

PALM TOCOTRIENOL RICH FRACTION CHEWABLE TABLET

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Chewable tablets are a convenient alternative to conventional tablets. They have the great advantage of not requiring water, which means that they can be taken at any time and in any place and are palatable. The chewable tablet is formulated to disintegrate in the mouth smoothly either with or without chewing. Chewable tablets are specially designed for children who have difficulty in swallowing and persons who dislike swallowing tablets or any solid supplements (Patil *et al.*, 2012). A good chewable tablet must have smooth texture upon disintegration, pleasant taste and does not leave a bitter or any other unpleasant taste in the mouth upon or after consumption. Ideally, upon chewing, the chewable tablet is broken down in the mouth and instantly releases its ingredients and therefore, the active ingredients can be absorbed faster in the stomach, as it does not have to be disintegrated in the stomach (Patel *et al.*, 2011).

The main ingredients of the chewable tablet include the active ingredient and excipient. The excipient which act as binder, filler and flavouring agent is a substance formulated alongside the active ingredient. The active ingredient is the main component which is important to deliver the function of the chewable tablet. However, the excipient also plays a very important role in a chewable tablet formulation. Successful chewable tablet formulation involves careful selection of the excipient in order to produce a stable solid dosage form with acceptable manufacturing performance. Each of the excipient ingredient carries its specific role in chewable tablet development, and contributes to the desired characteristics of the chewable tablet. The

binder and filler help the tablet in fulfilling its physical properties such as compressibility, disintegration, lubrication and stability. The flavouring agent and sweetener provide organoleptic properties to the chewable tablet by masking the unpleasant taste of the active ingredient to produce a tablet with better palatability and facilitate pediatric dosing (Udaykumar *et al.*, 2012; Lachmann *et al.*, 1989).

Vitamin E is an essential nutrient for the body and has to be obtained through the daily diet. Vitamin E comprises four tocopherols (T) and four tocotrienols (T3) isomers, namely alpha (α), beta (β), gamma (γ) and delta (δ). Palm oil (PO) is one of the most abundant natural sources of vitamin E *i.e.*, 800-1270 mg kg⁻¹ PO (Puah *et al.*, 2007). Palm vitamin E, assigned as palm Tocotrienols Rich Fraction (TRF) comprises about 20% T (α -T) and 80% T3 (22% α -T3, 46% γ -T3 and 12% δ -T3) (Hashimoto *et al.*, 1980).

Health enhancing benefits of vitamin E. Vitamin E, especially palm TRF, possesses a myriad of health-enhancing benefits. Vitamin E, especially its T3 isomers, is known for antioxidant properties and prevention against radical and oxidative damage. T3 exert more potent (40-60 times) antioxidant and free radical scavenging properties than T due to better distribution in the lipid layers of the cell membrane (Cerecetto and López, 2007). The scientific world has also explored more health enhancing benefit of vitamin E beyond their antioxidant effect. Vitamin E, especially T3 has cardioprotective (Mutalib *et al.*, 2003; Tomeo *et al.*, 1995), anti-cancer and cancer suppression (Husain *et al.*, 2011; Nesaretnam *et al.*, 1998), anti-diabetic (Siddiqui *et al.*, 2013), nephroprotective (Siddiqui, 2010) and gastroprotective (Azlina *et al.*, 2005) effects. Studies by Mangialasche *et al.*, (2010); Liu *et al.*, (2009) and Sen *et al.*, (2000) showed that T3, particularly α -T3 has a neuroprotective effect. α -T3 protects neuron death at an extremely low level (nanomolar concentrations). T3 is able to reach the brain to provide protection against stroke, Parkinson's and Alzheimer's disease. Vitamin E also helps in the maintenance of bone metabolism (Norazlina *et al.*, 2010). Vitamin E is critical to neurologic and brain development in the foetus and children below 3 years old (Traber, 2014a,b).

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Vitamin E dosage. The recommended dietary allowance (RDA) for vitamin E to maintain good health is about 15 mg day⁻¹ (or 22.4 IU) for people over the age of 14 and 20 mg day⁻¹ for lactating women (Traber, 2014a). The more common dosages fall within 50–360 mg day⁻¹ (Tan *et al.*, 1991). The upper limit for safety is 1000 mg day⁻¹ (Traber, 2014a).

Effect of deficiency in vitamin E. A lifelong proper intake of vitamin E is important to maintain good health. Adequate levels of this essential micronutrient are especially critical for infants, the elderly, and women who are or may become pregnant. Vitamin E deficiency happens with an alarming frequency globally, by the fact that this nutrient is one of the most difficult to obtain through diet alone (Traber 2014a,b, Butte *et al.*, 2010). Vitamin E deficiency can cause poor transmission of nerve impulse, muscle weakness and degeneration of retina that leads to blindness. Severe vitamin E deficiency can be lethal and cause the loss of life. According to Traber (2014b), vitamin E deficiency particularly for infants, the elderly, and women who are or may become pregnant may result in:

- increased infection, anemia, stunting of growth and poor outcomes during pregnancy for both the infant and mother.
- neurological disorders, muscle deterioration and cardiomyopathy, especially in children
- poor cognitive function in young children.
- acceleration of alzheimer’s disease progression and higher risk of developing all-cause dementia.
- smaller brain size and lower cognitive function.

Owing to the importance of vitamin E to human health, thousands of nutritional and wellness supplements, and food and beverage products fortified with vitamin E are launched in the global market every year, and the number is rising from year to year. For example, the number of food products containing vitamin E launched in the global market in 2006 was 2150 and the number rose to 9707 in 2015 (Innova Market Insights, 2016). Vitamin E is widely incorporated in baby food, cereals and nutritional/wellness supplements. With respect to palm TRF, palm TRF supplement is currently globally available in the form of soft gel capsules. The global volume consumption of natural source vitamin E which stood at 10.3 thousand tonnes in 2012 is projected to be 18.1 thousand tonnes in 2020 (Research and Market, 2013).

THE TECHNOLOGY

Technologies offered are palm TRF chewable tablet formulation and process for the manufacturing of the chewable tablet.

THE PRODUCT

The chewable tablet, 500-1000 mg in weight, is fortified with the RDA dosage of palm TRF. The chewable tablet which required to be chewed before ingestion, has smooth texture upon disintegration in the mouth and has a pleasant taste (flavoured with orange, grape, mango *etc.*). The chewable tablet may contain acacia gum that acts as a prebiotic that nourishes our digestive system. The composition of the chewable tablet can be varied to suit the market niche, such as fortified with folic acid to fulfill the need of pregnant women, omega fatty acid for children or co-enzyme Q10 for ageing women. The palm TRF chewable tablet has excellent physical properties and is palatable. The hardness and sensory evaluation scores of the chewable tablet are shown in Figures 1 and 2, respectively. There is no change in palm TRF content upon storage.

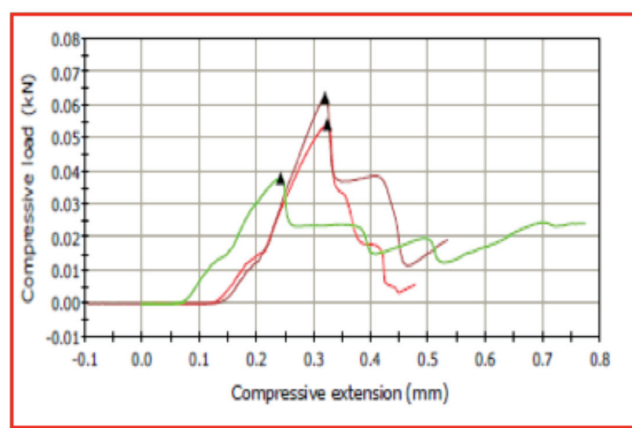


Figure 1. Hardness of palm Tocotrienol Rich Fraction chewable tablet.

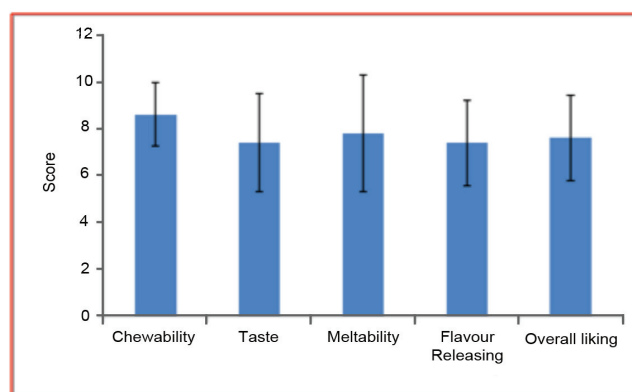


Figure 2. 9-point hedonic scale sensory evaluation of palm Tocotrienol Rich Fraction chewable tablet.

PRODUCT NOVELTY

Palm TRF chewable tablet formulation that can hold the RDA dosage of palm TRF, with excellent palatability and physical characteristics.

PRODUCT BENEFITS AND ADVANTAGES

- Healthful, nutritious and delicious.
- Fortified with RDA dosage of palm TRF.
- Helps increase vitamin E intake and prevents/tackles vitamin E deficiency.
- Palm TRF delivers unique biological functions to maintain a healthy body and provides myriad health enhancing benefits (anti-ageing, provides protection against heart disease, cancer, neurological diseases, premenstrual syndrome, eye disorders, diabetes *etc.*).
- Palatable, easily consumed, reduce risk of esophagitis and convenient for traveling.
- Suitable for children and adults who dislike or have difficulty in swallowing.
- Tablet composition can be varied to include specialised nutrients, vitamins or active ingredients for specific niche markets with different requirements, *e.g.*, children, pregnant women, ageing women/men, sportsmen, *etc.*



COMMERCIAL BENEFITS AND ECONOMIC ANALYSIS

The palm TRF chewable tablet has a great potential to be marketed as fortified food or nutraceutical products which can be sold at a premium price. The cost of production is estimated at RM 0.50 per tablet. The palm TRF chewable tablet containing 50 mg of palm TRF can be marketed at the price of RM 150.00 per bottle of 100 tablets. The investment prospective is attractive with a payback period of 3 years. The commercial venture is expected to yield benefit to cost ratio of 1:1.05, net present value of RM 2 182 468 and internal rate of return of 47%. The investment proposition is financially feasible.

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