

**Summer Training at
DelCure Lifesciences Limited, Pune**

**Market Analysis for Sales and Promotional Strategy For “Lactobacillus
Rhamnosus GG” in Kolkata**

**By
Dixsha Das**

**Under the guidance of
Dr. Saurabh Kumar**

**MBA Pharmaceutical Management
2017-2019**

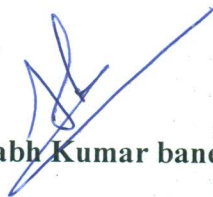

School of Pharmaceutical Management
**The IIHMR University, Jaipur
2018**

CERTIFICATE

This is to certify that **Ms. Dixsha Das** has undergone summer training at **Delcure Life sciences Ltd** on '**Market Analysis for sales and Promotional strategy for Lactobacillus Rhamnosus GG**' from 4th April 2018 to 4th June 2018.

The candidate herself completed the project assigned to her during summer training. Her approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management.

I wish her success in all her future endeavors.



Dr Saurabh Kumar Banerjee

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Pharmaceutical Management

DLL/HR/Certificate/Internship-2018

Date: 09th July, 2018

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Ms. Dixsha Das**, student of Master of Business Administration program of The IIHMR University, Jaipur, has successfully completed 8 weeks Summer Internship under the guidance of Mr. Ajinkya Dalal - Group Product Manager at Delcure Life Sciences Ltd.

During the period of training from **04th April 2018 to 04th June 2018**, Ms. Dixsha Das was found to be sincere, dedicated and committed.

We wish him the very best in all his future endeavours.

For DelCure LifeSciences Ltd.



Shirish Vankudre
GM - Human Resources

Acknowledgement

Having been exposed to a fair amount of theoretical concept, I was looking forward to get a firsthand experience of a business organization and try to relate what I am encouraged to do at Institute of Health Management Research, Jaipur.

I would like to thank to **Mr. P.K. Pathak, MD & CEO, DelCure Lifesciences Limited** for providing me an opportunity to learn and develop professionally.

My Acknowledgement is incomplete without heartfelt thanks to **Dr. Saurabh Banerjee**, Internal Project Guide for showing me the right direction in doing this project, Dr. sandeep narula as supervisor, **Mr. Bablu Modak** as area sales manager, **Mr. Ajinkya Dalal** , **Mr. Harishankar sahu** as product executive for supporting and helping me with their experience and knowledge and my father for mentoring me throughout everything.

I would like to give very special recognition to the countless other people who have been generous with their time, support & encouragement and have contributed to this project report in their own.

Thank you

Dixsha Das

MBAPM-09

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Company profile

DelCure LifeSciences Ltd. (DLL) is a full scale pharmaceutical company with an aim to bring differentiated high-quality products through international collaboration with innovator companies from the USA, Switzerland, and European countries. High quality products are assured from our manufacturing partner of high repute. DelCure Lifesciences Limited (DLL) is one of the fastest growing pharmaceutical companies in India. The Company, founded in 2013 by Mr. Prashant Kumar Pathak, the company has manufacturing collaboration with Akums Drugs & Pharmaceuticals, Internationally Recognized, WHO-GMP Certified units in oral solid dosage forms, hormonal preparations oral/ injectables & ointments, liquid orals, ointments and cosmetics, injectables, food supplements Nutraceuticals. DLL has a revenue of \$5.3 million and 56 employees. DelCure Lifesciences's main competitors are Celogen Pharma, Inventia Healthcare and Calyx. As of August 2017, DelCure Lifesciences has 35 fans on Facebook and 2.3K followers on Twitter.

DLL has two divisions which comprises various products and segments: -

First one is WinSpire- It is launched in June 2013 with 300 members in Pediatrics, ENT, and chest specialties. This Division has products with differentiated technology, “Fast Absol” in all Tablet range and “KuraFast” in all dispersible Tablets, which will lead to faster onset of action and thus faster relief.

Second one is Delvoice which is launched in August 2013. It is multispecialty division focus on Orthopedics, Gastroenterologists and Consulting Physicians.

Delvoice is credited in bringing innovative new products which are new to the country.

Vision:

To become the most respected, uniquely positioned leading pharmaceutical company in the chosen areas or specialty verticals in India and abroad with distinct value-based characteristics .

Purpose, Culture and Value at DelCure LifeSciences:

At DelCure LifeSciences, we strongly believe in promoting the purpose of Happiness and creating the culture of Helpfulness for DLL family members and the society, with the learning from Mother Nature, promoting sustainability and augmenting life with growth. We firmly believe in value of Truthfulness

The Visionary:

The company was envisioned by pharma veteran Mr. Prashant Kumar Pathak. An inspiring and visionary leader has approximately three decades of rich experience in pharmaceutical industry in Sales & Marketing, International Business, and Supply Chain Management & Operations. Mr. Pathak served as Chief Executive – Global Formulations with RPG Lifesciences and Senior Director – Sales & Marketing with Dr. Reddy's Laboratories.

He has well-rounded experience of running business arms in APAC, Central & Latin American countries & Africa. During his professional career he has managed large number of in licensing assignments and brought new products to India and has been instrumental in collaborating with institutions of repute in the country and USA.

Has been guide & mentor to many successful industry leaders and therefore, has created a highly competent top management team in DelCure Lifescience

INTRODUCTION

Diarrhea is the third leading cause of childhood mortality in India, killing an estimated 300,000 children each year.

- Average estimated incidence of diarrhea in children aged 0-6 years is 1.71 and 1.09 episodes/person/year in rural and urban areas, respectively.
- Total diarrheal deaths in India among children aged 0-6 years is estimated to be 158,209 and proportionate mortality due to diarrhea in this age-group is 9.1%

Lactobacillus rhamnosus GG is a bacteria that exists naturally in the body, primarily in the intestines. *Lactobacillus rhamnosus* GG has been used as a probiotic, or "friendly bacteria," to prevent the growth of harmful bacteria in the stomach and intestines.

Lactobacillus rhamnosus GG has been used in alternative medicine as a likely effective aid in treating or preventing diarrhea caused by rotavirus in babies and children.

This product has also been used as a possibly effective aid in treating colic in babies, and in preventing diarrhea in children that can occur while taking antibiotics.

- The ESPGHAN/ ESPID guidelines recommend the use of the specific probiotic strains, namely *Lactobacillus rhamnosus* GG (LGG) and *Saccharomyces boulardii*, for the management of children with acute gastroenteritis (AGE) as an adjunct to rehydration therapy.

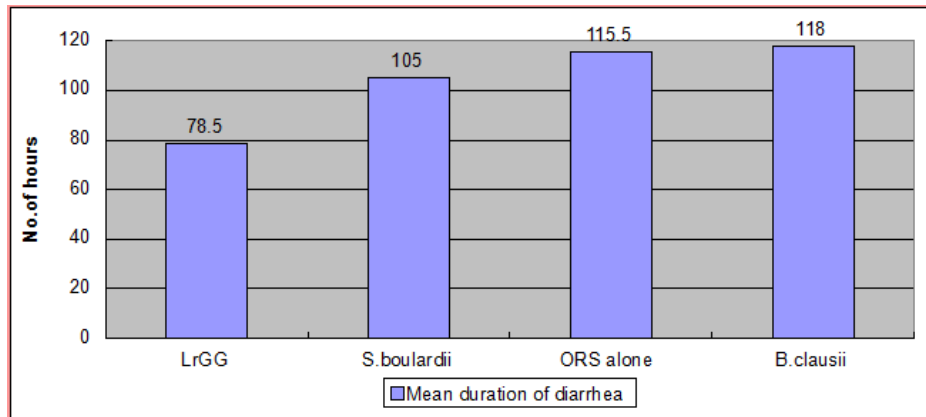


Figure: L.GG is associated with lower mean duration of diarrhea

(N= 571 children aged 3-36 months with acute diarrhea

Treatment: Children were randomized to receive ORS alone (control group); or *LrGG*; *S. boulardii*; *B. clausii*; probiotic mix.

Treatment period: 5 days.)

Research Questions

- What are the attributes of lactobacillus GG responsible for Prescribers?
- What is the market potential of preexisting probiotics in Kolkata?

Objectives

- To evaluate the Market Penetration for Lactobacillus rhamnosus GG.
- To analyse the competition scenario for Lactobacillus GG against the pre-existing probiotic in the market.
- To evaluate the views of Doctors regarding Lactobacillus rhamnosus GG

Methodology

Sample Design

The research conducted was descriptive (Cross-sectional)

Sampling Method

The sampling method was Non-Probability Sampling (convenience sampling)

Study Area

The study was carried out in Kolkata.

Sample population

It includes all doctors and Pharmacists

Sample size

Sample size for the study is 200:

Doctors: 100

Pharmacist: 100

Data collection

Primary and secondary data

Primary data- The primary data for this project was gathered through survey using questionnaire, face to face interview online format also.

Secondary data- The secondary data for this project was gathered through different dependable articles and research reports and data available in PMT Department.

Research Instrument(Tool and Techniques)

Research instrument is the semi-structured questionnaire consists of both type of open and close ended questions for both Pharmacist and doctors.

The information was collected by interviewing with doctors and Pharmacist.

Study Duration

2 months (4th april to 4th June)

LITERATURE REVIEW

1 Prevention OF Diarrhea By L.GG

In this issue of The Journal, Oberhelman et al¹ provide evidence that the probiotic, *Lactobacillus rhamnosus* strain GG, taken once a day, or 6 days per week, for 15 months reduced the occurrence of acute diarrhea in undernourished non-breast-fed infants 18 to 29 months of age in a poor peri-urban community of Lima, Peru. The effect was modest and not apparent in breast-fed infants or in those younger or older than 18 to 29 months of age. L-GG was occasionally transmitted from children exposed daily to it to family contacts. The efficiency of this spread was low and cannot be expected to contribute to community health when the preparation is administered

L-GG has been shown to shorten the illness observed with rotavirus-induced gastroenteritis in infants and children in an industrialized country,² and the preparation shortened nondysenteric watery diarrhea in children living in a developing region.³ In the study by Oberhelman et al,¹ there was no clear reduction in viral gastroenteritis in the L-GG-treated children. Enteric adenoviruses were more commonly identified in placebo-treated children than in L-GG-treated children, whereas rates of rotavirus detection did not differ significantly in the 2 treatment groups. There were slightly more rotavirus infections detected in the L-GG group than in the placebo group

2 L.GG AND ANTIOTIC ASSOCIATED DIARRHEA

Many antibiotics produce serious gastrointestinal side effects. Erythromycin, especially, is a frequent cause of such problems. In a study by Siitonen et al., (15,18) two groups of healthy volunteers took a moderate dose of erythromycin – 400 mg, three times daily for 7 days. One group received LGG-containing yogurt, while the control group was given conventional pasteurized yogurt. The number of daily bowel movements was fewer, the duration of diarrhea was shorter, and the frequency of stomach pain, abdominal pain, and nausea were significantly reduced in the LGG group. Fecal counts of LGG during erythromycin administration revealed that 75% of the volunteers had detectable levels of LGG despite the use of an antibiotic that is active against LGG in vitro. Several investigations are currently being conducted on childhood diarrhea in Europe and developing countries. The results that have been published thus far provide convincing evidence that LGG is beneficial in reducing the time-course and the symptoms of acute diarrhea in children

3 TREATMENT OF ACUTE CHILDHOOD DIARRHOEA BY L.GG

Randomized controlled trials in developed countries have reported benefits of *Lactobacillus* GG (LGG) in the treatment of acute watery diarrhoea, but there is paucity of such data from India. The study was aimed to evaluate the efficacy and safety of *Lactobacillus* GG in the treatment of acute diarrhoea in children from a semi-urban city in north India

METHODS

In this open labelled, randomized controlled trial 200 children with acute watery diarrhoea, aged between 6 months to 5 years visiting outpatient department and emergency room of a teaching hospital in north India were enrolled. The children were randomized into receiving either *Lactobacillus* GG in dose of 10 billion cfu/day for five days or no probiotic medication in addition to standard WHO management of diarrhoea. Primary outcomes were duration of diarrhoea and time to change in consistency of stools.

RESULT

Median (inter quartile range) duration of diarrhoea was significantly shorter in children in LGG group [60 (54-72) h vs. 78 (72-90) h; $P<0.001$]. Also, there was faster improvement in stool consistency in children receiving *Lactobacillus* GG than control group [36 (30-36) h vs. 42 (36-48) h; $P<0.001$]. There was significant reduction in average number of stools per day in LGG group ($P<0.001$) compared to the control group. These benefits were seen irrespective of rotavirus positivity in stool tests.

CONCLUSION

Our results showed that the use of *Lactobacillus* GG in children with acute diarrhoea resulted in shorter duration and faster improvement in stool consistency as compared to the control group

4 Functional Analysis of *Lactobacillus rhamnosus* GG Pili in Relation to Adhesion and Immunomodulatory Interactions with Intestinal Epithelial Cells

Lactobacillus rhamnosus GG, a probiotic with good survival capacity in the human gut, has well-documented adhesion properties and health effects. Recently, *spaCBA*-encoded pili that bind to human intestinal mucus were identified on its cell surface. Here, we report on the phenotypic analysis of a *spaCBA* pilus knockout mutant in comparison with the wild type and other adhesin mutants. The *SpaCBA* pilus of *L. rhamnosus* GG showed to be key for efficient adherence to the Caco-2 intestinal epithelial cell (IEC) line and biofilm formation. Moreover, the *spaCBA* mutant induces an elevated level of interleukin-8 (IL-8) mRNA in Caco-2 cells compared to the wild type, possibly involving an interaction of lipoteichoic acid with Toll-like receptor 2. In contrast, an *L. rhamnosus* GG mutant without exopolysaccharides but with an increased exposure of pili leads to the reduced expression of IL-8. Using Transwells to partition

bacteria from Caco-2 cells, IL-8 induction is blocked completely regardless of whether wild-type or mutant *L. rhamnosus* GG cells are used. Taken together, our data suggest that *L. rhamnosus* GG SpaCBA pili, while promoting strong adhesive interactions with IECs, have a functional role in balancing IL-8 mRNA expression induced by surface molecules such as lipoteichoic acid

Timeline

Process of Work	1 st schedule	2 nd schedule	3 rd schedule	4 th schedule	5 th schedule	6 th schedule	7 th schedule	8 th schedule
Reporting								
Training								
Project assigned								
Scholarly research								
Field study (Dr calls, chemist planning, RCPA)								
Data entry								
Analysis								
Conclusion/Report Submission								

DATA ANALYSIS (FINDINGS & INFERENCES)

Analysis of Doctors' views

Market scenario of Lactobacillus rahmnosus GG.

Preferred treatment of acute gastroenteritis & antibiotic associated diarrhea

It was found that approximately 36.36% in probiotics, 19.19%in rehydration salt and 44.44% both are preferred in the treatment of acute gastroenteritis and antibiotic associated diarrhea.

Table number as well as figure number provides a data of number of preferred of treatment and percentage of doctor's response in each array

SL NO.	PREFFERED TREATMENT	RESPONSE IN%
1	Probiotics	36.36%
2	Rehydration Salt	19.19%
3	Both	44.4%
TOTAL		100.00

Table 1: preferred treatment of acute gastroenteritis & antibiotic associated diarrhea

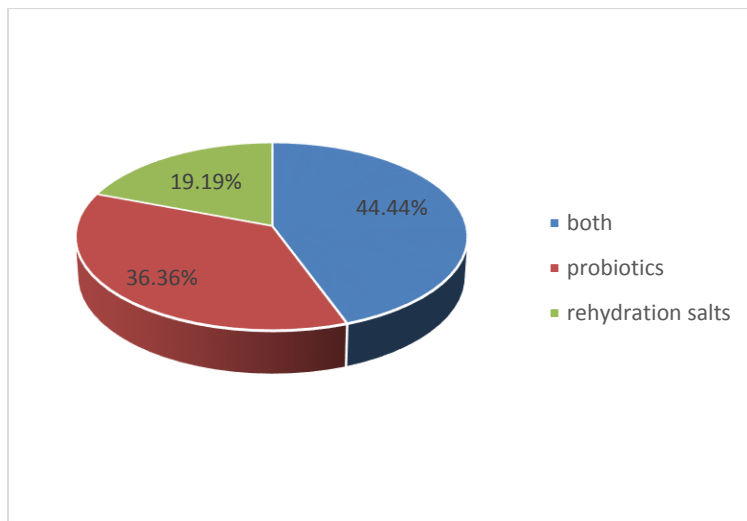


Figure 1: preferred treatment of acute gastroenteritis & antibiotic associated diarrhea

Is lactobacillus GG strain are more efficacious as compared to other probiotic strain?

It was found out that approximately 60% of doctors responded for the strain lactobacillus GG strain more efficacious when it is compared to other probiotic strain lactobacillus GG, Bifidobacterium bifidum, lactobacillus acidophilus, etc.

Table number as well as figure number provides a data of number of respondent by doctors and percentage of doctor's response in each array.

Table 2: Is lactobacillus GG strain are more efficacious as compared to other probiotic strain?

SL NO.	COUNT OF RESPONDENT	RESPONSE IN %
1	Yes	60%
2	No	40%
Total		100

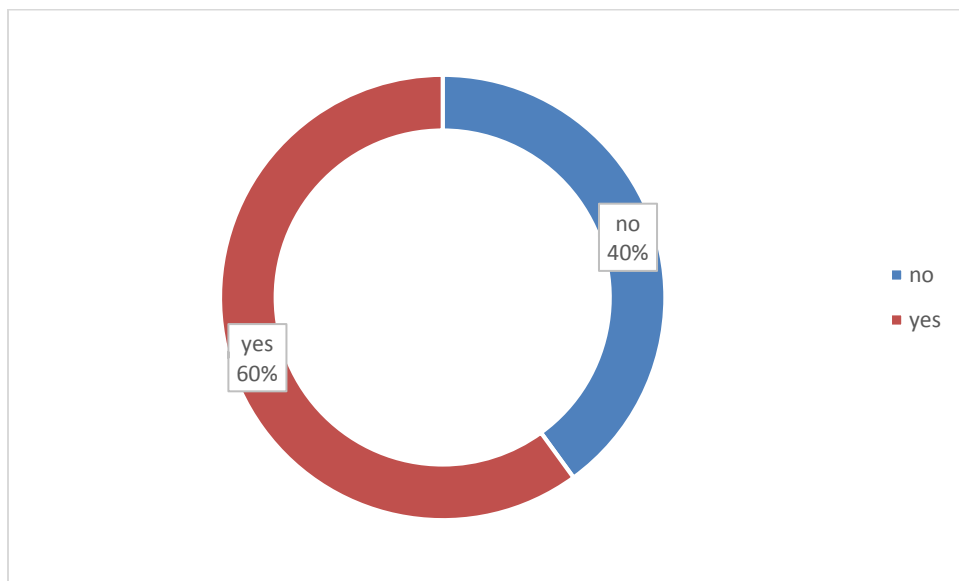


Figure2 Is lactobacillus GG strain are more efficacious as compared to other probiotic strain?

top 3 probiotic strains used by doctors in clinic practices

It was found out that approximately 42 in numbers out of 100 doctors preferred lactobacillus GG Strain as compared to other strain hence it is the most used strain.

“Table number as well as figure below number provides a data of Preferred strains of probiotics is been used by doctors and count of doctor’s response in each array.

SL NO.	STRAINS PREFFERED	COUNT OF RESPONSE
1	Lactobacillus GG	42
2	Lactobacillus acidophilus	19
3	Bifidobacterium bifidum	39
Total		100

Table 3: top 3 probiotic strains used by doctors in clinic practices

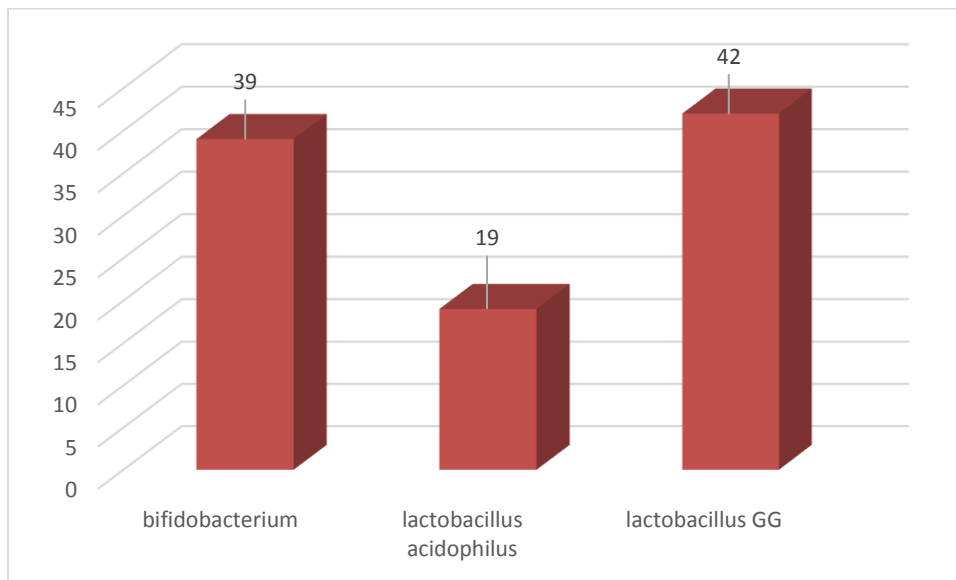


Figure 3: top 3 probiotic strains used by doctors in clinic practices

Lactobacillus GG is most widely researched strain

It was found that approximately 54% of doctors agreed that lactobacillus GG is most researched strain and hence efficacious.

Table number as well as below figure number provides a data of percentage of lactobacillus GG response in each array.

SL NO.	Is Lactobacillus GG widely researched?	Response in %
1	Strongly agree	27%
2	Agree	27%
3	Neutral	26%
4	Disagree	20%
Total		100%

Table 4: Lactobacillus GG is most widely researched strain

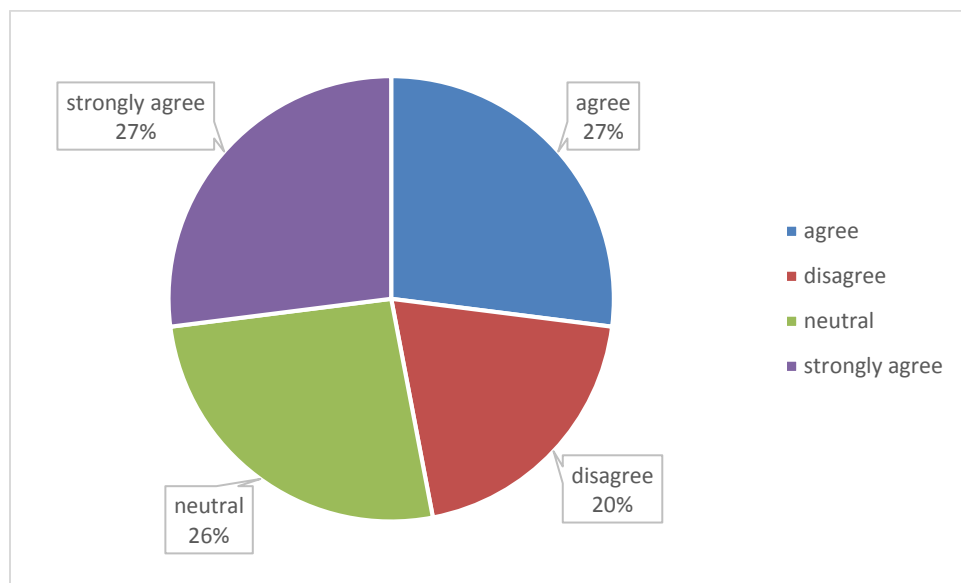


Figure 4: Lactobacillus GG is most widely researched strain

Activities which will influence Rx Lactobacillus rhamnosus GG

It was found out that of 100 doctors 26 in no. preferred activities like in clinic gimmick, 28 in no. Moa video, 20 in no. scientific leave behind literature, 26 in no. social media platform can be used to influence Rx the lactobacillus rhamnosus GG.

Table number as well as figure below number provides a data of activities influence the Rx of L.GG is been preferred by doctor's response in each array.

SL NO.	Activities	Count of respondent
1	In clinic gimmick activity	26
2	Moa video	28
3	Scientific leave behind literature	20
4	Social media platform	26
Total		100

Table 5: Activities which will influence Rx Lactobacillus rhamnosus GG

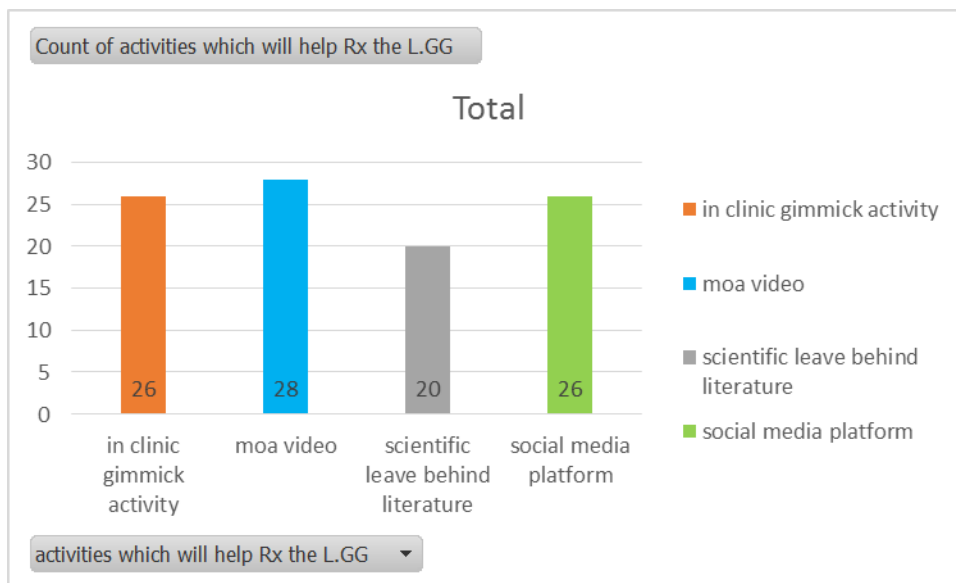


Figure 5: Activities which will influence Rx Lactobacillus rhamnosus GG

Attributes which influence Rx

It was found out that of 100 doctors 38 in no. preferred attributes like in efficacy, 32 in no. safety of molecule, 19 in no. research & scientific points, 11 in field force with equity can be used to influence Rx the lactobacillus rhamnosus GG.

Table number as well as figure below number provides a data of attributes which influence the Rx of L.GG is been preferred by doctor's response in each array.

SL NO.	Attributes	Count of respondent
1	safety of molecule	32
2	Research & scientific points	19
3	Field force with equity	11
4	Efficacy	38
Total		100

Table 6: Attributes which will influence Rx Lactobacillus rhamnosus GG

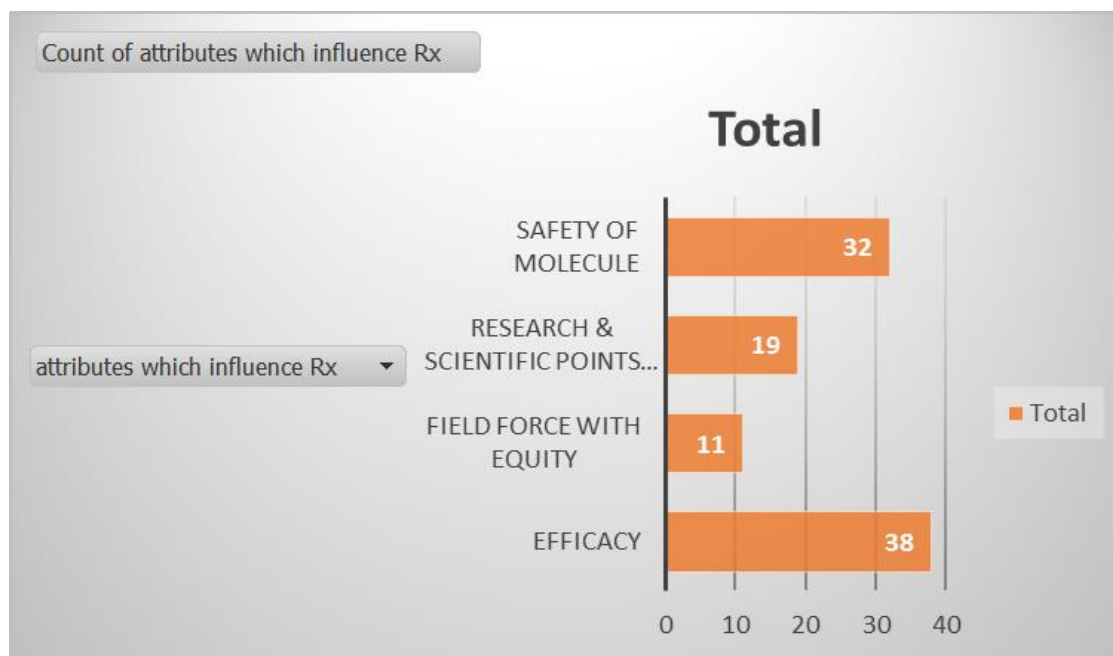


Figure 6: Attributes which will influence Rx Lactobacillus rhamnosus GG

CHEMIST FINDINGS

Sales per month of L.GG Molecule

It was found out that approximately 172 of capsules/sachets/tablets of enteroplus, 160 in no. of unobiotic, 122 in no. superfloara GG are sold per month to customers.

Table number as well as figure below number provides a data of SALES PER MONTH in each array.

Name of the company	Product or brand name	Sale per month (capsule/sachet/tablet)
GSK	enteroplus	172
Cipla	unobiotic	160
Sundyota	Superfloara GG	122

Table 1: Sale per month of L.GG Molecule

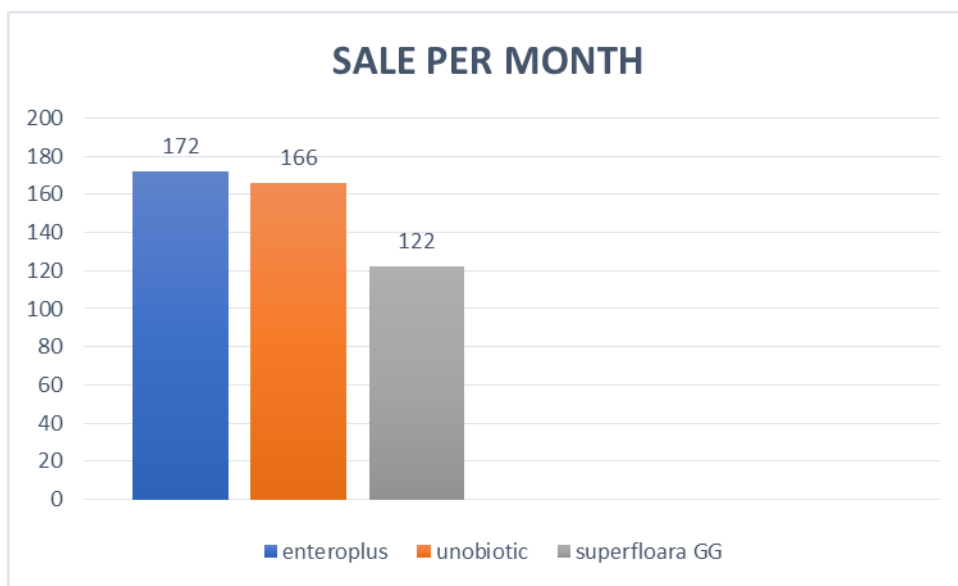


Figure 1: Sale per month of L.GG Molecule

Stock per month of L.GG Molecule

It was found out that approximately 233, 213 ,179 boxes of enteroplus, unobiotic, superfloara GG respectively kept in stock of pharmacies per month.

Table number as well as figure below number provides a data of Stocks per month in each array.

SL NO.	BRAND NAME	Stock in BOX
1	Enteroplus	233
2	Unobiotic	213
3	Superfloara GG	179

Table 2: Stock per month of L.GG Molecule

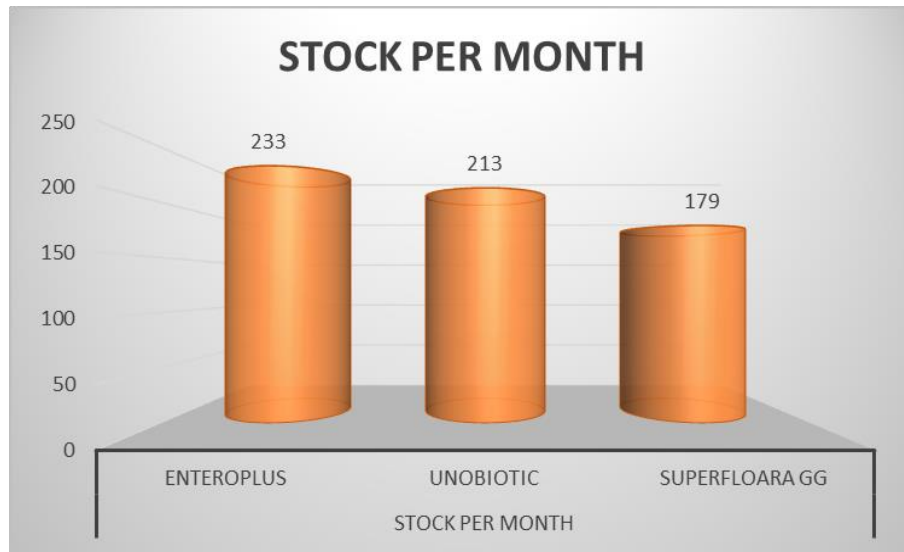


Figure 2: Stock per month of L.GG Molecule

prescription generated per month (RCPA)

It was found out that nearly 52, 46, 26 in no.of enteroplus, unobiotic, superfloara GG Respectively Rx are generated hence prescribed by the doctors via RCPA.

Table number as well as figure below provides a data of Rx generated in no. via RCPA response in each array.

SL NO.	BRANDS	Rx in no.
1	enteroplus	52
2	unobiotic	46
3	Superfloara GG	26

Table 3 : prescription generated per month

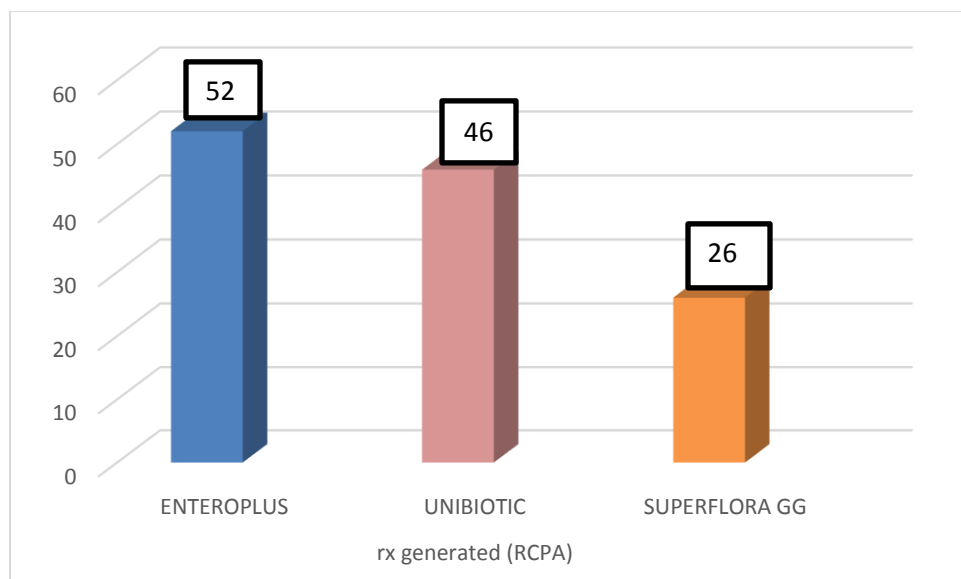


Figure 3: prescription generated per month

Findings based on observation & key opinions

- ❖ Number of Doctors prescribing Probiotics (L.GG) is increasing exponentially .
- ❖ According to the doctors Influence of Prescription of L.GG depends on activity like MOA videos
- ❖ According to some doctors prescription trend never residues equal, it keeps on changing as per Product being Promoted effectively
- ❖ Market is captured by enteroplus by GSK in L.GG as probiotic.
- ❖ Availability of these brands especially unobiotic and superfloara GG t is the major issue, so it can be substituted.

CONCLUSION

1. As Enteroplus by GSK has highest volume in sales as well as in prescription and unobiotic by Cipla and Superfloaraa GG by sundyota has moderate sales especially in the outer regions of Kolkata and in addition these two product's availability is less as compared to enteroplus which states that availability of your product in the market makes foundation as substitution and hence can be successfully launched as the competition is little low.
2. Many factors can influence to Rx the lactobacillus rhamnosus GG like short clippings of MOA videos, clinic gimmick activities. doctors also says efficacy and safety of the molecule is most important to them. As L.GG strain is now being most researched and prescribed strains as compared to others

Suggestions

1 As the intensity of diarrhoea is increasing in India so according to study the use of *Lactobacillus* GG in children with acute diarrhoea resulted in shorter duration and faster improvement in stool consistency and also *Lactobacillus rhamnosus* GG, a probiotic with good survival capacity in the human gut, has well-documented adhesion properties as compared to other strains.

2 The competitors have not captured the market fully especially in kolkata i.e unobiotic by Cipla and superfloara GG by sundyota, the main drawback is availability and rigorous brand promotion hence launching of your product can be a future market driver if focus on the loopholes.

3 During the study it was found that there is lack of technical knowledge like MOA and communication skill. For awareness of a particular product among doctors, company's sales representatives should know MOA and need of enhancement of better communication skill.

Limitations

- 1) Sample unit are limited for survey, it affect the accuracy of outcomes.
- 2) Survey was carried out in one region only (kolkata).
- 3) Time duration of the survey did not allow collecting more data.
- 4) The respondents were very busy and could not afford more time to answer.

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