SOLID DISPERSION AND FLOATING GEL *IN SITU* APPROACHES FOR IMPROVED SOLUBILITY AND SUSTAINED RELEASE BEHAVIOR OF β-CAROTENE EXTRACTED FROM PALM OIL

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Background: Free radical has caused numerous serious diseases around the world. β-carotene is one of antioxidant agents used to overcome this issue. However, this compound possesses low aqueous solubility and low bioavailability. Therefore, it is critical to enhance the solubility and sustain the release profile of β-carotene, resulting in high bioavailability. With respect to source, palm oil has been reported to be the rich source of β-carotene. Here, we extracted β-carotene from palm oil using saponification reaction. To improve solubility and sustain the release, β-carotene was further formulated into solid dispersion and floating gel *in situ*.

Methods: Palm oil was obtained using soxhletation method with isopropanol. β-carotene was further extracted using saponification method with KOH. Furthermore, solid dispersion formulation was optimized using central composite design. Solid dispersion was then characterized for their physical and chemical properties, as well as dissolution profile. Solid dispersion was finally incorporated into floating gel in situ which was evaluated for their physical properties and release behavior.

Results: The yield value of β-carotene obtained from the palm oil was 6.36%. Following optimization process, the final formulation of solid dispersion was PVP: PEG: cyclodextrin with the ratio of 0.334: 2: 0.983. The solid dispersion showed that there were no interactions between all compound in the formulation and the form of β-carotene changed from crystal to amorph. Importantly, the dissolution profile of β-carotene was improved from 7.98 ± 0.51 % to 88.81 ± 6.91% following the solid dispersion formulation, showing the successfulness of this approach to improve the solubility of β-carotene. In the floating gel in situ formulation, the formulation containing β-carotene solid dispersion, sodium alginate, sodium bicarbonate, calcium carbonate, and HPMC with the concentrations of 0.875, 1.5, 0.75, 0.5, and 1.5 % exhibited desired characteristics with optimum floating lag time. Finally, the *in vitro* release study showed that the incorporation solid dispersion of β-carotene was able to sustain the release β-carotene around 99.28 ± 17.11% over 24 h compared to solid dispersion formulation.

Conclusions: Solid dispersion-floating gel *in situ* containing β-carotene extracted from palm oil was successfully formulated. This combination approach could improve the solubility and sustain the release of β-carotene over 24 h.