

Development of Lycopene Chylomicron into a Botanic Drug: from Bench to Bedside

Y. S. Pu¹, F. F. Kuo², B. H. Chen³

¹Department of Urology, National Taiwan University Hospital, Taipei, Taiwan

²Health Ever Bio-Tech Co Ltd, Taipei, Taiwan

³Department of Food Science, Fu Jen Catholic University, New Taipei City, Taiwan

ABSTRACT

Numerous studies have demonstrated that the consumption of tomatoes can be beneficial to human health, which can be attributed to the presence of carotenoids, especially the highest content lycopene. However, the high instability and low bioavailability of lycopene in vivo made it difficult to develop into a botanic drug. In this study we used a nanoformulation technique for encapsulation of lycopene extract from tomatoes, with this product being named as “lycopene chylomicron”. TEM analysis showed that lycopene chylomicron possessed a thick layer with an average particle size of 131.5 nm and zeta potential of -24 mV. The bioavailability of lycopene chylomicron was shown to be about nine-fold higher than the original lycopene extract based on an animal study. Then a total of 3 clinical trial phases were conducted to explore the possibility of developing lycopene chylomicron into a botanic drug for treatment of patients with prostate hypertrophy syndrome. Both phase-1 and phase-2 received outstanding clinical trial results at the National Taiwan University Hospital. The phase-3 passed investigations by 12 medical centers in Taiwan conducted by over 70 doctors as well as 27 medical centers across 19 states in the US by over 200 doctors. A total of 446 subjects were recruited in the phase-3 clinical trial study. The blind test results revealed even better improvements of lycopene chylomicron compared to traditional western medicines and can effectively treat prostate hypertrophy without causing any side effects. Now we are applying for Taiwan and US FDA drug approval. Expectedly lycopene chylomicron will become the first botanical drug worldwide for prostate hypertrophy treatment.

Keywords: tomato lycopene extract, lycopene chylomicron, prostate hypertrophy, bioavailability, phase-3 clinical trial.