Executive Summary

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1): Title of the Project:

Extraction of catechins from green tea leaves and production of low cost antioxidant powder/tablets

2): Date of Start of the Project: 01/10/2020

3): Aims and Objectives:

a) Separation and purification of catechin compounds (antioxidant) from green tea leaves.

(b) Formulation of Catechins (using suitable excipients chosen after pre-formulation studies with catechins) for making antioxidant powder/tablets.

(c) Formulation of catechine based health supplement & to evaluate the antioxidant potential of such formulation.

(d) Establishment of linkage with at least two renowned tea gardens of Assam for field trial and demonstration of catechin tablet production from their green tea leaves.

(e) Establishment of a startup company for commercial production of catechins based health supplement powder/tablets.

4): Significant achievements (not more than 500 words to include List of patents, publications, prototype, deployment etc)

a) Extraction purification of catechins (widely used as an antioxidant):

Commercial dried green tea leaves (Camellia sinensis) are used as the natural source to extract green tea catechins (GTC's) widely used as an antioxidant. Hot water with leaf to water ratio of 1:200 at 65°C for 30 min was optimized for better extraction of GTC. The obtained extract contains all the GTC's including caffeine, chlorophyll & phenolic components; higher molecular weight polymers and their degraded products. Higher molecular weight components were removed and the extract was concentrated by membrane technology using an appropriate molecular cut-off (MWCO) membranes. The permeate flux increased from 9.23×10^{-6} to 17.8×10^{-6} $m^3m^{-2}s^{-1}$ when cross-flow velocity increased from 2 to 6 LPM at 30 Psi pressure. The permeate was decaffeinated by partitioning in dichloromethane. The GTC's were enriched by partitioning the decaffeinated extract with a 1:1 ratio of ethyl acetate. Ethyl acetate was evaporated under reduced pressure using rota-vapour. Thereafter, yellowish jelly-like enriched GTC's were obtained. The GTC's gel was reconstituted in purified water and dried using freeze-drying to obtain GTC's powder suitable for formulation into a required solid-dosage form such as tablets, capsules, beads, etc.

b) Crystallinity of GTC for tablet compression:

PXRD of the GTC's powder shows a typical amorphous halo. Amorphous phases gradually change from meta-stable form to finally crystalline phases. As opposed to the amorphous phase of APIs, crystalline phases are pharmaceutically more suitable for tablet compression due to higher stability against phase change and have better compressible properties. Hence, microcrystalline cellulose was added as an additional compressible aid to overcome the incompressibility issues arising out of amorphous phases.

c) Hygroscopicity of GTC tablet:

GTC's are prone to absorb moisture due to the presence of multiple hydroxyl groups, leading to textural changes in the final formulation. Marketed formulations of tablets and capsules have shown excessive moisture absorption leading to softening of tablet formulation and liquefication of contents of the capsule's constituents. Management of moisture absorption in catechin-based solid dosage forms is of utmost importance for a successful commercial product

for formulation scientists. Higher moisture content may provide sufficient water activity for microbial spoilage. Though the % moisture gain was not very significant in our GTC's powder, the change of powdered GTC's to a uniform mass was observed under controlled humidity and temperature conditions, which will have substantial consequences during and after tableting. The coalition of powdered GTC particles to a uniform mass will negatively affect the disintegration and dissolution profile of the formulation. Capping the hydroxyl groups of GTC's using a co-amorphous crystal engineering approach has the potential for controlling the hygroscopicity-related issues. We have identified suitable non-hygroscopic co-formers with potential hydrogen bonding capacities with GTC's to manage the Hygroscopicity of GTC's.

d) Suitable formulation of GTC's tablet:

GTC's are reported to be absorbed in the intestine, but the alkaline pH in the intestinal environment is not suitable for the stability of GTC's. Hence, enteric-coated formulations (for targeting the intestine) with mucoadhesive properties are investigated for targeting GTC's delivery at the intestinal mucosa to obtain suitable bioavailability. Due to antimicrobial and inherent astringent/ protein precipitating properties of phenolic/ tannins present in green tea, GTC's are investigated as a suitable candidate for local action at the oral cavity for the management of mouth ulcers.

5): Concluding remarks

(i) Green tea catechins being an unstable molecule requires unique pharmaceutical strategies of stabilization / protection at every step of production from extraction to formulation of catechin powder and tablets.

(ii) There were continuous disruptions of availability of quality green tea leaves (our primary raw material) from the vendors due to pandemic restrictions.

(ii) Potential stakeholders capable of using our developed technology are skeptical of quickly shifting from their existing products (raw processed green tea leaves) towards moving to value added green tea products (green tea based formulations such as antioxidant tablets and powders).