

Excipients help preserve efficacy, safety and functionality of APIs

DR SANJAY AGARWAL

MEDICINAL products are a dosed combination of two types of constituents: the active principles and the excipients. Excipients are inert substances which are used as diluents, fillers, binders or vehicles for the development of drug formulations and are responsible for desired pharmacological actions.

Almost all the marketed pharma products contain excipients thereby the excipients play a crucial role in the manufacture of medications by helping to preserve the efficacy, safety and functionality of the APIs. Recognising the critical role that excipients play in pharmaceutical dosage forms necessitates that excipients meet the quality requirements of the pharmaceutical industry. The adulteration of pharmaceutical excipients has resulted in adverse effects in patients.

Incidents had been observed where excipients act as potential toxicants. Examples of known excipient-induced toxicities include renal failure and death from diethylene glycol, osmotic diarrhoea caused by ingested mannitol, hypersensitivity reactions from lanolin, and cardiotoxicity induced by propylene glycol.



Given that there is no set rules and regulation to control excipient manufacturing and distribution, it must be considered as a key priority by regulatory authorities.

Today it is required that the excipient must pass all the toxicological tests envisaged for an active principle before it can be accepted as an excipient and the safety aspect should not be compromised. There has been instances where these so-called 'inert ingredients' sometimes interact with the active principles, lowering their titre and generating undesirable impurities, or altering the assimilation processes and the bioavailability of the drug itself. These problems may be overcome by

adopting and carefully adhering to good manufacturing practices similar to those for active principles (GMPs).

"Excipient has an important role in guaranteeing the dose, stability and release of the active principle, and the patient's 'compliance'. Hence the necessity has emerged of examining not only the quality and performance but also the safety of the excipients. The importance of evaluating the possible adverse effects of excipients is underestimated, considering the inertia and innocuity were taken for granted," according to pharmaceutical consultant Anshu Yadav.

(The author is leading pharmaceutical consultant)

Unwanted waxy taste and lipid rancidity

CONTINUED FROM p26

good compatibility with other coating materials and having high water vapour and gas-barrier properties. However, lipid-based coatings show unwanted waxy taste and lipid rancidity.

Protein-based Edible Coating

To increase the shelf life and maintain the edible quality of food produce, various edible coatings are prepared which are made of protein, polysaccharide and oil-containing materials which help to prolong the shelf life and maintain the quality of fruits and vegetables. Protein and polysaccharide films are generally good barrier against intermediate relative humidity (RH) and good mechanical properties. Much attention has been lately paid to whey protein concentrate (WPC) films because they are transparent with excellent barrier properties to oxygen and flavours. Generally, meat and other foods are covered with dry particles (breaded) or dipped in liquid solutions of these particles (battering). Owing to their structural characteristics, flours, gluten, protein-based materials such as whey proteins and supportive polysaccharides structured by gum and starch are commonly used.

Herbal Coating

Edible coatings can be securely eaten with the food product which is applied on surface of food produce to maintain their quality & enhance their shelf-life after harvesting. Edible coating mate-

Unwanted flavour is added to the food produce as applied some of the coating material which results unnecessary sensory attribute

rial can be prepared from various herbal extract such as Aloe Vera, tulsi, mint, lemongrass, cinnamon, oregano, neem and clove for food produce. Herbs-based edible coatings can be used in various fruits and vegetables such as papaya, apple, orange, grapes, tomato, cucumber and mango in order to prevent loss of moisture, delay ripening of fruits & reduce microbial growth. Herbal edible coatings can increase the storage time of fruits/vegetables of about 15-35 days when kept at low temperature while untreated fruits are deteriorated within 8-10 days. Use of herbal extracts as an edible coating for fresh produce would be an innovative & interesting thing that can be used

as an alternative for chemical treatment that can be commercially applied.

Challenges in Developing Edible Coatings for Food Produce

The success of an edible coating depends on its permeability to moisture and gases (O₂ and CO₂) and chemical attributes of the coating material, types of food produce, and environmental factors in which produce is stored.

There are some points which should be considered when developing an edible coatings formulation:

- Edible coating materials which have hydrophilic in nature show inadequate moisture-barrier properties;
- Due to inappropriate storage condition, unsuitable transportation and marketing of food produce O₂ and CO₂ barrier properties were varied;
- Improper technique of coating and poor coating adhesion between coating layer and the surface of fruits and vegetables; and
- Unwanted flavour is added to the food produce as applied some of the coating material which results unnecessary sensory attribute.

(The authors are Ph D scholar, HoD and ADP, College of Food Technology, VNMKV, Parbhani)