ABSTRACT

Cancer is a major killer throughout human history. Its statistics lifted eyebrows across the world. One in every 15 men & 12 women develops cancer during their lifetime. Chances of getting cancer are increasing day by day; unfortunately, there is no true answer that eradicates cancer completely. Prevention is always better than cure.

The idea of the present work is to hamper the cancer death rate by developing chemopreventive formulation. The objective of the work is to develop safe and potential herbo mineral formulation for prophylactic use of cancer i.e. to prepare and standardize conventional oral tablets, which are able to suppress the tumor incidences and tumor multiplicity. The objective also includes carrying out the quality, safety and efficacy of the formulation.

Green tea herbal and sodium selenite mineral are potential chemopreventive agents and they are safe and economical. Green tea leaves were collected, and its aqueous extract was prepared by roto evaporator. Sodium selenite was procured from Seeko Biotics, Guntur.

A protocol for the preparation of 12 formulations was developed. Each formulation containing 200 mg of Green tea and 1 mg of Sodium Selenite and variable quantities of excipients to make up the total tablet weight up to 400 mg. Drug excipient interactions were studied by FTIR. Active components geometrically mixed with excipients. Derived properties like bulk density, tapped density, and flow properties like Angle of repose, Carr’s index, Hausner’s ratio of granules were noted.
Six formulations were compressed by direct compression; remaining six formulations were prepared by wet granulation method. Weight variation, hardness, friability, disintegration were carried out of all the 12 formulations. Out of all, formulation ‘GST-6’ passes the disintegration test.

Eight basket paddle type dissolution apparatus was used to study the dissolution profile of the best formulation. The release profiles of all six types of catechins, and mineral compounds were analyzed by HPTLC, LC-ICP-MS respectively. Safety assessment of the formulation was carried out in female albino rats, according to OECD guidelines number 420. The best formulation was blister packed and expiry date was determined as per ICH guidelines. Marker compounds were used to quantify the catechin and sodium selenite present in the prepared green tea aqueous extract and tablets by respective methods.

The chemo preventive efficacy of tablets were found against lung, liver, colon and skin cancers induced by tobacco smoke, alcohol, Azoxymethane and UV radiation respectively. The prominent effect of green tea extract/ sodium selenite/ herbo mineral tablets was calculated.

The prepared formulation shows even anti cancer activity in human lung and skin cancer cell lines.

The formulation contains safe herbals and minerals and holds promise to restrict cancer death rate. Its method of preparation and standardization complies the guidelines provided by regulatory bodies.
PARENTS ARE THE FIRST TEACHERS & TEACHERS ARE THE SECOND PARENTS

奉獻

TO ....
MAITHA
PITHA
GURU
DAJVAM