

Formulations & Solutions Using Parry Tomato Lycopene Complex

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Kuldeep Wayase

Parry Nutraceuticals, Division of EID Parry (India) Ltd, Chennai, India.
e-mail: phyto remedies@vsnl.net • www.parrynutraceuticals.com

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United States Office: Valensa International, 2751 Nutra Lane, Eustis, Florida 32726
(877) 876-8872 • e-mail: sales@valensa.com • www.valensa.com

Introduction

Lycopene is a red plant pigment found in tomatoes, apricots, guavas, watermelons, papayas, pink grapefruits and rosehips, with tomatoes being the largest contributor to the dietary intake of humans (Chalabi et al., 2004). Chemically it is a 40-carbon acyclic carotenoid which contains 11 conjugated double bonds and belongs to a sub-group of carotenes consisting only of hydrogen and carbon atoms (Stahl and Sies, 1996). These eleven conjugated double bonds give it a deep red color and are responsible for its antioxidant activity. Therefore, lycopene exhibits higher singlet oxygen (O₂) quenching ability. Due to its strong color and non-toxicity, lycopene is a useful food coloring (registered as E160d).

Lycopene is not an essential nutrient for humans, but is commonly found in the diet, mainly from dishes prepared with tomato sauce. When absorbed from the stomach, lycopene is transported in the blood by various lipoproteins and accumulates in the liver, adrenal glands, and testes. Lycopene, a proven antioxidant that neutralizes free radicals which may damage the body's cells, is typically deposited in the prostate, liver, lungs, colon and skin. Epidemiological studies have shown that high intake of dietary lycopene is inversely associated with the incidence of certain types of chronic diseases.

Key Issues

In general, tomato lycopene products have been a challenge to use in Dietary Supplement and Functional Food applications. Questions arise concerning the poor quality encapsulation of softgels - will there be leakers? The retention of stability, purity and compression strength in lycopene powders and dry forms have caused concern. The poor flexibility in the manufacturing process of beadlets for tablets and capsules has led to limitations in the production of formulations. And, the ease-of-use and uniformity of the dispersion of CWD powders and suspension grade liquids in Functional Food and Drink applications has yielded less than desirable results.

Lycopene is a highly unstable by itself. It requires unique extraction technology processes to provide highly stable lycopene formulations in a versatile range of Oils, DC grade microencapsulated powders, beadlets, and cold water dispersible (CWD) powders. In addition, these formulations have to go through rigorous stability tests throughout the manufacturing process (ie. tablet punching, capsule filling, etc.). Parry Tomato Lycopene Complex is manufactured to offer guaranteed stability for a minimum of two years.

Strictly monitored and well documented QA and QC tests and analysis are performed after the completion of every batch, giving our customers complete comfort in our guaranteed lycopene formulations.

Tomato Lycopene Oils

Issue:

After extraction, Tomato Lycopene is in the form of particles which are similar to needles. These "needles" are quite large in size and vary in shape and can lead to various types of losses due to breaking of microcapsules at the time of softgel capsulation.

Parry's Solution:

The tomato lycopene matrix is micronized. During this manufacturing process, lycopene particles

are sheared, ground and milled under mild conditions. This ensures that the structure of all micro-nutrients in the tomato matrix and the trans/cis ratio of the tomato lycopene remain unaffected.

This fine matrix is further thoroughly homogenized and blended in various non-GMO vegetable oils as per customer requirements. Generally over a long period of storage time, lycopene crystals have a tendency to settle down at the bottom of containers. We ensure that the tomato lycopene remains in an uniformly blended state within the oils, which prevents settling and separation of these crystals.

Lycopene is kept in the presence of a higher percentage of tomato lipids which enhances long-term stability and increases shelf life. Trans and cis isomers in the ratio of 91-93: 7-9 are achieved. A minimum of two years of stability and shelf life are guaranteed. In addition, the ratio of non-GMO vegetable oils which are used as excipients is kept at a higher percentage to ensure very low viscosity and high flow-ability of lycopene oils which increases ease at the time of softgel capsulation.

The micro-nutrient composition of phytoene, phytofluene, natural tocopherols and beta-carotene is in compliance with USP-32. Residual solvents used in this process are in strict conformity with E-160 d and USP 30 and are food grade. Dioxins, furans, PAH and PCB's are strictly monitored as per various applicable regulations.

Microencapsulated DC Grade Powders & Beadlets

Issue:

The processing of the tomato lycopene matrix to dry forms presents a challenge, as it starts becoming highly unstable leading to the issues in terms of shelf life. It is necessary to ensure that Lycopene is still in the presence of lipids but at the same time the particles have enough compression strength for the ease in tableting.

Parry's Solution:

The Tomato Lycopene Matrix is selectively enriched to a level of purity sufficient enough to micro-encapsulate the tomato lycopene particles with successive layers of ingredients, This process prevents contact with air and moisture, enhances stability and provides the compression strength needed to withstand the pressure applied during the tableting process. As a result, the micro-capsules are easily formed into tablets and retain high bio-availability for maximum efficacy.

This manufacturing process achieves the required bulk density and flow-ability and is compliant with Karr index. The process ensures that a wide range of standard and non-standard purity, quantity and pack sizes are available for the customers without any additional burden of cost. The process is also quite flexible to deliver the particle size as per the requirements of individual customers.

The processing of our tomato lycopene beadlets combines the features and benefits of our micro-encapsulation process for DC grade powders with the advantages of pre-formulation, which can be customized as per the needs of each customer. The technology and infrastructure to pre-mix various ingredients with various types of coating, including wruster bottom spray coating, has been developed to maintain the stability of coats of various forms of mixtures.

The process is extremely flexible and can be applied dynamically. Any batch size can be produced with the same efficiency without customers having to incur additional costs. Finished beadlets can be used in manufacturing of tablets as well as in filling two-piece hard shell capsules as a formulated product.

Cold Water Dispersible (CWD) Powders and Suspension Grade Liquids

Issue:

For use in the manufacture of food items, it is necessary that the tomato lycopene is dispersible in water but the tomato lycopene matrix presents a special challenge as it is in the nature of being dispersible in fats. The other challenge is to be able to make the tomato lycopene stable at high temperatures and certain pH levels.

Parry's Solution:

A special process has been developed in which the tomato lycopene is selectively separated from the tomato lipids, coating it with stabilizers and forming a matrix with modified starches, xanthan gum, solubilizers and dispersants. This highly stable tomato lycopene powder immediately disperses easily and uniformly in water.

The manufacturing of food products is made at various levels of pH and at high temperatures. This powder has displayed good stability at high heat temperatures for shorter processing times and at various levels of pH ranging from 3 to 9.

Our cold water dispersible powders are widely accepted and utilized in the manufacturing and production of Soups, Breakfast Cereals, Nutritional Bars, Bakery products, Meat substitutes, etc.

We have also developed a special process of suspension of tomato lycopene in a liquid matrix for the beverages, dairy and confectionery industry. This process also achieves selective separation of the tomato lycopene from the tomato lipids, coating it with stabilizers and forms a liquid matrix with modified starches, xanthan gum and dispersants in water base. This tomato lycopene suspension liquid immediately disperses easily and uniformly with the liquid mixtures. This is highly stable for processes at high temperatures and at various levels of pH ranging from 3 to 9.

About Parry Tomato Lycopene Complex

Overview

Valensa, through its partnership with Parry Nutraceuticals, offers a uniquely processed Natural Tomato Lycopene, that not only includes lycopene but also all the naturally occurring phytonutrients found in tomatoes including Phytoene, Phytofluene, Tocopherols and Beta-carotene and eliminates the sugar and water. These phytonutrients act in synergy with lycopene to collectively form the Parry Tomato Lycopene Complex.

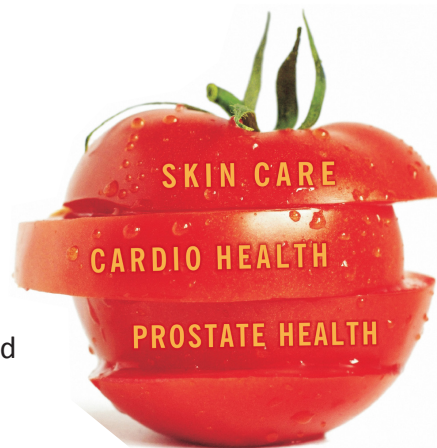
A dedicated manufacturing facility was specifically designed for the selective extraction of tomato lycopene from a tomato slurry in milder temperatures and less turbulent conditions, thereby retaining all the good health benefits of the various tomato phytonutrients and eliminating the risk of cross-

contamination with other extracted products. Parry's innovative technology and proprietary research and production process allows for the optimum recovery of the highest quality, pure lycopene content which guarantees efficacy and increases cost-competitiveness.

Parry Tomato Lycopene Complex has been certified Star-K Kosher and Halal by regulatory authorities. No gelatin or sugars are used. In addition to attaining ISO 22000-2005 certification for food safety management, Parry Tomato Lycopene products comply with USP32 and all applicable regulations and directives of EU and other nations on non-GMO, non-allergen, non-irradiation, TSE/BSE, Dioxins and PCB's. Full integration of manufacturing and production operations ensures the use of non-GMO tomatoes and provides full traceability for all Parry Tomato Lycopene products.

Condition-Specific Formulations using Parry Tomato Lycopene Complex

Parry Tomato Lycopene Complex is a wholesome and natural tomato extract that can be used in a wide variety of condition specific formulations. The unique extraction methods and dedicated facilities, combined with the selection of only the finest tomatoes, make our formulations the most stable and efficacious lycopene-based products available.



Prostate Health

Issue:

Lycopene and Saw Palmetto are two well known prostate health ingredients. Unfortunately they are unstable when blended together. The high acidity of Saw Palmetto oil extracts make the lycopene oil unstable. However, most marketers have been inadvertently using this combination.

Valensa-Parry Solution:

Valensa has developed a unique stabilization and encapsulation process in which the clinically proven Parry Tomato Lycopene and patented USPlus® saw palmetto extract (US Patent # 6,669,968 & 6,319,524) can be combined in a stable, efficacious formula for prostate health, called **Prostate 360™**.

Cardiovascular Health

Our Lycopene and Omega-3 blend, **T-Omega 360™**, combines the cardiovascular benefits of lycopene and ALA to create an efficacious healthy heart formulation.

Skin Health

Derma-360™ is a propriety blend of proven ingredients, including lycopene, designed to protect and enrich the skin.

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