

**Summer Training at
Ranbaxy Laboratories
(April 9-June 1, 2012)**

Usage of Ofloxacin + Flavoxate Combination in UTI Associated with Spasm

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Certificate

This is to certify that Ms. Nikita Morbia from Institute of Health Management Research, Jaipur has undergone summer training in Ranbaxy Laboratories, Mumbai from 9th April to 2nd June 2012.

The Candidate herself carried out the project. Her approach to the study has been sincere, scientific and analytical. This summer training is partial fulfilment of the course requirement is recommended for the award Post Graduate Diploma in Pharmaceutical Management.

I wish her success in all her future endeavours.



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We hope that this study will prove to be a useful to the company's marketing strategies and success of the product in near future.

Table of Contents

Sr. No.	Topic Name	Page No.
I	Company Profile	8-9
1	Introduction	11
1.1	Urinary Tract Infection	11
1.2	Urinary Tract Infection + Spasm	11
1.3	Ofloxacin	12
1.4	Flavoxate	12
1.5	Rationale for combination	12
II	Review of Literature	13
2	Objectives	13
2.1	Research design	13
3	Findings & Analysis	14
3.1	Patient profile	14
3.2	Signs & Symptoms for UTI & UTI associated with spasm	15
3.3	Molecule preference	16
3.4	Preferred Ofloxacin dosage & duration with Reasons	17-18
3.5	Preferred Flavoxate dosage & duration with Reasons	19-20
3.6	Treatment options	21
3.7	Recalling of brands	22
3.8	Medical & Marketing parameters	23
3.9	Promotional activities	23
4	Conclusion	24
5	Summer Training learning's	25
6	Annexure	26

List of Table

Sr. No.	Table Name	Page No.
1	Top 10 molecules	8
2	Commonly used drugs	11
3	Sample Distribution	13
4	Patient profile	14
5	Promotional activities done by the Company	23

List of Figures:

Sr. No.	Figure Title	Page No.
1	Diagnosis of UTI	15
2	Diagnosis of UTI + Spasm	15
3	Molecule preference for UTI	16
4	Molecule preference for UTI + Spasm	16
5	Preferred Ofloxacin dosage & duration	17
6	Reason for preference of Ofloxacin	18
7	Reason for no preference of Ofloxacin	18
8	Preferred Ofloxacin dosage and duration	19
9	Overall preference	19
10	Reason for preference of Flavoxate	20
11	Reason for no preference of Flavoxate	20
12	Available Treatment options	21
13	Top of Mind recall	22
14	Prescribing information	22
15	Medical & Marketing parameters	23

Abbreviations

-  Avg.: Average
-  CP: Consultant Physician
-  Co-Rx: Co-Prescribe
-  GP: General Practitioner
-  Rep.: Representative
-  TOM: Top of the Mind Recall
-  URO: Urologist
-  UTI : Urinary Tract Information
-  USFDA: United States Food & Drug Administration

Company Profile

Ranbaxy Laboratories Limited (Ranbaxy), India's largest pharmaceutical company, is an integrated, research based, international pharmaceutical company, producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies. Ranbaxy today has a presence in 23 of the top 25 pharmaceutical markets of the world. The Company has a global footprint in 43 countries, world-class manufacturing facilities in 8 countries and serves customers in over 125 countries.

Mission:

'Enriching lives globally, with quality and affordable pharmaceuticals'.

Values:

-  Achieving customer satisfaction is fundamental to our business.
-  Provide products and services of the highest quality.
-  Practice dignity and equity in relationship and provide opportunities to our people to realise their full potential.
-  Ensure profitability growth and enhance wealth of the shareholders.
-  Foster mutually beneficial relation with all our business partners.
-  Manage our operations with high concern for safety and environment.
-  Be a responsible corporate citizen.

Top 10 Molecules (2010):

Table 1: Top 10 molecules (2010)

Valacyclovir
Simvastatin
Donepezil
Atorvastatin & Combinations
Co-amoxyclav & Combinations
Ciprofloxacin & Combinations
Ketorolac Tromethamine
Imipenem+Cilastatin
Ginseng+Vitamins
Loratadine & Combinations

Recent Up gradation:

- Ranbaxy announces USFDA approval of CIP-ISOTRETINOIN NDA.(May 2012)
- Ranbaxy launches SynriamTM- India's first new drug
- Daiichi Sankyo and Ranbaxy to expand hybrid business model in Romania

SUMMER TRAINING REPORT

1. Introduction

1.1 UTI:

- Urinary tract infections are caused by germs, usually bacteria that enter the urethra and then the bladder.
- This can lead to infection, most commonly in the bladder itself, which can spread to the kidneys.
- Women tend to get them more often because their urethra is shorter and closer to the anus than in men.
- Because of this, women are more likely to get an infection after sexual activity or when using a diaphragm for birth control. Menopause also increases the risk of a UTI.

Table 2: Commonly used molecules for UTI infection

Urinary Tract Infection	Commonly Used Molecule Name
	Acetohydroxamic Acid
	Atropine, Hyoscyamine, Methenamine
	Cephalosporins
	Flavoxate
	Fluoroquinolones
	Loracarbef
	Methenamine
	Penicillins

1.2 UTI + Spasm

- 🌈 During infection, inflammation takes place, due to it there is uncontrolled sudden muscle contraction that is called Spasm.
- 🌈 A bladder spasm, or "detrusor contraction," occurs when the bladder muscle squeezes suddenly without warning, causing an urgent need to release urine. The spasm can force urine from the bladder, causing leakage. When this happens, the condition is called urge incontinence or overactive bladder.

- ✚ People who have had such spasms describe them as a cramping pain and sometimes as a burning sensation.

1.3 Ofloxacin:

- ✚ Ofloxacin time tested Quinolones in UTI Management
- ✚ Cure rates ranging from 98.5% - 100%¹
- ✚ 86% women freed of symptoms²
- ✚ 80% negative UTI cultures²

1.4 Flavoxate:

Flavoxate works on the taming Spasms

- ✚ Flavoxate prevents spasms in the urinary tract and relieves the painful or difficult urination³.

1.5 Rationale for Combination:

- ✚ The UTI symptoms are often caused by overactive bladder, prostate enlargement, infections, or irritation of the urethra.
- ✚ Severe spasmodic pain is usually co-morbidity with UTI.
- ✚ Ofloxacin time tested proven antibiotic for UTI.
- ✚ Flavoxate reduces muscle spasms of the bladder and urinary tract.

Therefore it is an ideal combination to treat Urinary tract infections with spasms.

Review of Literature:

1. John L Brusch, MD, FACP “Cystitis in Female, Medscape” Feb 1, 2012

According to this study it was concluded that Urinary tract infections (UTIs) are common in females, and cystitis (bladder infection) represents the majority of these infections. *Escherichia coli* causes the majority of uncomplicated cystitis cases, *E coli* cause 70-95% of both upper and lower UTIs. Various organisms are responsible for the remainder of infections, including *saprophyticus*, *Proteusspecies*, *Klebsiella* species, *Enterococcus faecalis*, other Enterobacteriaceae, and yeast. Some species are more common in certain subgroups, such as *Staphylococcus saprophyticus* in young women.

The most important risk factor for bacteriuria is the presence of a catheter. Eighty percent of nosocomial UTIs are related to urethral catheterization, while 5-10% is related to genitourinary manipulation.

2. Miler Jonae Sarka, Natural news article, Feb 29, Wednesday 2012

A urinary tract infection in women may cause pain or burning during urination, lower abdominal cramps or pain, nausea, blood or pus in urine, frequent urination and pain during sexual intercourse. Antibiotics are the conventional treatment for UTIs. However, conventional treatments only suppress the bacteria that cause most UTIs. Women can develop a new UTI from the same bacteria, typically within six to 12 months.

2. Objective

- To study the usage of Ofloxacin + Flavoxate in UTI associated with Spasm

Sub-objectives

- Prevalence of Spasm associated with UTI
- Treatment options given frequently for UTI + spasm
- Propose a dosing which is most prevalent
- Marketing Efforts required for great future of Zanolcin F
- Competitor Information

2.1 Methodology

- ✚ Research Type: Primary Research
- ✚ Tool: Questionnaire
- ✚ Technique: Face to Face interview
- ✚ Sample Size: 149
- ✚ Study area: Mumbai, Mohali, Jodhpur, Hyderabad

Target specialties: CP, GP, Surgeon, Gynecologist, Urologist

Table 3: Sample Distribution by Area

Target specialties	Study Area				
	Mumbai	Mohali	Jodhpur	Hyderabad	Total
URO	6	4	3	6	18
GP	10	10	16	11	47
CP	6	6	8	6	27
GYNAE	6	7	8	6	27
SURGEON	6	7	11	6	30
TOTAL	33	35	46	35	149

3. Findings & Analysis

3.1 Prevalence of UTI & UTI associated with Spasm:

Overall it is observed that considering total patient as 100%, UTI patients are 19% and out of them 75% patients have UTI associated with spasm which is large population. Gender wise it can be observed that females(64%) are more affected than male(33%) as Urethra of female is shorter than males, among females; female had a baby(49%) is more affected, followed by others(28%) and pregnant(23%).

Table 4: Prevalence of UTI & UTI associated with Spasm

Specialty	Overall (N=149)	General Practitioner (N=47)	Consultant Physician (N=27)	Gynecologist (N=27)	Surgeon (N=30)	Urologist (N=18)
Avg Patient / Day	21	17	27	25	20	20
UTI	19%	18%	15%	20%	20%	19%
UTI + Spasm	75%	100%	50%	60%	75%	83%
Sex of the patient						
Male	33%	37%	32%		43%	42%
Female	64%	63%	68%	100%	57%	58%
Female						
Had baby	49%	46%	45%	52%	48%	49%
Pregnant	23%	23%	28%	22%	20%	22%
Others	28%	31%	27%	26%	32%	30%

3.2 Signs and Symptoms of UTI

According to Figure 1 & 2, all the specialties, burning micturation and abdominal pain are the major diagnosis factor for UTI whereas except Gynecologist Dysurea is the major diagnosis factor for UTI associated with spasm, this will help to position the product with indications for relief of major signs and symptoms.

Figure 1: Signs and Symptoms for UTI

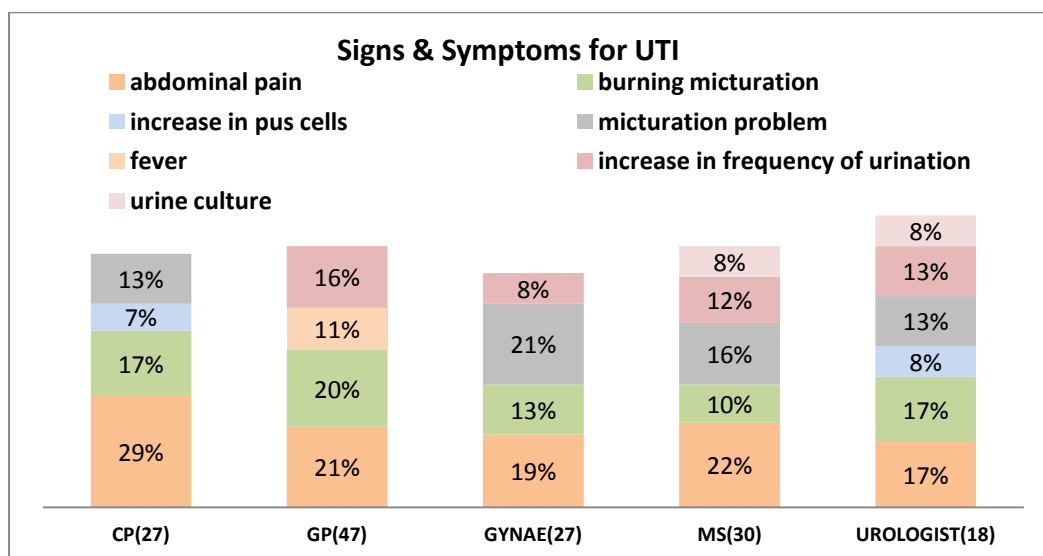
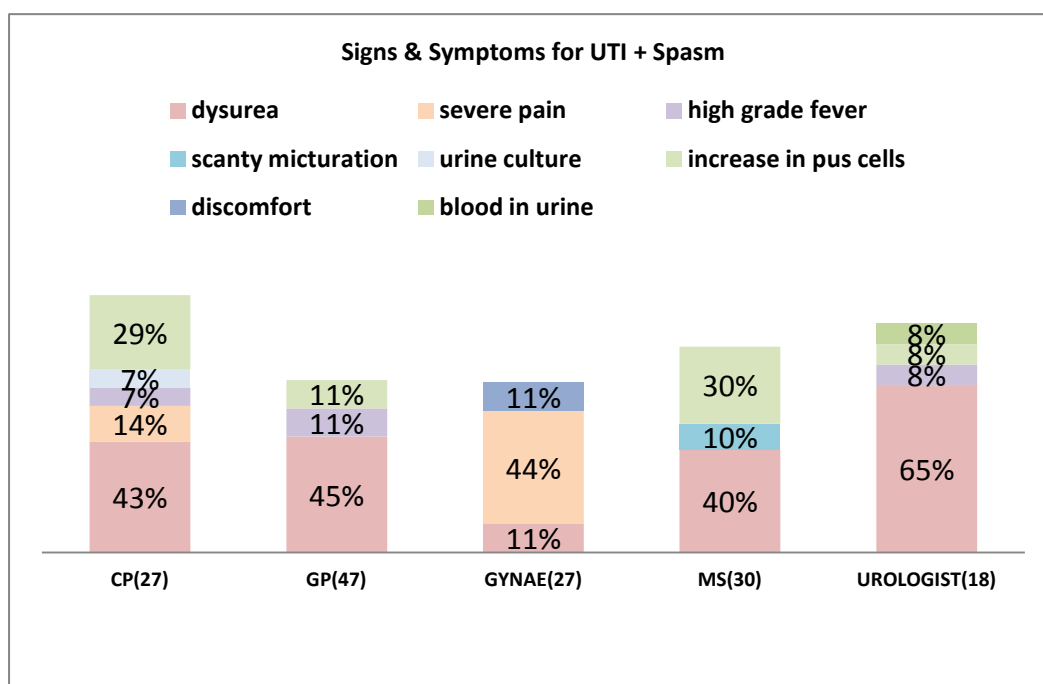


Figure 2: Signs & Symptoms of UTI + Spasm



3.3 Molecule Preferred by target groups

Figure 3 & 4 shows that Ofloxacin & Norfloxacin are majorly preferred for the treatment of UTI whereas for UTI + Spasm, along with anti-biotic, anti-spasmodic like Flavoxate & Dicyclomine are co-rxed, this helps to study the ongoing demand or preference for the product.

Figure 3: Molecule Preference for UTI

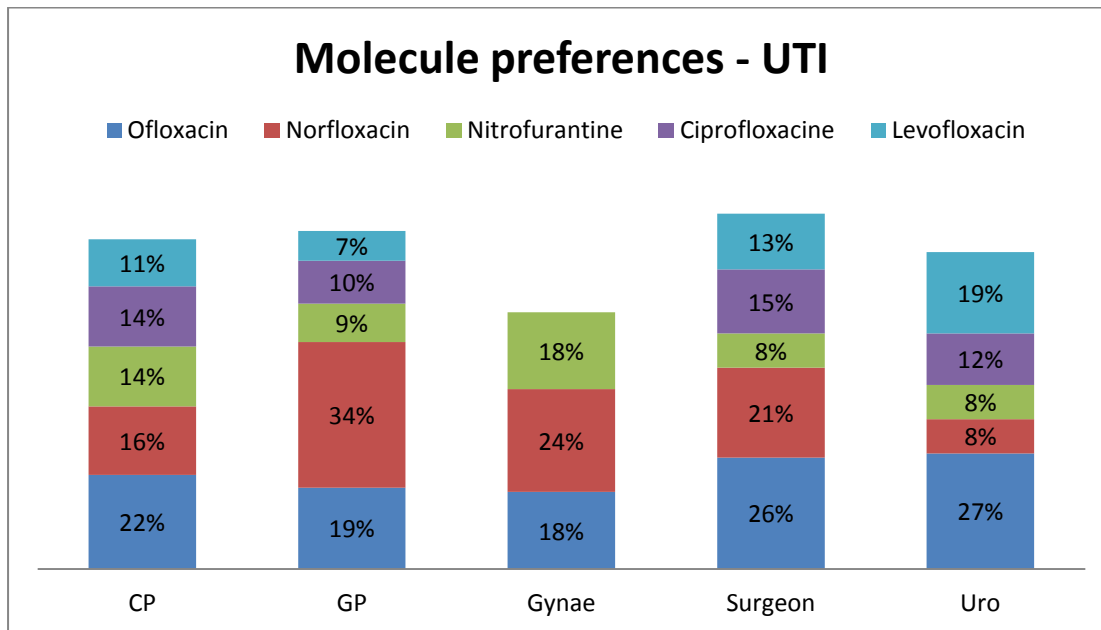
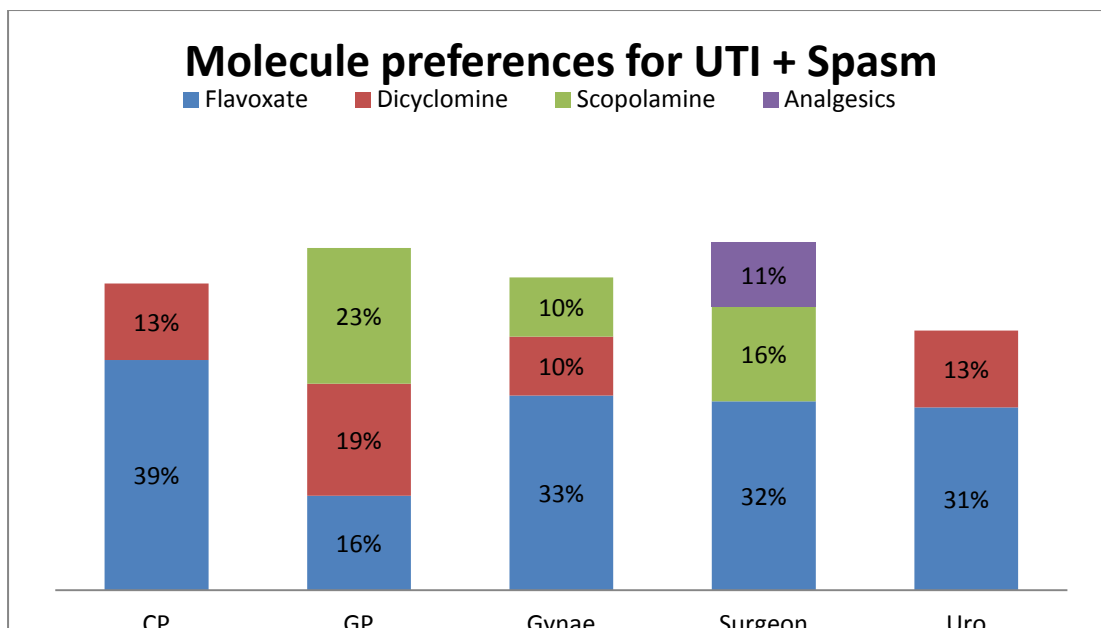


Figure 4: Molecule preference for UTI +Spasm



3.4 Preferred Ofloxacin dosage & duration:

The dosage for Ofloxacin is 200 MG & 400 MG among these; plain Ofloxacin 200 MG for 5 to 7 days is a choice of treatment in UTI for all the major specialities, this helps us to understand the preferred medication for the disease and to promote the product accordingly.

Figure 5: Preferred Ofloxacin dosage & duration (N=149)

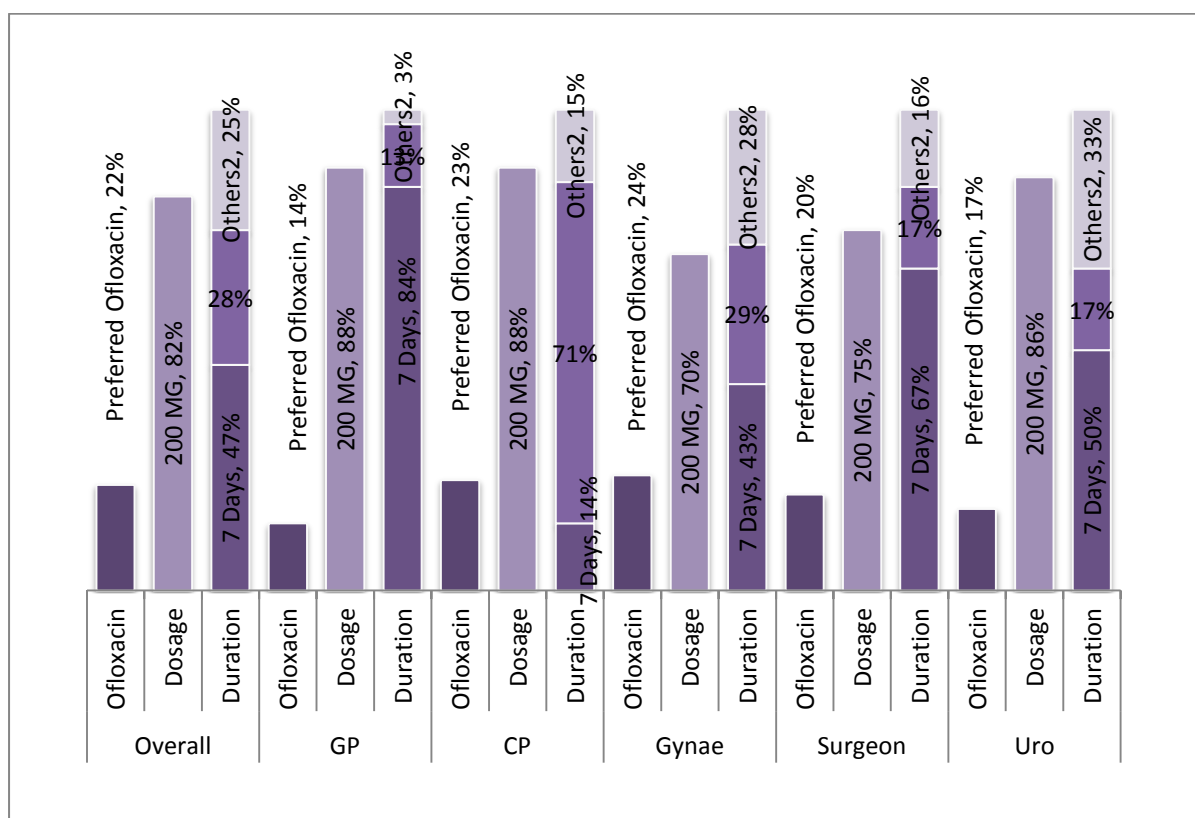
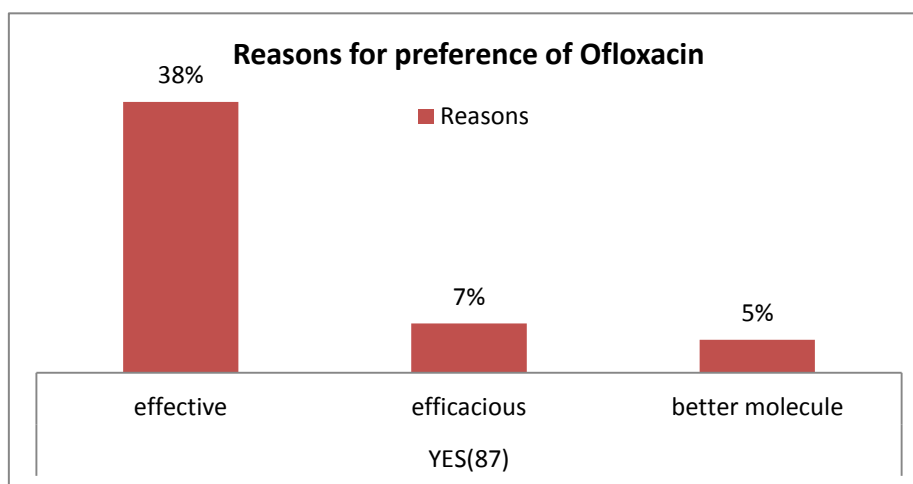


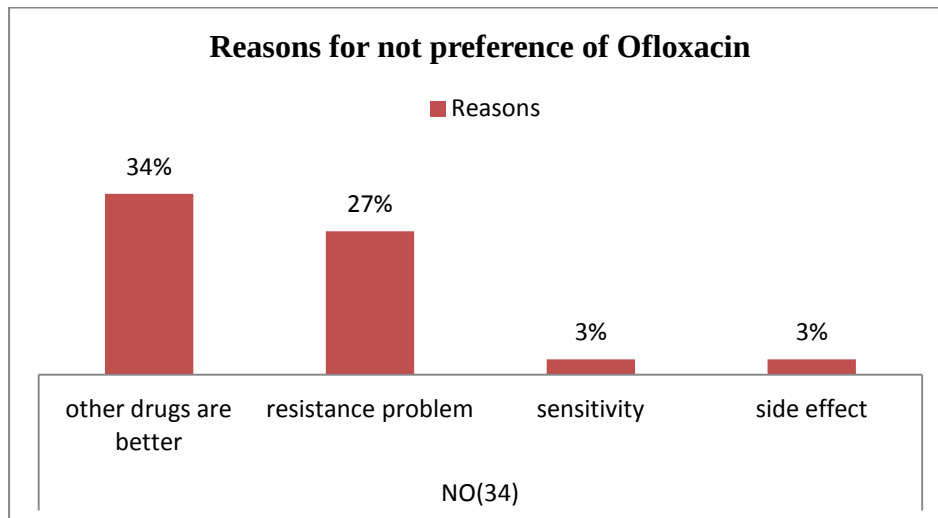
Figure 6: Reason for preference of Ofloxacin (N=121)



Reasons for preference of Ofloxacin:

Major reasons for not preferring Ofloxacin as a choice of treatment for UTI includes they feel other drugs are better, resistance problem, sensitivity & side effect

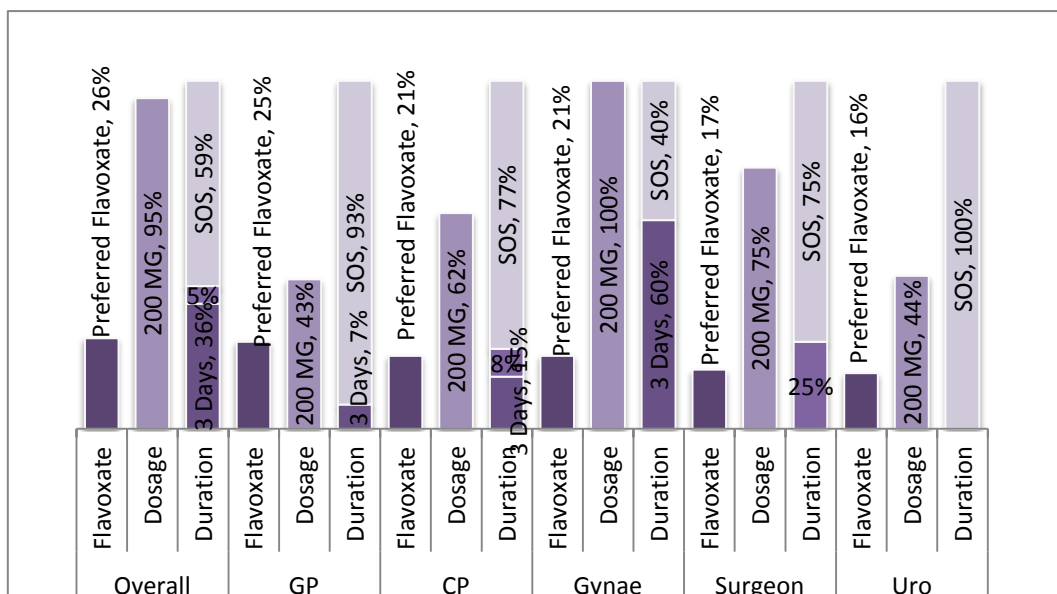
Figure 7: Reason for no preference of Ofloxacin (N=121)



3.5 Preferred Flavoxate Dosage & Duration:

Flavoxate molecule is available only in dosage of 200 MG, therefore 200 MG Flavoxate is co – Rxed with other antibiotic for 3-5 Days or in others mostly it is SOS is a choice of treatment for UTI + Spasm. As it is observed majority of doctors perception is to provide anti-spasmodic in SOS form, this group can be converted into target groups which will be very beneficial.

Figure 8: Preferred Flavoxate Dosage & Duration (N=149)



Reasons For preference of Flavoxate dosage & duration:

77% do not prefer Ofloxacin + Flavoxate combinations however 23% who prefer Ofloxacin + Flavoxate combination, among them 80% needed more information on the combination usage (Awareness is very less), therefore there is a need to create more awareness among doctors regarding combination.

Figure 9: Overall Preference (N=107)

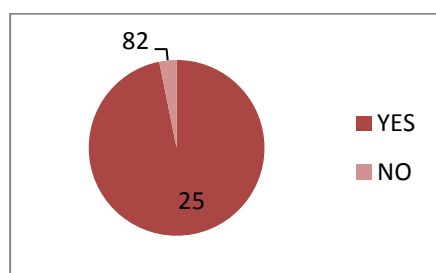


Figure 10: Reason for preference of Flavoxate (N=107)

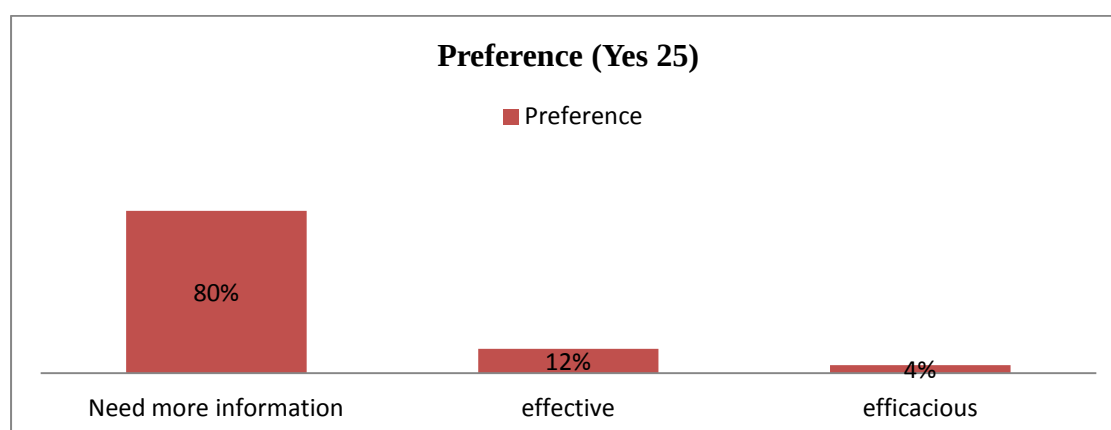
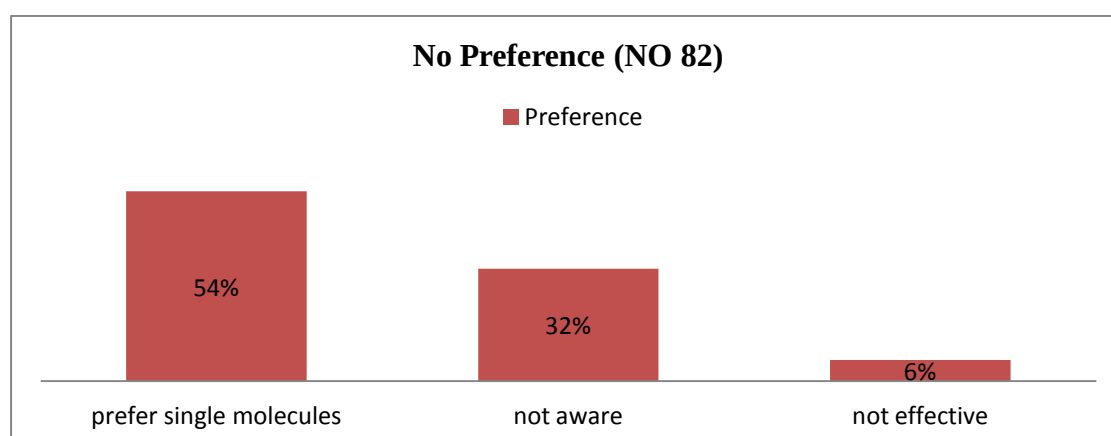


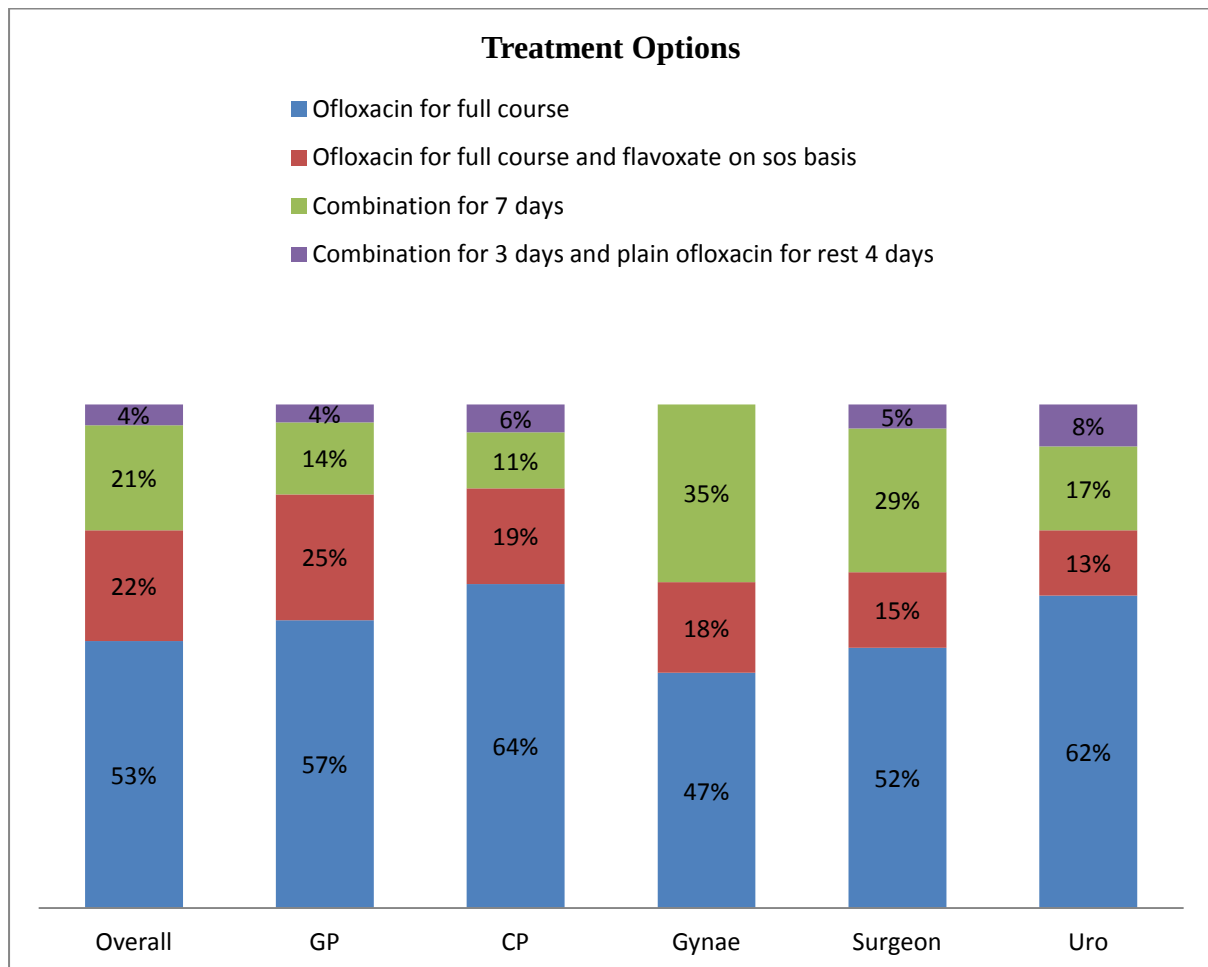
Figure 11: Reason for no preference for Flavoxate (N=107)



3.6 Available treatment Options

Nearly 50% of the doctors prefer using plain Ofloxacin as a treatment option for UTI + Spasm, but Co-Rx Flavoxate on SOS basis. Nearly 25% of the doctors prefer combination and out of which 21% prefer for full course.

Figure 12: Treatment options for UTI + Spasm



Recalling of Brands

Highest Top of Mind Recall & prescribed brand was Zenflox UTI followed by Product x, there is a need to create more awareness among the doctos regarding our product by doing rigours promotional activities by competitors product.

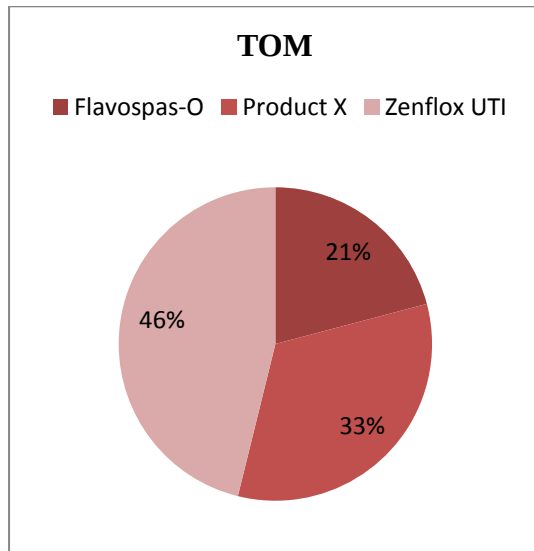


Figure 13: Top of mind recall

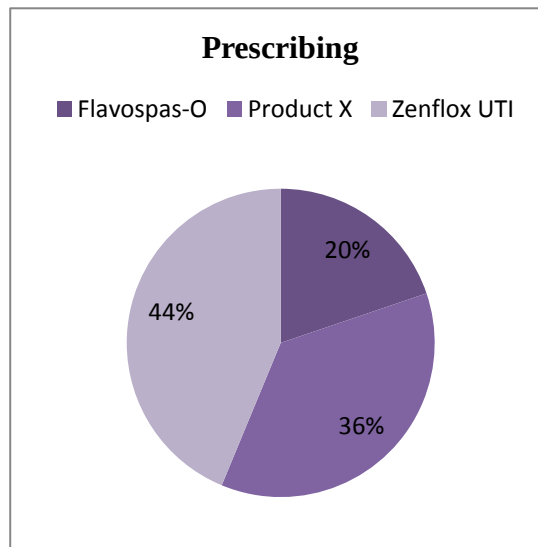
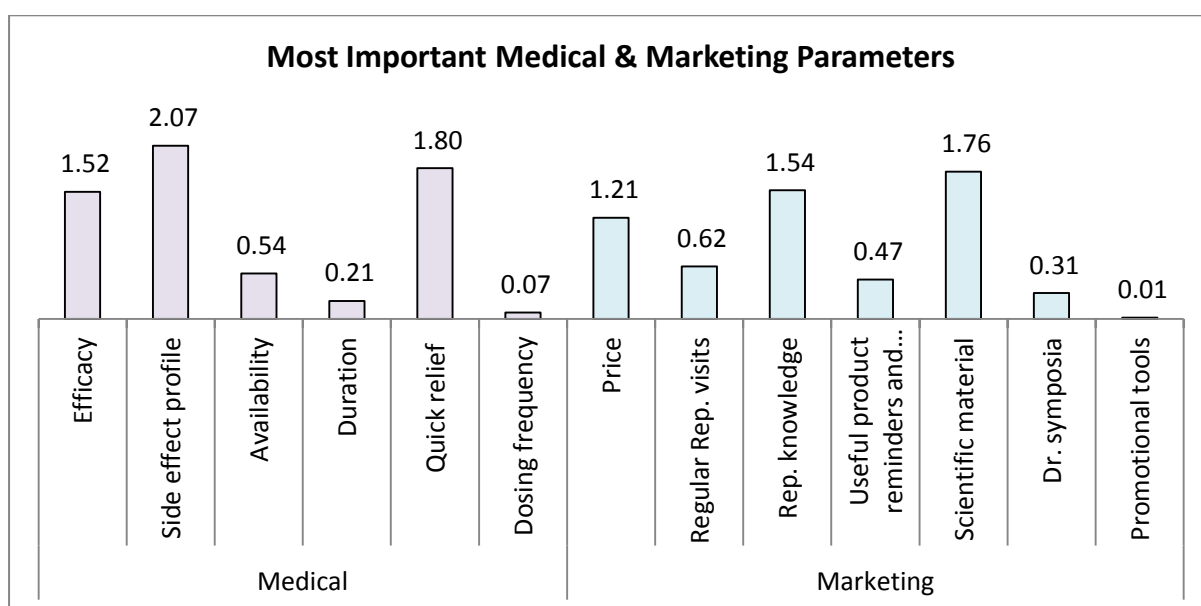


Figure 14: Prescribing Information

3.7 Medical and Marketing Parameters which influences doctors:

Most important factor while selecting a choice of treatment includes; Side effect profile followed by Quick relief & Efficacy whereas marketing factors having influence on the prescription behaviors of doctors includes scientific inputs followed by Rep. knowledge about the promoted brand and price.

Figure 15: Medical and Marketing Parameters



3.8 Promotional activities by the Company:

Table 5: Promotional activities by the Company

Promotional activities								
Brand	Samples	Scientific articles	Knowledge about the drug	Brand added tools	Regular rep. visits	Trends	No promotional activities	Total respondents
Flavospas – O	25%	25%	-	25%	-	-	25%	8
Product X	9%	54%	-	9%	14%	5%	9%	17
Zenflox UTI	10%	15%	5%	45%	10%	-	15%	18

4. Conclusion

- ✚ Nearly 75% of the patient for UTI is diagnosed with UTI + Spasm, moreover 64% of them are female and mostly falling within reproductive age group, therefore this is can be the target group.
- ✚ Ofloxacin and Norfloxacin the most preferred molecule for UTI whereas Flavoxate and Dicyclomine is preferred for UTI associated with spasm.
- ✚ Plain Ofloxacin 200 MG for 5-7 days is a choice of treatment, while Flavoxate in UTI + Spasm for 3-5 days is preferred choice of treatment in addition to Ofloxacin.
- ✚ 77% do not prefer Ofloxacin + Flavoxate combinations, while 23% will prefer Ofloxacin + Flavoxate combination but need more information, the reason behind no preference was lack of awareness, and therefore it should be taken into consideration.
- ✚ Most important factor while selecting a choice of treatment includes; Side effect profile followed by Quick relief & Efficacy
- ✚ Marketing factors having influence on the prescription behaviors' of doctors includes Scientific inputs followed by Rep knowledge about the promoted brand and price, as Marketing Representative plays a vital role for marketing of the product more focus should be given on their training.
- ✚ Zanocin F scores high of the most important factor having effect on the behaviors' of prescription i.e. scientific inputs. Competition scores high on Brand added tools and sampling about the combination.

5. Summer training learning's

- ✓ **Practical insights into Market Research**

Market Research is an integral part of any Pharmaceutical Company as it makes a company aware about its position in the market as well gives us critical insights into development of right strategies at right time.

- ✓ **Importance of Ethics in Corporate World**

Ethics is one of the important rules before conducting any research otherwise it is considered as a part of misconduct by the researcher.

- ✓ **Organizational Behavior**

This was one of the very good learning at Ranbaxy which helps me to understand psychology of the individuals within the organization and how to deal with the situation.

- ✓ **Learned interpersonal skills and Marketing skills**

Ranbaxy gave me great learning's about the soft skills of how to interact with the people, individually and in groups.

- ✓ **Proper management of resources**

Managing resources with limitation is very important such as time, money, manpower.

Annexure

Dear Doctor,

As a part of my curriculum I have been assign the project on ' To study the usage of Ofloxacin + Flavoxate combination in Spasm associated with UTI' so please spare your valuable time for few minutes with me and so this will help me for my study.

Respondent Details

Name:-	
Specialty:-	
City:-	
Years of Experiences	

1. Doctor, please tell me now in your clinical experience.

Parameters	Number of Patients
A. How many patients do you see in a day	
B. No. of UTI patients seen in a day	
C. Avg. no. of UTI patients associated with spasm do you see in a day	

2. Doctor, Of all the UTI patients with Spasm Problem that you treat, what would be the breakup of the same in terms of Age, Gender

Age	Proportion of Patients
Less than 12 years	
12 – 18 years	
19 – 40 years	
41 – 65 years	
Above 65 years	
Total	100%

Age	Proportion of Patients
Male	
Female	
Total	100%
Condition	Proportion of Patients
Female had Baby	
Pregnant Female	
Others	
Female total	100%

3. What is your line of treatment for UTI associated with the Spasm?

UTI	
- Procedure	
- Molecules	
- Dosage + Duration	
- Do you prefer Ofloxacin	
- Why?	
UTI + Spasm	
- All Patients / % patients	
- Difference in diagnosis	
- Molecules	
- Dosage + Duration	
- Do you prefer any combination of Ofloxacin + anti spasmotic	
- Why?	
Will you prefer any FDC	
Which drug you prefer as an FDC?	

Why?

4. Which is your most prescribed practice for the treatment of UTI associated with spasm patients?

- Prescribe only Ofloxacin for full course
- Prescribe Ofloxacin and Co-Rx Flavoxate or any other anti-spasmodic _____ for few initial days
- Prescribe Ofloxacin + Flavoxate FDC for all days
- Prescribe Ofloxacin plain for 2-3 days initially and Rx Ofloxacin + Flavoxate FDC for the rest of the days in a course of therapy
- Prescribe FDC for 2-3 days initially and plain ofloxacin for the rest of the days in a course of therapy

5. Reason to prefer the above option in Q.5? _____

6. Doctor, can you recall any brand name for Ofloxacin + Flavoxate currently prevailing in the Market? (Tick)

Brands	TOM	Spontaneous	Prompted	Ever Prescribed	Currently Prescribing	Most Often
	(Single response)	(Multiple responses)	(Multiple responses)	(Multiple responses)	(Multiple responses)	(Single response)
FLAVORIDE-PLUS	1	1	1	1	1	1
FLAVOSPAS-O	2	2	2	2	2	2
UROCONKIT	3	3	3	3	3	3
ZANOCIN-F	4	4	4	4	4	4
ZENFLOX-UTI	5	5	5	5	5	5
Others	6	6	6	6	6	6

7. Doctor, can you provide the reasons for prescribing _____ Most Often? (Name of Brand from Q8)

8. Doctor please ranks the following parameter from not at all important to extremely important?

Medical Parameters		Marketing Parameters	Not at all important
Efficacy		Price	
Side effect profile		Regular Rep. visits	
Availability		Rep. knowledge	
Duration		Useful product reminders and articles	
Quick relief		Scientific material	
Dosing frequency		Dr. symposia	
		Promotional tools	

9. In case you are prescribing both Ofloxacin plain + fixed dose combination for patients would you prefer same brand extension or switch to any other brand?

- Yes (Brand name & reason for same) _____
- No (Reason for same) _____

10. Doctor, Can you mention promotional activities done by the players with in Ofloxacin + Flavoxate, which made you prescribe the specific brand for UTI associated with Spasm?

FLAVORIDE-PLUS	FLAVOSPAS-O	UROCONKIT	ZANOCIN-F	ZENFLOX-UTI	Others

11. Doctor, According to you

Parameters	%
A. What is the incidence of UTI in India as a percentage to the total population?	
B. If UTI patient population taken as 100%, what % accounts for the UTI cases associated with spasm?	