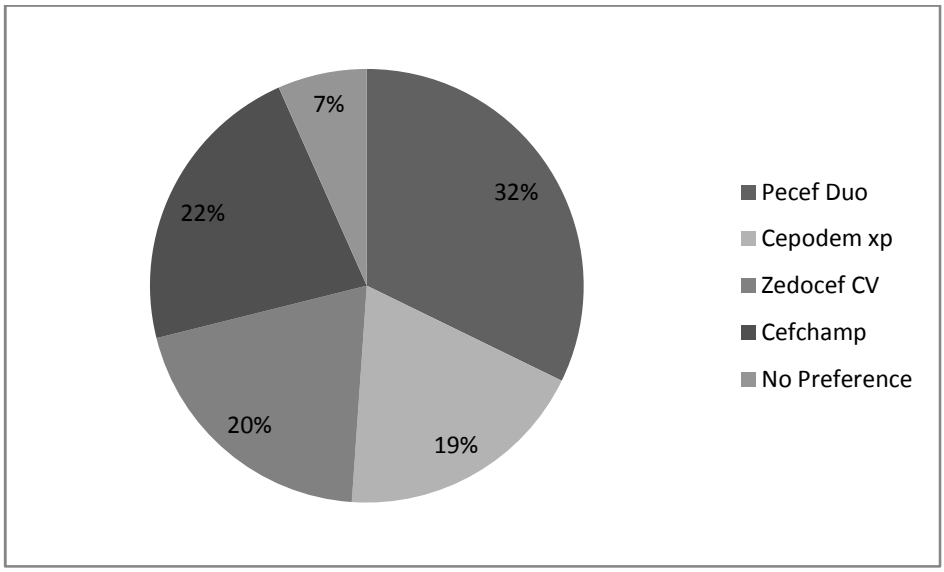

Fig. 4.6 Preference of Brand of Cefpodoxime and Clavulanic Acid Combination

Inference: Pecef Duo is the most preferred brand of Cefpodoxime and Clavulanic Acid combinations.

Preference of Brands of Cefadorxil and Clavulanic Acid Combination

S. No.	Name of the Brand	No. of Doctors
1	Droxyl Clav	42
2	Zadro CV	39
3	No Preference	9

Table 4.7 Preference of Brands of Cefadorxil and Clavulanic Acid Combination

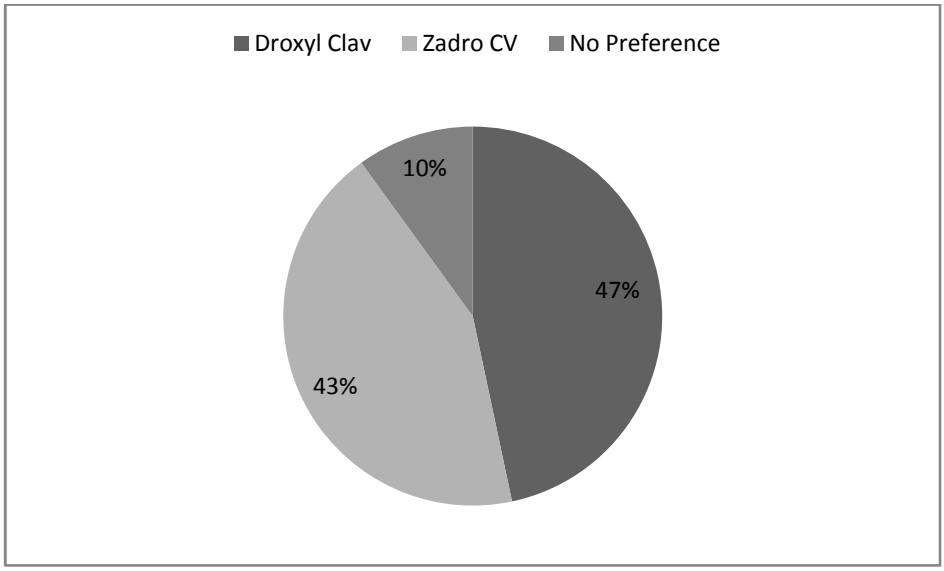

Figure 4.7 Preference of Brands of Cefadorxil and Clavulanic Acid Combination

Inference: Droxyl Clav is the most preferred brand of Cefadorxil and Clavulanic Acid Combination

Reason Behind the Selection of a Particular Brand

S.No.	Reason Behind the selection of a brand	No. of Doctors
1	Medical Representative Visits	44
2	Availability	22
3	Quality	23
4	Affordability	26

Table 4.8 Reason Behind the Selection of a Particular Brand

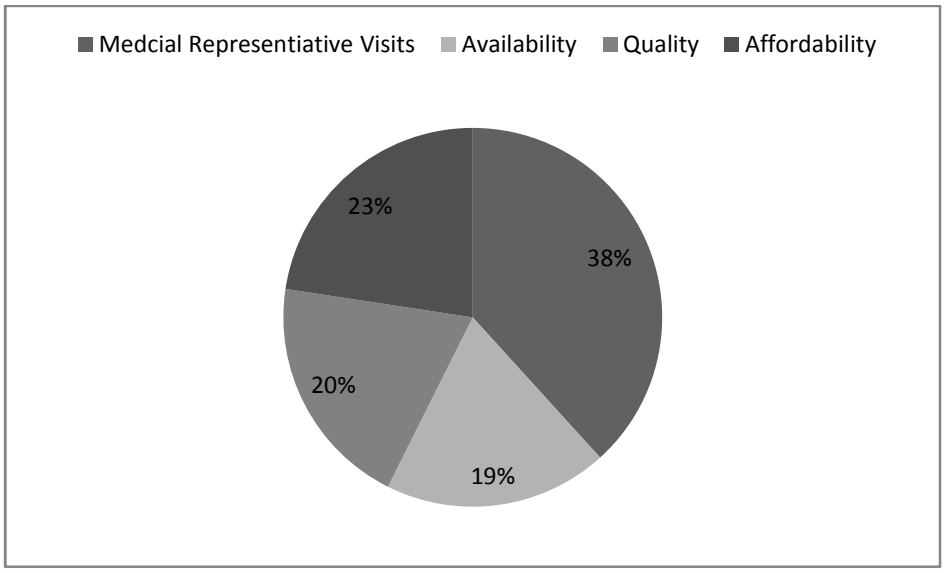

Fig.4.8 Reason Behind the Selection of a Particular Brand

Inference: Medical representative visit is the reason which contributes most behind the selection of a particular brand.

Conclusions

1. Good efficacy, safety and effectiveness is the major reason behind the selection of Clavulanic acid combinations.
2. Good efficacy, safety and effectiveness is the major reason behind the selection of Clavulanic acid combinations.
3. Augmenntin is the most preferred brand of Amoxicillin and Clavulanic acid combinations (adult dose)
4. Augmentin Syrup is the most preferred brand of Amoxicillin and Clavulanic acid preparations by the doctors.(paediatric dose)
5. Omnatax CV is the most preferred brand of Cefixime and Clavulanic Acid combination.
6. Altacef CV is the most Preferred brand of Cefuroxime Clavulanic Acid combination.
7. Pecef Duo is the most preferred brand of Cefpodoxime and Clavulanic Acid combinations.
8. Droxyl Clav is the most preferred brand of Cefadorxil and Clavulanic Acid Combination
9. Medical representative visit is the reason which contributes most behind the selection of a particular brand.

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Questionnaire for Doctors

1 .Name –

2. Area of Specialization –

a. General Practitioner b. General Medicine c. ENT d. Gynaecology
e. Urology f. Paediatrics g. Dentistry h.Orthopaedics

3. Type of Practice :

a. Government Hospital b. Private Hospital/Nursing Home

c. Private Practice/Clinic

4. Area:

a. Rural b. Urban

5. In which of the following indications the given combinations of Clavulanic acid are preferred in oral administration, why and what dose?

Indication	Reason	Dose
Respiratory Infections and ENT Infections		
Otitis Media (acute and chronic)		
Sinusitis (acute and chronic)		
Mastoiditis		
Chronic Recurrent Tonsilitis		
Pharyingitis		
Laryngitis		
Bronchitis		
Bronchietasis		
Pneumonia		
Emphysema		
Lung Abscess		
Urinary Tract Infections		
Skin and Soft Tissue Infections		
Abscess		
Cellulitis		
Furunculosis		
Wound Infection		
Obstetric And Gynaecological Infections		
Pelvic Inflammatory Disease		
Endometriosis		
Salphingitis		
Septic Abortion		

Sexually Transmitted Disease		
Neisseria gonorrhoeae		
Haemophilius duceryl		
Chlamydia trachomatis		
Phrophylactic in surgical procedures		

4. Which brand/brands of the given Clavulanic Acid combinations you prefer in oral therapy?

a. **Amoxycillin with Clavulanic Acid**

Indication	**Reason**	**Dose**

b. **Cefuroxime With Clavulanic Acid**

Indication	**Reason**	**Dose**

c. **Cefpodoxime With Clavulanic Acid**

Indication	Reason	Dose

d. **Cefixime with Clavulanic Acid**

Indication	Reason	Dose

e. **Cefadroxil with Claculanic Acid**

Indication	Reason	Dose