

Evaluation of Marketed Nutraceutical Weight gain/Weight loss Capsules

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NUTRACEUTICAL

A nutraceutical is defined as any substance that is a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease.

GLOBAL MARKET OVERVIEW AND GROWTH OF NEUTRACEUTICAL GROWTH

The nutraceutical market is predicted to record a revenue of USD 671.30 billion by 2024. Developing countries have a high prevalence of non-communicable diseases like cancer, diabetes, cardiovascular ailments therefore the demand for nutraceutical is expected to rise in these nations.

Nutraceutical are also gaining global importance and have become a part of daily diet due to improper life style and people consciously adapting preventive healthcare measure. The gradually increasing healthcare expenses are also stimulating the demand for nutraceutical. Developed countries like United States and Europe have seen an fast emerging segment of customized products especially functional foods and beverages.

Nutraceutical have become an opportunity economic growth of many developing countries which have a rich source of medicinal herbs and traditional knowledge of such plant, especially India, China, and South American countries.

Nutraceutical Market: CAGR(%), Developing Countries, 2018 12.30%.

Here are some nutraceutical market CAGR% forecasts for developing countries:

India :

The Indian nutraceutical market is expected to grow at a CAGR of 22% by 2023. During the pandemic, the Indian nutraceuticals industry grew at 25% annually.

China :

The nutraceutical market in China is expected to expand at a CAGR of 5.5% by 2033.

Asia Pacific :

The nutraceutical market in Asia Pacific is expected to grow at a CAGR of 10.11% in the coming years.

The nutraceutical market is expected to grow due to a number of factors, including:

Increasing health awareness, Consumers are becoming more aware of health and wellness, and are looking for preventive healthcare options.

Aging population Aging Population :

The aging population has led to an increase in chronic health conditions, and nutraceuticals are seen as a complementary approach to conventional medicine.

Natural and organic ingredients :

Consumers are increasingly preferring natural and organic ingredients.

E-Commerce :

The popularity of e-commerce websites is increasing, and more products are available online

SCOPE OF NUTRACEUTICAL

Nutraceuticals provide all the essential substances that should be present in Nutraceuticals provides A healthy diet for the human. Energy and nutrient supplements to body, which are required for maintaining optimal health.

Scope of nutraceuticals

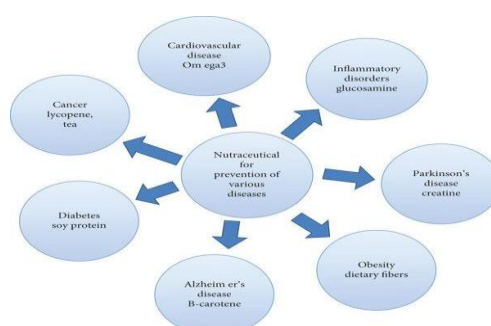
1. To reduce antinutritional factors of feed components.
2. To activate immunity.
3. Growth promotion-promote substantial aquaculture production.
4. Nutrition security to fishes and shellfishes and quality nutritional security for human population.
5. Increased feed consumption.
6. Induce maturation.
7. Stress mitigation.
8. Antimicrobial capability.

TYPES OF NUTRACEUTICAL PRODUCT AVAILABLE IN THE MARKET



The nutraceutical market is segmented into functional foods, functional beverages and dietary supplements which are again subcategorized into different products which are as follows :

ROLE OF NUTRACEUTICAL IN VARIOUS DISEASES



Nutraceutical plays an important role in therapeutic areas such as arthritis, cancer, diabetes, digestion, cholesterol, blood pressure, pain killers, depression and various other disorder.

The following table depicts the role of few plants and their constituents in the prevention and management of disease.

CLASSIFICATION OF NUTRACEUTICAL

They can be classified according to their chemical nature and therapeutic properties as follows :

1. Inorganic Mineral Supplements :

Calcium, magnesium, manganese, boron, copper, zinc, phosphorus etc.

2. Antioxidants :

They are present in fruits, vegetables and fishes. They are used to prevent thereactive oxygen species and free scavenging radicals Eg. Vit- E, C, A, Beta carotene.

3. Poly Unsaturated Fatty Acid :

These are fatty acids which contains more than one double bond and includeessential fatty acids Eg. Omega-3-fatty acid, safflower oil, cornoil soybean oil.

4. Probiotics :

5. These are living microorganisms, which when taken with or without food improves intestinal microbial balance and functioning of large intestine Eg: Bifido bacterium, lactobacillus, etc.

Prebiotics :

These are non digestible substances that provides beneficial effect and protection to the prebiotics from gastric acid and digestive enzymes. They also promote the growth of probiotics bacteria. Eg: oligo fructose, Insulin,Lactulose.

6. Dietary Fibres :

They are two types viz:- water soluble fibres and water insoluble fibres. They are present in fruits vegetables, grains, legumes, etc. They are used to correct consumption, bowl irregularities, haemorrhoids.

INTRODUCTION OF CAPSULE



Definition:- A solid pharmaceutical dosage form that contains medicinal agent within either a hard or soft soluble container or shell, usually used for the oral administration of medicine. The shells are made of a suitable form of gelatin or other substance.

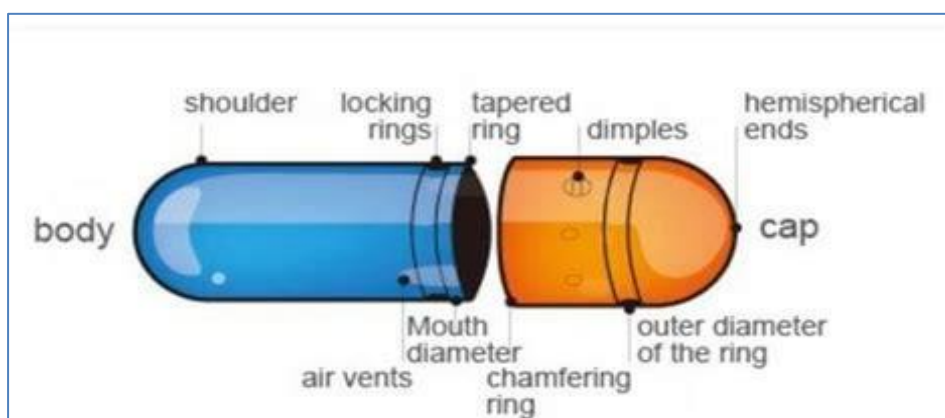
TYPES OF CAPSULE

Capsule are available in two types :

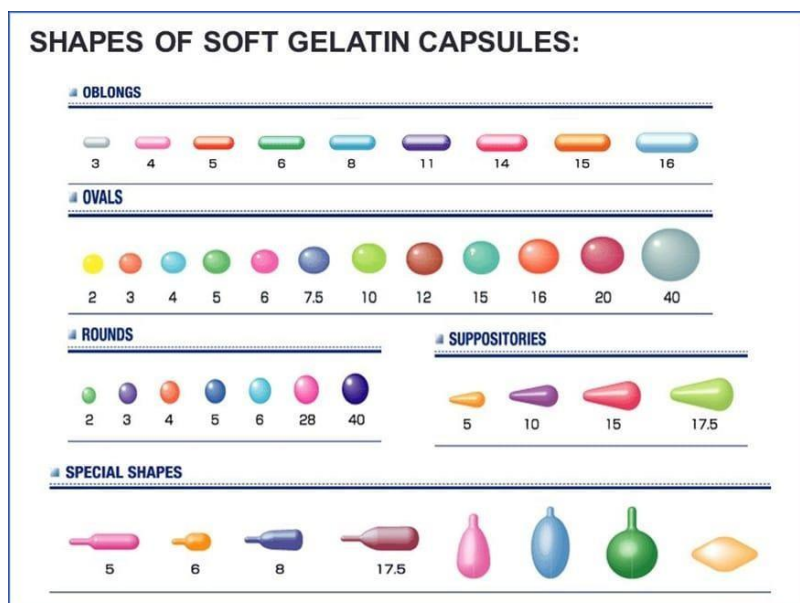
- 1:- Hard gelatin capsule
- 2:- Soft gelatin capsule



Hard gelatin Capsule:- 1. A hard gelatin capsule is a type of capsule that is usually used to contain medicine in the form of dry powder or very small pellets.



2. Hard gelatin capsules are usually filled with powders, granules, or tiny pellets.



Soft Gelatin Capsule:- soft gelatin capsule is a type of capsule that is Usually used to contain medicine in the form of liquid or powder, and which dissolves more quickly than a hard gelatin capsule. Soft gelatin capsules dissolve readily in the gastric juices of the stomach, and may work faster than other capsules.

OBJECTIVE OF CAPSULE :

Capsules are tasteless, odourless and can easily administered :

- Combination of powder can be used • They are attractive in appearance
- The drug having unpleasant odour and taste can be enclosed in a taste less shell
- They can be filled quickly and conveniently
- They are economical
They are easily to handle and carry

Advantages of Capsules :

1. The drugs having unpleasant odour and taste can be administered by enclosing them in a tasteless shell.
2. They are smooth, become very slippery when moist and can be easily swallowed.
3. They are economical.
4. They are easy to handle and carry.
5. The capsules release the medicament as and when desired in gastro-intestinal tract.
6. Capsules are made from gelatin and hence they are therapeutically inert.

7. They are attractive in appearance.

Disadvantages of Capsules :

1. Difficult to swallow in case of children and older people.
2. May be bitter.
Less or no flexibility of dose.

Introduction of Revital Capsule :

Revital Capsule :- Revital capsule is a capsule manufactured by Sun Pharma Laboratories Ltd. It is commonly used for the diagnosis or treatment of Improves immunity, improves mental alertness, improves health, immunity. It has some side effects such as nausea, loss of appetite, stomach cramps, constipation.

Composition		
	Nutritional Value (Approximate Values)	Per Soft Gelatin Capsule (1.3g approx.)
Vitamins	Energy	1.96 kcal
	Carbohydrate	0.03 g
	Protein	0.01 g (0.02%)
	Fat	0.2 g
	Vitamin A	1500 IU (75.0%)
	Vitamin B1	1 mg (58.8%)
	Vitamin B2	1.4 mg (66.7%)
	Vitamin B3	10 mg (47.6%)
	Vitamin B6	0.8 mg (40.0%)
	Vitamin B12	0.8 mcg (80.0%)
	Vitamin C	33 mg (82.5%)
	Vitamin D3	300 IU
	Vitamin E	7 mg
Minerals	Vitamin K1	25 mcg
	Folic Acid	0.08 mg (80.0%)
	Zinc	10.29 mg (85.8%)
	Iodine	0.10 mg (66.7%)
	Iron	10 mg (58.8%)
	Magnesium	3.13 mg (0.9 %)
	Manganese	0.6 mg
	Copper	0.52 mg (26.0%)
	Calcium	76.9 mg (12.8%)
	Phosphorus	59.43 mg (9.9%)
Potassium	2.07 mg	
	Panax Ginseng Root Extract (2%)	212.5 mg

• EVALUATION OF MARKETED NUTRACEUTICAL CAPSULE (REVITAL CAPSULE) :

1. Shape and size
2. Content uniformity test
3. Thickness of the capsule
4. Disintegration test

5. Colour
6. Weight variation test
7. Dissolution test
8. Moisture permeation test
9. Percentage of medicament test

Content Uniformity Test

To check content uniformity of Soft gelatin capsule we need to following stepsbelow



Weight capsules individually then cut and open capsule



Remove the contents by washing with a suitable solvent

Temperature

Allow the solvent to evaporate from the shells at room



Weight individual shells and calculate net contents

Disintegration Test :

1. Apparatus used for disintegration test for capsule is same as that used for the disintegration test for tablet
2. Place one capsule in each of six tubes of the basket and suspend the assembly in water maintained at 37-39 degree
3. When testing soft capsule, discs may be used
4. Operate the apparatus for 30 minutes in the case of hard capsule and 60 minutes in the case of Soft gelatin capsule
5. The capsule passes the test if no residue is left on the screen of apparatus or if a residue remains in the form of fragments of the shell
6. If 1-2 capsule fail to disintegrate, repeat the test on twelve additional capsules so as not less than 16 of total no of 18 capsules tested get disintegrated



DISSOLUTION TEST

The apparatus used for the dissolution test for capsule is the same as that for dissolution test for tablet

1. Place 1000ml of water free from dissolved air having temperature of 36.5 to 37.5 degree in to the vessels.
2. Place the specified no. of capsule in the dry basket.
3. Assemble the apparatus.
4. Start the motor and adjust it's speed to 100 rpm or such other speed as given in market in monograph.
5. Withdrawal the required volume of the solution from the vessels after 45 minutes or after the period specified in monograph.
6. Filter and determine the amount of active ingredients present by the method given in the monograph.
7. Repeat the complete operation.

Sample passes the test if the amount of active ingredients in the solution is not less than 70% of the stated amount given in the monograph.



LEAKAGE TEST

The leakage of Soft gelatin capsule are determined by :

1. Bloom or gel strength – It is a cohesive strength of cross -linking that occurs between gelatin molecules and is proportional to the molecular weight.
2. Viscosity of gelatin – It is a measure of molecular chain length & determines manufacturing characteristics of gelatin film.
3. Iron content – It is present in raw gelatin as well as water used in manufacturers. Excess quantity of iron can effect the formulation and react with organic compounds.

Weight Variation Test

1. 20capsule are taken at random and weighed. Their average weight is calculated, then each capsule is weighed individually and their weight is noted.
2. The capsule passes the test if the weight of individual capsule falls within 90-110% of the average.

BENEFITS OF REVITAL CAPSULE

1. Provides energy and fights weakness and tiredness.
2. Keeps bones healthy and strong.
3. Keeps hair and skin healthy.
4. Improves mental alertness.
5. Relaxes the mind and increase the ability to the health Stress.
6. Helps improve your immunity.
7. Helps maintain normal vision, bones and teeth.
8. Promote anti-aging.

9. Helps in the normal functioning of the nervous system.

USES

Revital H Health Supplements Combo capsule – is meant for men and women, catering to their specific needs. It keeps you active and mentally fit for your daily routine. The Ginseng present in it helps in boosting concentration. It increases oxygen consumption in the body and helps to maintain energy and stamina throughout the day. Folic Acid helps in maintaining normal blood formation, it is an ideal health supplement formulated for women. Iron keeps women physically and mentally fit. It also contains antioxidants. It helps control daily stress.

Low to use – One capsule to be taken with one glass of drinking water/milk/juice and take a break of 15 days after 3 months of daily usage or as directed by the physician.

SAFETY INFORMATION

- Read the label carefully before using it.
- Store it in a cool and dry place away from direct sunlight.
- Keep it out of the reach of children.
- Do not exceed the daily recommended dose.
- Use it under medical supervision.
- Check its expiry date.

Side Effects -Just like its women's counterpart, Revital H for men benefits men, especially those who are over 45. However, some mild side effects may occur due to allergic reactions or exceeding the recommended dosage of Revital H health supplement.

These include:

- Nausea
- Vomiting
- Loss of Appetite
- Gastric Discomfort
- Headache
- Increased heart rate
- Constipation
- Stomach cramps

If these side effects do not improve over time or get worse, please consult with your doctor promptly

Precautions and Warnings:

- Please read the label carefully to check if you are allergic to any of its components.
- If you are pregnant or breastfeeding, please take Revital H only after a recommendation/consultation with your doctor.
- Do not give Revital H to children.
- Do not consume expired medicine.
- In case of an accidental overdose, please talk to your physician for appropriate guidance and treatment.

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