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Key to pharm technology

www.k2pharm.cz

Filling two-piece hard capsules with oils, semisolids and pellets/oil

Two-piece hard capsules have been used for almost a century in the pharmaceutical field, and gelatin has been adopted as the main material of these capsules due to its excellent characteristic. Several materials have been examined as a substituent for the gelatin in two-piece hard capsules. Hydroxypropylmethyl cellulose (HPMC) has become one of the successful alternative material for two-piece capsules.

The thickness of a hard two-piece capsule shell is about 0.1 mm. The capsule shell acts as a container and/or a protective wall. The important matter for the capsule with oily fill is a permeability of vapor water and oxygen through the capsule shell, and moisture content in capsule shell. Because hard gelatin capsules contain from 13% to 15% of water, water-sensitive drugs are not considered to be suitable to them. HPMC contains only from 4% to 6% of water in the shell and is able to be filled with water-sensitive drugs. The moisture content in the capsule shell also influences the brittleness of hard capsules. Capsules can be broken easily when the moisture content decreases to below of 10% in the gelatin capsule shell. The permeability rate of water vapor through the gelatin and the HPMC film is 446 and 263 g/m2/24 hours, respectively, indicating water vapor permeated more rapidly through the gelatin film than the HPMC film.



Figure 1 - Oil in a HPMC capsule

The structure of the HPMC film is lower than that of the gelatin film. Oxygen permeability relates to the looseness of film. Due to the oxygen permeability, the oxygen-sensitive products or the anti-oxidant products filled in the HPMC capsule should be packed as to minimize the oxygen permeation.

Our company K2pharm has a technology to fill wide range of oils into HPMC capsules (Figure 1). We also developed a semisolid form to fill capsules with lipophilic active ingredients as an oil phase or their combinations and water soluble ingredients in pellets (Figure 2).

Figure 3 - Band-sealed HPMC capsules

leaking (Figure 3). Some micronutrients can be added to sealing band to solve incompatibility between oily content and hydrophilic active ingredient.

Finally, K2pharm has a technology to seal capsules to prevent

Figure 2 - HPMC capsules filled with oils and pellets

Band-sealing for hard capsules with oily fills is ordinarily effected with gelatin for hard capsules made of gelatin or with HPMC for hard capsules of HPMC. Same material in band-sealing as the material of construction for hard capsules can allow mutual dissolution of the material at the portion of sealing, thus yielding the potent bonding. On the other hand, pullulan and polyvinyl alcohol copolymers are soluble in water and, when aqueous solutions of such materials are used in the sealing, leave the resultant hard capsule partly vulnerable to dissolution even after cooling the sealing portion. In order to avoid such phenomena, there has been adopted the procedure which involves admixing water with ethyl alcohol to accelerate the moisture drying rate.

Formulations:

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Shark liver oil	300 mg
Band – Selenium	55 mcg
Yeast betaglucans pellets	300 mg

Mental health:

Magnolia bark extract	250 mg
Omega-3 oil	300 mg
Band – Folic acid	200 mcg

Technology:

• IMA and Qualicaps line







