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Commentary

Pharmaceutical Formulation of Soft Gel Capsules

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DESCRIPTION

Capsules are solid preparations that include medicinal ingredients and excipients within a soluble shell that might be soft or firm. The sell is often composed of gelatin or another suitable polymeric substance, resulting in a simple, tasteless, odourless, beautiful and easy-to-swallow dosage form that does not require a further coating procedure. Capsules are classified as hard or soft depending on the composition of the capsule shell, with soft capsules having a flexible, plasticized gelatin film and hard capsules having two pieces in the form of cylinders closed at one end; the shorter piece, called the cap and the longer piece, called the body.

TYPES OF CAPSULES

Hard gelatin capsules, also known as hard-shell gelatin capsules or two-piece capsules are solid dosage forms that contain one or more therapeutic substances and/or inert ingredients within a tiny shell. They are a well-established dosage form that gives solutions to many of today's medication delivery and nutraceutical formulation difficulties.

Soft gelatin capsules, also known as soft gels or soft elastic capsules, are hermetically sealed one-piece capsules that contain a liquid or semisolid fill without a bubble of air or gas. They are formed of a more flexible gelatin film that has been plasticized with glycerine, sorbitol, or a similar polyol.

BASIC COMPONENTS

Gelatin

Gelatin is the primary component of the soft gelatin capsule shell. Depending on the nature of the liquid fill matrix, a wide range of gelatin shell compositions are available. The gelatin used most commonly is alkali (or base) processed (type B) gelatin, which accounts for 40% of the wet molten gel mass. Acid-processed gelatin of type A can also be utilised. The qualities of gelatin shells are influenced by the gelatin grade used and the amount of plasticizer in the shell.

Plasticising agents

To guarantee suitable flexibility, plasticizing chemicals are added to the formulation of a soft gelatin capsule. They interact with gelatin chains to lower the glass transition temperature of the gelatin shell and to increase moisture retention (hygroscopicity). Glycerol is the most common plasticizer used in soft gelatin capsules. Sorbitol, mannitol, and polypropylene glycol can also be used in conjunction with glycerol.

Water

Water typically accounts for 30-40% of the wet gel formulation, and its presence is critical both throughout the production process and in the completed product to ensure the capsule's flexibility. The ideal water content of the gelatin solution used to manufacture a soft gelatin capsule shell is determined by the viscosity of the specific grade of gelatin employed. It normally ranges between 0.7 and 1.3 parts water to one component dry gelatin.

Preservatives

Preservatives are frequently added to prevent the formation of germs and mould in gelatin solutions during storage. Potassium sorbate, as well as methyl, ethyl, and propyl hydroxybenzoate, are examples.

Colorants and opacifier

A colorant (soluble dyes, insoluble pigments) and opacifier (e.g., titanium dioxide) may be added to the shell for visual appeal or to reduce light penetration for the encapsulation of a photosensitive medicine. The colour of the capsule shell is usually chosen to be darker than the colour of its contents.

Other excipients

Flavouring agents and sweeteners can also be employed as excipients to increase palatability. Acid-resistant polymers are utilised to impart enteric release properties. They can also be used to make chewable soft gelatin capsules. A chelating agent,

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such as Ethylene Diamine Tetracetic Acid (EDTA), can be added to avoid chemical degradation of oxidation sensitive medications catalysed by free metals in gelatin, such as iron.