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Evaluation of Shelf Life Study for the Formulated Nutraceutical Product - Oriens® Naturovita

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Abstract: ***Herbal drugs are of different kinds and have many constituents. The finished products of herbal medicine generally have active constituent(s). Stability testing of herbal nutraceutical product is a challenging task because the entire herb or herbal product is regarded as the active matter, regardless of whether constituents with defined therapeutic activity are known. The aim of this study is to evaluate the real time shelf life study of Oriens® Naturovita over the period of one year. The various quality components and active ingredients were analyzed. The present investigation supports the Oriens® Naturovita was stable up to 12 months storage and it showed very good stability.***

Keywords: Oriens® Naturovita, Active ingredients, Stability, Nutraceutical

1. Introduction

Natural product market has seen tremendous growth in the last few years. It has resulted in the formulation of a number of proprietary herbal products, the majority of them being multi-component formulations. With the advancement of herbal drug treatments, it has now been observed that many of the constituents present in the drug may react with each other, raising the serious concern about the stability of such formulations which is an important issue in the field of phytochemistry and natural medicines. Natural products are often prone to deterioration, especially during storage, leading to loss of an active component, production of metabolites with no activity and, in extreme cases, production of toxic metabolites (Thakur, 2011).

The most important aspect in the evaluation of the stability study of a product is its storage condition. The purpose of a stability testing is to provide proof on how the quality of the herbal products varies with time under the influence of environmental factors such as temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial contamination, trace metal contamination, leaching from the container. These facts are necessary for establishing the recommended storage condition and shelf-life.

Stability studies should be performed on at least three production batches of the herbal products for the proposed shelf-life, which is normally denoted as long-term stability and is performed under natural atmospheric conditions. Due to their natural origin, questions on microbiological quality arise more often for herbal medicinal products than for chemically defined medicinal products (International Conference on Harmonization, 2003).

Modern analytical techniques such as Spectrophotometer, HPLC, and HPTLC with proper guidelines could be employed to generate robust stability data of herbal products. The data so generated could be used in predicting the shelf-life and improving global acceptability of the herbal products. The aim of the proposed study is to find out the stability of Oriens®Naturovita that are herbal combination and intended for use over a period of one year.

2. Methodology

The lifestyle of people worldwide has changed in the last century due to a rise in income, reduced physical activity and preference for junk foods. In addition to this several other factors such as lack of time to show interests in the preparation of nutrient-dense foods, improper selection, planning and consumption of healthy foods has led to the occurrence of several diseases. As a parallel development, there is a worldwide increase in health awareness and use of herbal alternatives as a remedy for these lifestyle diseases. Today, Herbal preparations occupy an indisputable position in the prevention and treatment of chronic diseases.

Herbs have been used for medicinal purposes throughout history. Their health properties are linked to a number of chemical constituents, including vitamins, flavonoids, terpenoids, carotenoids, phytoestrogens and minerals (Calucci*et al* 2003; Suhaj 2006).

3. Quality Analysis of Oriens® Naturovita

The disintegration of herbal products

Disintegration test was carried out for the Oriens® Naturovita by introducing one capsule in each tube; a disc being added to each tube. Suspended the assembly into the beaker containing water at 37 ± 2 ˚C (volume of water is such that the wire mesh at its highest points is at least 25 mm above the bottom of the beaker). Operated the apparatus till all capsules were disintegrated or some impalpable mass remained on the mesh. Recorded the time required for disintegration. If the capsules adhered to the disc and preparation being examined failed to comply, the test was repeated. The preparation complied with the test if all capsules in the repeat test disintegrated (Aulton *et al* 1989).

Dissolution

The dissolution test was carried out for the Oriens® Naturovita to demonstrate the appropriate release of the

active substance(s).The vessels of the dissolution method are usually either partially immersed in a water bath solution or heated by a jacket. An apparatus was used on water bath solution within the vessels for a predetermined amount of time which depends on the method for the particular drug. The dissolution medium within the vessels is heated to 37°C with an acceptable difference of ± 0.5°C. The general procedure for dissolution involves a liquid known as Dissolution Medium which is placed in the vessels of a dissolution unit. The medium can range from degassed or sonicated deionized water to pH adjusted chemically-prepared solutions and mediums that are prepared with surfactants.

Weight variations

Weight variations of the Oriens® Naturovita were analyzed. Weighed the intact capsule individually to obtain their gross weights, took care to preserve the identity of each capsule. Then cut open the capsules by means of a suitable clean, dry cutting instrument such as scissors or a sharp open blade, and removed the contents by washing with a suitable solvent. Allowed the occluded solvent to evaporate from the shells at room temperature over a period of about 30 minutes, took precautions to avoid uptake or loss of moisture.

Organoleptic Property

The organoleptic properties were evaluated for color, odorand smell. For color, the 5 g of sample was taken into the Petri-dish and placed against the white background. The color was observed by the naked eye. 2 g of sample was taken to smell and a pinch of the sample was taken to examine the taste on the taste buds of the tongue.

Active Ingredient Analysis of Oriens® Naturovita

The assay analysis for the combination of herbs such as Spirulina and Boswellia serrata extract was conducted. The active ingredient present was analyzed by HPLC (Shah *et al*2008) and was found to be **Boswellic acid**.

Procedure for assay analysis – Boswellic acid

Preparation of mobile phase: Preparedacetonitrile: water (90:10, % v/v) adjusted to pH 4 with glacial acetic acid.

Preparation of stock solution: Accurately weighed 50 mg standard sample and dissolved in 25 ml of methanol to get a stock solution.

Preparation of sample solution: Weighed the capsules accurately and powdered it finally. Weighed capsule powder equivalent to 100 mg of standard sample and transferred to a 50 ml volumetric flask, and added 20 ml of methanol. The mixture was sonicated for 30 min, diluted to the mark with methanol, and filtered through Whatman filter paper (No. 41, 0.45 µm).

Chromatographic condition

Flow rate	:	2.0 mL/min
Injection volume	:	20 µL
Run time	:	18 minutes
Temperature	:	27 ± 2ºC
Detector	:	260 nm

Method

Thealiquots of the standard solution of BSE were diluted up to 10 ml with methanol. Then twenty micro liters of solution was injected from each flask manually into the chromatographic system. By plotting peak areas the calibration curvewas prepared.

4. Results and Discussion

The stability study included a series of tests conducted on the herbal products for a period of one year for the purpose of obtaining information on its shelf-life and utilization period under specified packaging and storage conditions.

Oriens® Naturovita is a combination of Boswellia serrate extract and spirulina.Boswellic acid extracted from *Boswellia serrata* posses good anti-inflammatory, anti-arthritic and analgesic activity. Spirulina, a number of features of particular interest from the nutritional standpoint have been demonstrated, a balanced protein composition, a presence of rare essential lipids, numerous minerals and vitamins. The Oriens® Naturovita (VNL17-018) were kept for stability by estimating disintegration, dissolution, organoleptic property, active ingredient and microbial content. The sample was periodically analyzed consequently at 0 months and then at 3, 6, 9 and 12th month respectively.

Disintegration of Oriens® Naturovita

The disintegration time for the zero month of Oriens®Naturovita17.45 minutes respectively. The disintegration time was analyzed up to 12th month for the Oriens® Naturovita. The disintegration time did not exceed 30 minutes for the samples at any period of estimation and all values were well under specified limits. Only minor changes in the disintegration time from the initial month to 12th month was observed in all herbal products examined.Disintegration of formulated herbal products, market sample A and sample B for 3, 6, 9 and 12 months were done and the results are presented in table 1.

Table 1: Disintegration Time of Capsules

Disintegration time (minutes)	Oriens® Naturovita
0th month	17.45
3rd month	17.50
6th month	17.42
9th month	18.05
12th month	17.58

Dissolution of herbal products

The dissolution test for the Oriens® Naturovita was analyzed from 0th month to 12th month. There were only slight changes in the dissolution value in both Oriens® Naturovita. For the initial month, the dissolution value was 52.1% whereas at the 12th month the dissolution value was 52.1%.

The dissolution test for different samples is given below in Table 2.

Table 2: Dissolution Test of Capsules

Dissolution Test (%)	Oriens® Naturovita
0th month	52.1
3rd month	52.8
6th month	53.1
9th month	52.23
12th month	52.1

Weight variations

The weight variation for Oriens® Naturovita was analyzed from 0 to 12th month with an interval of 3 months. For the 0th month, the weight variation for the Oriens®Naturovitawas590 mg whereas for the 12th month, the weight variation of Oriens®Naturovita was (variation of 1 mg) 591 mg. The weight variation for Oriens® Naturovita given below in Table 3.

Table 3: Weight variation of Capsules

Weight variation (mg)	Oriens® Naturovita
0th month	590
3rd month	591
6th month	589
9th month	592
12th month	591

Organoleptic property

The organoleptic property for the formulated Oriens®Naturovita was analyzed for the initial month, 3rd, 6th, 9th and 12th month respectively. The samples were evaluated for organoleptic characters which included color, odorand taste. The color was brownish green containing an astringent odor and bitter taste No changes were noticed in color, odorand taste up to the storage period of 12 months. The organoleptic property is given in Table 4.

Table 4: The Organoleptic property of Capsules

Test Parameters	Oriens® Naturovita				
	0th Month	3rd Month	6th Month	9th Month	12th Month
Colour	Brownish green	No Change	No Change	No Change	No Change
Odour	Astringent	No Change	No Change	No Change	No Change
Taste	Bitter	No Change	No Change	No Change	No Change

Active ingredient analysis of Oriens® Naturovita

Stability is aimed at assuring that the product remains within specifications established to ensure its identity, strength, quality, and purity. It can be interpreted as the length of time under specific conditions and storage that a product will remain within the predefined limits for all its important characteristics (Jain, 2006).

Table 5: Active ingredient analysis for the Oriens® Naturovita

Product sample	Active ingredients	Result (%)				
		0th month	3rd month	6th month	9th month	12th month
Oriens® Naturovita	Boswellic acid	17.98	17.85	17.01	16.26	14.23

The active ingredient was analyzed for Oriens® Naturovita by HPLC method. Oriens® Naturovita was a combination of Boswellia Serrate extract and Spirulina.

Initially, the Boswellic acid present in the Oriens® Naturovita which is a combination of herbs was found to be 17.93%. After the interval of 3 months, the boswellic acid remained the same with a slight change in value to 17.85%. The Oriens® Naturovita was analyzed for the stability at 6th and the 9th month which showed a 1 percent difference in boswellic acid value to 17.01 percent for 6 months and 16.26 percent at 9 months. The assay analysis for sample A at 12th month depicted a value of 14.23 percent. The maximum degradation level for active ingredients was 5%. This showed that the product was stable for 12 months showing a maximum decrease in Boswellic acid by 3% which indicates stability of Oriens® Naturovita.

Microbial Analysis

The microbial analysis conducted for the Oriens® Naturovita in the initial month showed the bacterial and fungal count to be 35 CFU/g and <10 CFU/g which were within the prescribed limits and the pathogenic bacteria like E.coli, Salmonella sp, Staphylococcus aureus were absent. All the pathogenic bacteria analyzed were absent till the 12th month. The bacterial and fungal counts were under the limit till 9th month and it declined completely in the 12th month. Thus the Oriens® Naturovita was found to be stable till a 12th month.

Table 6: Microbial Analysis of Oriens® Naturovita

Parameters	0th month	3rd month	6th month	9th month	12th month
Total bacterial count	35 CFU/g	<10 CFU/g	<10 CFU/g	300 CFU/g	Nil
Total fungal count	<10 CFU/g	<10 CFU/g	<10 CFU/g	10 CFU/g	Nil
E. coli	Absent	Absent	Absent	Absent	Absent
Salmonella sp.	Absent	Absent	Absent	Absent	Absent
Staphylococcus aureus	Absent	Absent	Absent	Absent	Absent

5. Conclusion

The importance of stability study is to justify the preservation of quality of the herbal products in terms of shelf life. Evaluation of the herbal products on the basis of parameters determining quality standards revealed the product examined Oriens® Naturovita is in good condition throughout the one year period of study without any major deviation in quality.

We found that the present investigation supports the contention that the Oriens® Naturovita was stable at room temperature. It also suggests that the stability lasted for one full year. No deviations or decline in the assay and microbial load were found. The outcome of this study indicates that the Oriens® Naturovita could be safely stored at room temperature. Oriens® Naturovita showed a very good response in the stability studies conducted.

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