Summer Training at
Bioplasma Immunologicals Research Pvt. Ltd.,
Gurgaon
(April 09 - May 26, 2012)

Sales and Availability of Different Brands of Bioplasma in Gurgaon

By
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Under the guidance of
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Post Graduate Diploma in Pharmaceutical Management
2011-2013

Institute of Health Management Research,
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Certificate

This is to certify that Amit Sheoran from Institute of Health Management Research, Jaipur has undergone Summer Training at Bioplasma Immunologicals Research Pvt. Ltd, Gurgaon. 9 April, 2012 to 26 May, 2012.

The candidate himself carried out the project. His approach to the study has been sincere, scientific and analytical. This summer training is partial fulfillment of the course requirement is recommended for the award of post graduate diploma in Pharmaceutical Management.

I wish him success in all his future endeavors.

Dr. P.R. Sodani
Dean (Academic and Students Affairs)
IHMR, Jaipur

Dr. Nutan Jain
Professor,
IHMR, Jaipur

LV Bioplasma Immunologicals Research Pvt. Ltd.

(Working with Nature through Bio-Technology for Healthy Life)

From the Desk of:
Manager Corporate

Date: 26/05/2012
Ref: 25/SS01/LVBIR

To Whom It May Concern

This is certify that **Mr. Amit Sheoran** has completed the training from 9th April 2012 to 26th May 2012 under **Mr. Ashish Sharma** and successfully submitted the project report as this training is a part of his course curriculum at **Indian Institute of Health Management Research Jaipur**. His area of training was marketing product management and market research. He is efficient and enthusiastic for his Work n is a good team member and bears a good character.

We wish him a great success in all his future Endeavour

With Warm Regards

Sandeep Kumar

Manager Corporate
LV) Bioplasma Immunologicals Research Pvt. Ltd

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Finally, yet importantly, I would like to express my thanks to my parents for their blessings, my friends/classmates for their help and wishes for the successful completion of this project.

AMIT SHEORAN

PGDPM – 03

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Section - 1

INTRODUCTION OF PHARMACEUTICAL INDUSTRY

PHARMACEUTICAL INDUSTRY OVERVIEW

The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. Accounting for two percent of the world's pharmaceutical market, the Indian pharmaceutical sector has an estimated market value of about US $8 billion. It's at 4th rank in terms of total pharmaceutical production and 13th in terms of value.

It is growing at an average rate of 7.2 % and is expected to grow to US $12 billion by 2011. Over the last two years the pharmaceutical market value has increased to about US $ 355 million because of the launch of new products. According to an estimate, 3900 new generic products have been launched in the past two years. These have been by and large launched by big brands in the pharma sector. And in the year 2005 Indian pharmaceutical companies captured around 70% of the domestic market.

Earlier these big firms had apprehensions in launching new drugs in the Indian market. As in the present scenario, only a few people can afford costly drugs, which have increased price sensitivity in the pharmaceutical market. Now the companies are trying to capture the market by introducing high quality and low price medicines and drugs. With the Product Patent Act, which came into action in January 2005, this industry is able to attract big MNCs to India

At present, a large number of Indian pharmaceuticals companies are looking for tie-ups with foreign firms for in-license drugs. GlaxoSmithKline is among the top choices for the firms that wish to launch their product in India, but do not have any branch over here. Contract research and pharmaceutical outsourcing are the new avenues in the pharmaceutical market. Contract manufacturing is growing at a very fast pace and is estimated to grow to US $30billion, whereas contract research is estimated to reach US$6-10 billion.

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.

Table 1.1: Top 10 pharmaceutical companies in India by their rank, as of 2010

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

CURRENT TRENDS AND SCENARIO:

The global pharmaceutical market in 2012 is expected to grow by 8.6 percent and will reach at a level of $990 billion USD, driven by stronger near-term growth in the US market. In 2011, the pharmaceutical market has grown meager to 5.1 percent with market size of $920 billion USD. With the global pharmaceutical market registering sluggish growth (4-6%) multinational companies have shifted their attention on emerging markets like India, China Brazil and other emerging market which grow at double digit rate of round 13-15% in 2011. Economic growth increasing healthcare expenditure and improved intellectual property frame work has made these emerging countries as attractive destination.

Currently, the global pharmaceutical market is dominated by US, which accounts for about 28 percent of global sales in 2009 followed by the EU accounting for roughly 15 percent and Japan accounting for 12 percent. Together, these three regions represent nearly 55 percent of the global market.

Due to much patent expiration and rising cost pressure on healthcare, the generic drug industry has experienced great growth in the past few years. The global market for generic drugs was worth $107.8 billion USD in 2009 and is projected to reach $129.3 billion USD by 2014 with a CAGR of 9 percent. Generic drugs cost 30 to 80 percent less than their original equivalents this lead to emergence of Highly Competitive generic Market in Pharmaceutical industry.

According to MC Kinsey Report –India pharma 2015: unlocking the potential of Indian pharmaceutical market, multinational company have been vying for a piece of this pies for some time now, but India represents ,myriad of challenges and it differ greatly from developed market. Apart from this, India has highest number of USFDA compliant manufacturing units (outside the US) to produce huge quantities of bulk drugs and formulation products complying stringent quality norms for global pharmaceutical companies, thus Indian companies have huge opportunity to export their quality driven low cast generic product.

KEY FACTS AND FIGURE:

1. Global pharmaceutical market is expected to grow with 8.6% and reached at level of $990 billion USD by 2012.
2. Generic industry is projected to reach at $129.3 billion USD by 2014 with CAGR of 9.5%.
3. Global pharma market is expected to expand $1.1 trillion USD by 2014.
4. During the next five-year period (2010- 2014), the revenues of drugs having patents that will expire are about $89.5 billion USD.
5. Through 2015, biologic drugs worth more than $80 billion USD in global sales will lose patent protection, presenting a major opportunity.
6. Spending on medicines will reach nearly $1,100Bn in 2015, reflecting a slowing growth rate of 3-6% over the five year period compared to 6.2% annual growth over the past five years.
7. McKinsey & Company's report, "India Pharma 2020: Propelling access and acceptance, realizing true potential," predicted that the Indian pharmaceuticals market will grow to US$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach US$70 billion by 2020.
8. The global pharma market is in its transformation phase, with its focus changing from a blockbuster to a healthy outcome-based approach.
9. The growth of these markets is expected to lead to a new world order in the pharma industry. Global Over the counter (OTC) market is expected to revenue of $78.5bn by 2015.(kaloroma)
10. China has emerged as the leading emerging market, with Brazil, India and Russia featuring in the next tier of emerging markets.

Section - 2

INTRODUCTION OF ORGANIZATION

BIOPLASMA IMMUNOLOGICALS RESEARCH PVT.LTD.

Bioplasma Immunologicals Research (P) Ltd. (working with Nature through Biotechnology for healthy life) is a part of fastest growing biotech industry of 2000 cr. group of India & accounts for about 70% of market share in vaccines, therapeutics, diagnostics & animal health care - now striving towards excellence in the segment of nuessential vitamins & part of vitamin market which accounts for 35% share of drugs worldwide.Bioplasma Immunologicals Research offers : The ultimate biological active coenzyme form of vitamin B12. Having launched its flagship brands 1st time in Asia i.e., adenosyl, lycovit, bio-immune and AAMEE-1 has a strong presence in major states in India and now exploring international markets.

Bioplasma's manufacturing alliance is committed to quality manufacturing standards; thus rigid testing is conducted for every phase of manufacturing from raw material to finish products to ensure that all products comply with high quality standards.

Bioplasma utilizes the experience of some of the world's best qualified scientists, health advisors, product formulators and product manufacturers in order to research and produce the most appropriate patent and off patent affordable products. Bioplasma utilizes the experience of some of the world's best qualified scientists, health advisors, product formulators and product manufacturers in order to research and produce the most appropriate patent and off patent affordable products.

BASIC INFORMATION:

Legal Representative / CEO: Mr. Lalit Virmani

Business Type: Distributors/Wholesalers

Year Established: 2004

Objective of the company:

According to the website of the organization "We cannot grow all alone when you are growing. You have to take your associates with you in order to make institution where in time to come we all get the dividends".

PRODUCTS:

- Adenosyl – OD : Coenzyme form of vitamin B -12.
- Lycovit : Antidisease formula biological significance in human defence system.
- AAMEE -1 : World's most safest mood elevator [anti-depressant].
- Bio-immune : A strategy for acceleration of progress in combating vitamins deficiency.
- Thio-XL : Muscle relaxant , anti-inflammatory , analgesic , anaesthetic.
- UB-10 : Co-enzyme Q10
- Obfree : anti-obesity drug.
- Preimmune Cap./Sachet
- Biocital
- Premet
- 3-EFA
- Axanthine
- Ewioc
- D3

Section - 3

BACKGROUND OF PROJECTS

This Summer Training Report Consist of two Projects:

- The first project entitled as **"Comparative study between Adenosylcobalamin and Methylcobalamin".**
- The second project entitled as **"Sales & Availability of different brands of company in Gurgaon"**. This project was done to analyze and interpret in-depth study to availability, sales, major selling products in market of Gurgaon.

Project -1

Comparative study between Adenosylcobalamin and Methylcobalamin.

INTRODUCTION:

Vitamin B_{12} also called cobalamin, is a water-soluble vitamin with a key role in the normal functioning of the brain and nervous system, and for the formation of blood. It is essential for DNA synthesis, fatty acid synthesis, production of the mood-affecting substance SAMe (S-adenosyl-L-methionine) and cellular metabolism. Vitamin B12 is not synthesized in the human body. It is synthesized by certain bacteria, in particular those found in the digestive system of ruminant animals. It is the largest and most structurally complicated vitamin and can be produced industrially only through bacterial fermentation-synthesis.

Forms of B12

Vitamin B12 exists in several chemical forms. A synthetic form, cyanocobalamin, is commonly used in pharmaceutical products and nutritional supplements. The human body is capable of converting the synthetic form into the biologically active natural forms methylcobalamin and adenosylcobalamin.

Commercialization of Cobalamins :

1948 – Cyanocobalamin, 1971 to 2000 – Hydroxycobalamin, 2001 onwards Methylcobalamin, 2003 onwards Adenosylcobalamin.

Scientific Analysis :

Human vitamin B12 requirement have been estimated from 3 different type of studies. Year 1991 – Ellenbogen & Cooper. Year 2002 – Baik & Russel [Vitamin B12 deficiency effects 20% of peopleover 60s]. 23 developing topical countries in Latin America and Asia have noted cobalamin deficiency.

Comparative study between methylcobalamin and adenosylcobalamin :

Although the basic cobalamin molecule is only synthesized by microorganisms, all mammalian cells can convert this into the coenzymes adenosylcobalamin and methylcobalamin.

Adenosylcobalamin is the major form in cellular tissues, where it is retained in the mitochondria. Methylcobalamin predominates in blood plasma and certain other body fluids, and in cells is found in the cytosol. Adenosylcobalamin functions in reactions in which hydrogen groups and organic groups exchange places.

The vitamin B12-transcobalamin II complex is degraded intracellularly via lysosomal proteases to yield cobalamin (cyanocobalamin, methylcobalamin, adenosylcobalamin, hy-droxocobalamin). Cobalamin is metabolized to methylcobalamin in the cytosol and to adenosylcobalamin in the mitochondria. Methylcobalamin is the principal circulating form of cobalamin. Adenosylcobalamin comprises more than 70% of cobalamin in the liver, erythrocytes, kidney and brain. The total body content of cobalamin ranges from two to three milligrams, with approximately 50% of it residing in the liver.

While methylcobalamin is active immediately upon absorption, cyanocobalamin must be converted by the body to either methylcobalamin or adenosylcobalamin by removing the cyanide molecule (the amount of cyanide produced in this process is extremely small) and adding either a methyl or adenosyl group.

Table : Conditions Reported to Improve by Coenzyme Forms of B12

Conditions Reported to Improve by Coenzyme Forms of B12		
	Therapeutic dose recommended by Kelly	Conditions reported to improve from treatment[3,A]
Methylcobalamin	1500-6000 µg/day	Diabetic neuropathy Infertility Hyperhomocysteinemia in diabetes Sleep disorders[B] Bell's Palsy
Adenosylcobalamin, aka: 5'-deoxyadenosylcobalamin, dibencozide, coenzyme B12, cobamamide, and cobinamide	1000-6000 µg/day	Neurological problems secondary to anorexia Hepatitis A Viral hepatitis[B]
A - In many cases, treatment was not compared to cyanocobalamin B - More effective than cyanocobalamin		

Methylcobalamin:

Some of the disorders that may be preventable or treatable with this vitamin therapy, including chronic fatigue syndrome, Parkinson's disease, peripheral neuropathies, Alzheimer's disease, muscular dystrophy and neurological aging.

Published studies show that high doses of methylcobalamin are needed to regenerate neurons as well as the myelin sheath that protects nerve axons and peripheral nerves.

The chemical name for methylcobalamin is *Co*α-[α-(5,6-dimethylbenz-1*H*-imidazolyl)]-*Co*β-methylcobamide. Synonyms and trade names are mecobalamin, methylcobalamin, cobaltmethylcobalamin, Algobaz and Cobamet.
The molecular formula is C63H91CoN13O14P and its molecular weight is 1344.4 g/mol.

CFIDS and B-12
In the Summer 1998 issue of Health*Watch*, an important research article reported a fascinating new finding. Over 60% of CFIDS and FM patients' cerebral spinal fluids contained subnormal levels of vitamin B-12. On the other hand, vitamin B-12 levels in the blood did not significantly deviate from normal ranges.

According to Dr. Paul Cheney's treatment pyramid for CFIDS, vitamin B-12 in its non-cyanocobalamin form – the commercially available - is a potent detoxifier of the brain. Recent studies in Europe suggest that it needs to be given in large doses in the range of 10 - 20 mg per day, or even more. This supplementation of methylcobalamin might protect the cognitive function of patients with CFIDS by preventing the death of brain cells.

One cause of brain cell death is glutamate toxicity. Brain cells use glutamate as a neurotransmitter, but unfortunately glutamate is a double-edged sword in that it can also kill brain cells. The release of glutamate from the synapses is a usual means by which neurons communicate with each other.

Effective communication means controlled release of glutamate at the right time to the right cells, but when glutamate is released in excessive amounts, intercellular communication ceases. The flood of glutamate into the receiving neurons drives them into hyperactivity, and the excessive activity leads to cellular degradation.

The good news is that it may now be possible to protect brain cells against glutamate toxicity by taking methylcobalamin supplementation. In a study in the *European Journal of Pharmacology*, it was shown that methylcobalamin protected against glutamate-, aspartate- and nitroprusside- induced neurotoxicity in

rat cortical neurons.

Researchers concluded that methylcobalamin protects against neurotoxicity by enhancing brain cell methylation. The CFIDS & Fibromyalgia Health Resource recommends methylation-enhancing therapies such as vitamin B6, vitamin B-12, folic acid and trimethylglycine (TMG), taken together, to protect against heart disease, stroke and other aging-related diseases.

The scientists who conducted the methylcobalamin studies emphasize that ongoing intake of methylcobalamin is necessary to protect against neurotoxicity. Thus for methylcobalamin to be effective in protecting against neurological disease, daily supplementation may be required.

An appropriate dose to protect against neurological aging might be 1 to 5 mg a day taken under the tongue in lozenge form.

The effects of methylcobalamin on human immune function was investigated in the *Journal of Clinical Immunology*. The study showed that methylcobalamin demonstrated remarkable T cell-enhancing effects when the T cells were exposed to certain antigens.

The scientists also showed that methylcobalamin improved the activity of T helper cells. The scientists concluded that methylcobalamin could modulate lymphocyte function by augmenting regulatory T cell activities.
Methylcobalamin should be considered for the treatment of any neurological disease. For example, based on its unique mechanisms of action, methylcobalamin could be effective in slowing the progression of "untreatable" diseases such as ALS (Lou Gerhig's disease).

Since methylcobalamin is not a drug, there is little economic incentive to conduct expensive clinical studies on it, so it may be a long time before we know just how effective this unique form of vitamin B-12 is in slowing the progression of common diseases like Parkinson's disease.

The sublingual intake of methylcobalamin is an affordable and effective natural therapy, and has proven even safe when given in large doses.

Adenosylcobalamin :

The full name of 5'-deoxyadenosylcobalamin is 5,6-dimethylbenzimidazolylcobamide-5'-deoxyadenosine. Synonyms and trade names are adenosylcobalamin, dibencozide, cobamide, and Coenzyme B12.

The molecular formula is C72H100CoN18O17P and its molecular weight is 1579.6 g/mol. 5'-Deoxyadenosylcobalamin is a naturally occurring coenzyme form of vitamin B12 and is commonly present in the human diet (organ meats, fish, eggs and dairy products). This coenzyme form bypasses the body's need to synthesize the active form of vitamin B12 from cyano- or hydroxycobalamin. 5'-Deoxyadenosylcobalamin is the predominant form of vitamin B12 in human tissues (up to 70%) (Castle and Hale, 1998).

Adenosylcobalamin is one of the two active forms of vitamin B12. It plays an essential role in the production of blood and the maintenance of normal cerebral and nervous functioning in the human body. Also known as cobamamide or dibencozide, adenosylcobalamin occurs naturally in animal derived food types such as fish, meat, eggs, and milk. Vitamin B12 is synthesized commercially for use as a dietary supplement by a process of bacterial enzyme production. A deficiency of adenosylcobalamin can cause a variety of disorders in humans including pernicious anemia, infections, fatigue, and depression.

Vitamin B12 is actively present in the human body in the form of adenosylcobalamin and methylcobalamin. This complex vitamin is an important dietary component and plays an critical role in several essential biological functions. These include cellular metabolism, DNA synthesis, energy and blood production, fatty acid synthesis, and healthy brain and nervous system functioning. Adenosylcobalamin occurs naturally in a number of food types derived from animals such as eggs, milk, meat, and fish. Synthetic forms of the vitamin are produced from bacterial enzymes and include cyanocobalamin and hydroxocobalamin.

Manufacturing Process:

Adenosylcobalamin

5'-Deoxyadenosylcobalamin is prepared from vitamin B12 obtained from a fermentation process using a basis of beet molasses and mineral salts. The petitioner indicates that vitamin B12 should be stored in the dark.

Methylcobalamin

The petitioner indicates that methylcobalamin may be manufactured semi-synthetically following extraction of vitamin B12 from animal material. The petitioner states that alternatively, it may be produced from Genetically Modified Micro-organisms (GMMs). However this source is not part of the present opinion because it would require a separate submission under Regulation no1829/2003 (EC, 2003).

The second petitioner for methylcobalamin indicates that the manufacturing process comprises three steps which are described in detail and include preparation of methylcobalamin from vitamin B12, followed by chromatographic purification and crystallization of methylcobalamin. Because methylcobalamin is highly labile upon exposure to light the whole manufacturing process and the analytical controls require an effective protection from light.

Case of need and intended levels of use:

Methylcobalamin

It is intended to be used in food supplements, e.g. in capsules, tablets, ampoules or powders at a proposed level of use of 2 µg /day.

Adenosylcobalamin

The petitioner proposes to use 5'-deoxyadenosylcobalamin in food supplement capsules or tablets at use levels up to maximum 500 µg 5'-deoxyadenosylcobalamin daily.

Project 2

To study Sales & Availability of different brands of company in Gurgaon.

Objective:

- To study the Availability of different brands of Bioplasma in Gurgaon.
- To findout the sales of different brands of Bioplasma in Gurgaon.

Study area: Gurgaon , Haryana.

Target area: Secor – 4 , 7 , 14 , 15 , 17 , 21 , 22 , 23 , 30 , 31 , 40, South city – 1 & 2, Super mart – 1 & 2, Galleria & Vayapaar kunj, DLF Phase – 1 & 2, Old railway road & New railway road, Khandsa road, Jhadsa road.

Type of research: Cross sectional.

Sample Size: 150 Stockiest / Chemists.

Sampling method: Purposive Sampling.

Duration: 9th April to 5th May 2012.

Method of Data collection: Interview.

Data collection tool: Interview schedule.

Sampling:

Area	Proposed Sample of stockiest and distributors	Actual Sample of respondents Covered
South City - 1 & 2	15	10
Super Mart 1 & 2	10	6
DLF Phase – 1 & 2	20	14
Sector – 15	15	9
Sector – 17	15	8
Sector – 21	15	8
Sector – 22	15	8
Sector – 23	10	7
Sector – 30	15	6
Sector – 31	15	9
Sector – 40	15	8
Sector – 4	10	5
Sector – 7	10	6
Sector – 14	20	11
Khanda Road	20	10
Jhadsa Road	20	9
Galleria & Vayapar kunj	15	7
Old Railway Rd. & New Railway Rd.	20	9

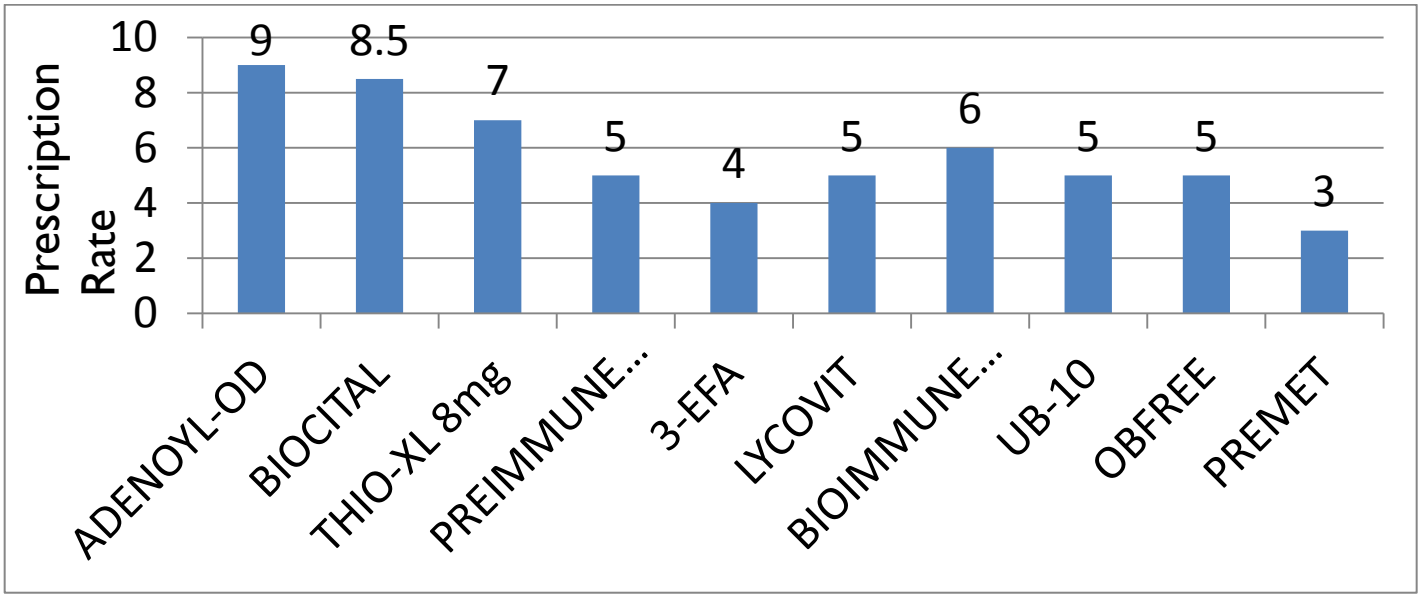
Task assigned and key learning:

Weeks	Task Assigned	Key Learning
Week – 1 and 2	Orientation and Training on tools and data collection	Company's work culture, Organization structure, practical field knowledge of the market , analysis of data.
Week - 3	Field work and reporting	Collection of data from field, organize the collected data into excel worksheet and daily reporting to mentor.
Week - 4	Orientation and Training on Sales	How to interact with doctors , drug's indications, side effects, features and benefits.
Week - 5	Sales field work	Prescribing pattern of doctors , how to convince physicians.
Week - 6	P.M.T.	Company's brands and services , Company's planning and strategy building for their brands.

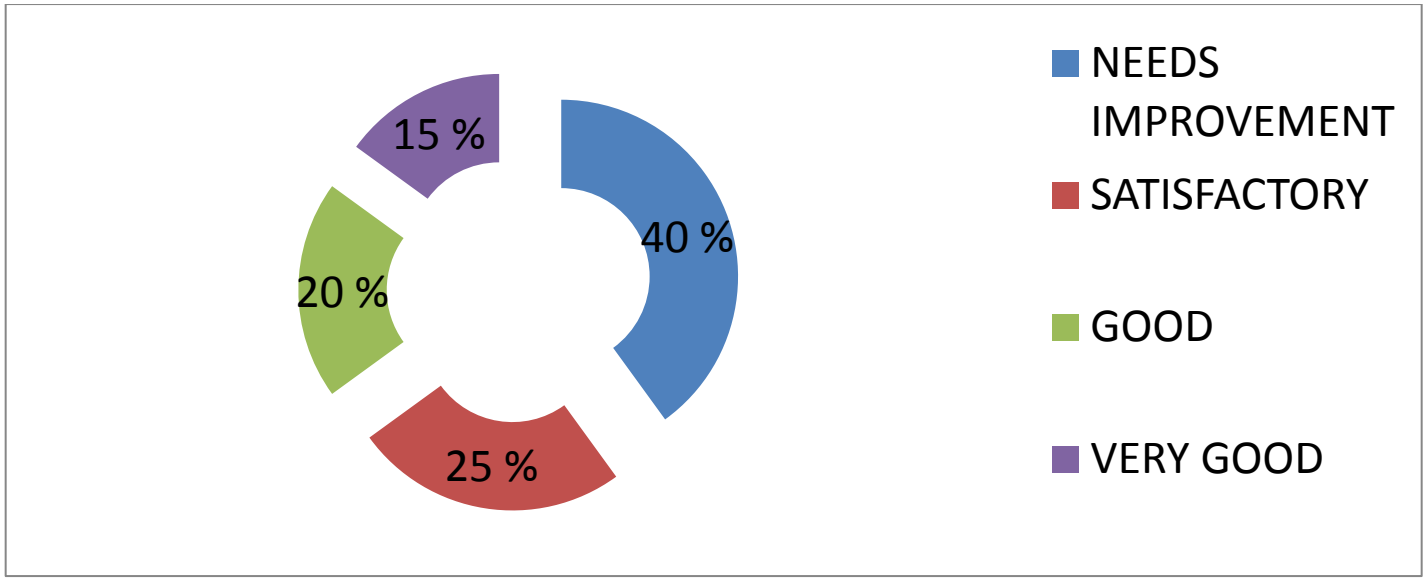
Section - 4

DATA ANALYSIS AND INTERPRETATION:

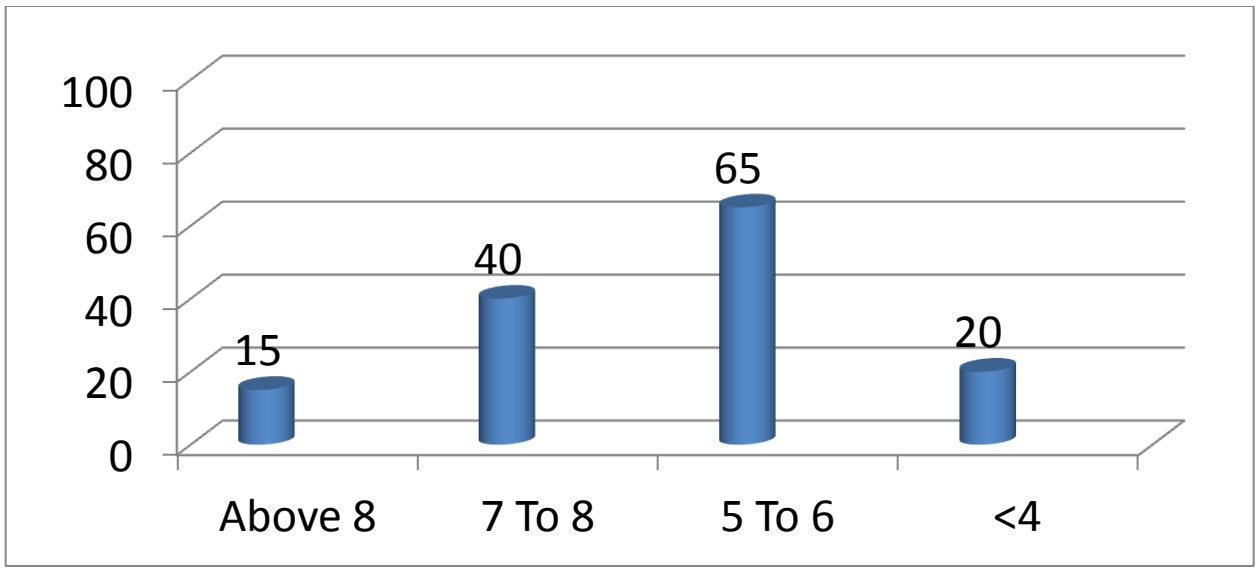
Most running brands of Bioplasma:



Representation of Bioplasma :



Percent distribution of respondents by rating to Bioplasma:



Section - 5

Findings:

- Three most running brands of Bioplasma are Adenosyl – OD , Biocital & Thio – XL.
- Adenosylcobalamin is more effective than Methylcobalamin against fast growing malignant cells.
- Adenosylcobalamin is equally effected at much lesser concentration.
- Adenosylcobalamin has comparatively less side effects.

Section - 6

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5. http://www.livestrong.com/article/533034-is-methylcobalamin-the-best-form-of-vitamin-b-12/
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