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Formulation and evaluation of herbal extract coated pellets with anti-inflammatory and hepatoprotective activity for prophylactic daily use as food supplements

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With increasing incidences of hepatitis, fibrosis and cirrhosis due to lifestyle changes, food habits, drug adverse effects, alcoholic and fatty damage, it is relevant that focus should now be on prophylactic and preventive measures, to take care of day to day factors causing cellular injury and inflammatory processes. Traditional foods and traditional therapeutic systems in the world including Ayurveda point to the benefits of regular herbal intake, which indirectly provided a prophylactic anti-inflammatory activity and show antiarthritic action. Slurry comprising herbal extracts was prepared by suspending in a solution of the excipients, dissolved or suspended in sufficient water and Isopropyl alcohol (IPA) to make the slurry sprayable. After milling through a machine adapted for grinding suspension, in order to reduce the particle size of extract, the suspension was applied on the excipient pellets in the classic pharmaceutical fluidized bed coating device, which consists simply of a vertical cylinder with an air-permeable bottom and an upward spraying nozzle close above the bottom, or a downward-spraying nozzle mounted above the product mass. The temperature of the fluidizing air was balanced against the spray rate to maintain the mass of pellets at the desired level of moisture and stickiness while the coating was built up. A finishing layer over the extract layer of 1% of an anti-static ingredient such as talc or silicon dioxide simply dusted on the surface of the pellets and other coats were applied. The pellets were made palatable and colored with colorants and flavors added to increase patient compliance for daily intake as prophylactic food and optimized for uniformity of content, dissolution and moisture content and then for anti-inflammatory and hepatoprotective activity. The Hepatoprotective pellet (HDT) treatment stimulated hepatoprotective effects that were proven by attenuating serum AST and ALT activities. The antioxidant activities of the HDT pellets can ameliorate oxidative stress contributing to the amount of intracellular antioxidant enzymes, which was confirmed by GSH and CAT assay. Centrilobular necrosis, lymphocytes infiltration and steatosis were apparent in CCl₄-treated group, whereas administration of the HDT significantly reverses these abnormal indexes. This indicates that HDT can ameliorate oxidative stress to preserve hepatic function and hepatic injury induced by CCl₄.

Biography

Sandeep Arora carries a professional experience spanning 23.5 years; 3.5 years in pharma production and quality assurance in Glaxo I Ltd, Blue Cross Ltd and 20 years in teaching/training and research in the fields of pharmacognosy and natural products, regulatory affairs, industrial pharmacy and management. He is the author of the book entitled, "Pharmaceuticals-Issues for Industrial Management" and has been the honorary Editor of *Advanced Drug Review* and has to his credit about 60 national and international publications. His area of specialization and research are medicinal natural products (phytochemical, pharmacological evaluation and standardization), development and regulatory aspects of herbal and other products and industrial management. He has to his credit 4 patents as Lead Investigator and 4 as Co-Investigator and involved in 2 product launches at international level. He is a Member APTI and Pharmacy Council and Life Member Inflammation Society, and Consultant and Advisor to pharma industry on regulatory compliance and herbal product standardization.

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