

Application

Gelatin capsule manufacturing

Targets: Pharmaceutical machine manufacturers, pharmaceutical companies, other capsule manufacturers, gelatin manufacturers

Application

In pharmaceutical processes, gelatin use is widespread and covers a large variety of processes. From production to filling and sealing (encapsulation), gelatin is the key ingredient throughout capsule manufacturing.

The combination of ingredients determines whether the capsule will be rigid or soft. In either case, the capsule walls may be comprised of gelatin plus another suitable polymer such as hypromellose. Hypromellose (HPMC, short for hydroxypropyl methylcellulose) is a semisynthetic, inert, viscoelastic polymer used as a controlled-delivery component. A pharmaceutical company determines ideal absorption characteristics which then dictate the **capsule's physical characteristics like the formula's viscosity and the temperature at which the capsule should be filled.**

Hard capsules are produced in a separate operation and supplied empty to the pharmaceutical company for in-house product development and manufacturing. They are always cylindrical in shape, consist of a cap and body, and have domed ends. Capsules housing a liquid or semi-solid are filled and sealed sequentially.

There are various, industrially practical techniques for sealing hard gelatin capsules. The first most commonly used method is banding. In this instance, **a gelatin band is applied around the overlap between the cap and body.** A second common procedure is sealing, in which a hydroalcoholic solution is applied to the overlap. Regardless of which ingredients are used, the zone between the cap and body must be kept clean and free of fill material in order to produce an effectively sealed and properly produced capsule.

All gelatin-related operations in the pharmaceutical industry present interesting characteristics and may be compared to mixing or coating processes where the viscosity of a deposit or residue plays a major role in the quality of sealing or banding.

Challenges

Described further is the capsule banding for capsule sealing, which is a crucial operation because the banding must guarantee that no product escapes the capsule. However, when rollers apply the gelatin band on the capsule, air bubbles might be created and their presence creates defects in the capsule's seal.

In this banding operation, banding gelatin viscosity is crucial, as it directly relates to the presence of air bubbles. By controlling viscosity, the manufacturer optimizes the process and avoids damaging consequences.

Some of the consequences of inferior sealing on hard shell capsules are:

- Increased quality controls
- Process slow-downs and required maintenance (downtime)
- Irregular drug dosage / dramatic consequences for patients
- Money losses linked to production inefficiency and product forfeitures
- Money losses due to public product recalls / bad reputation

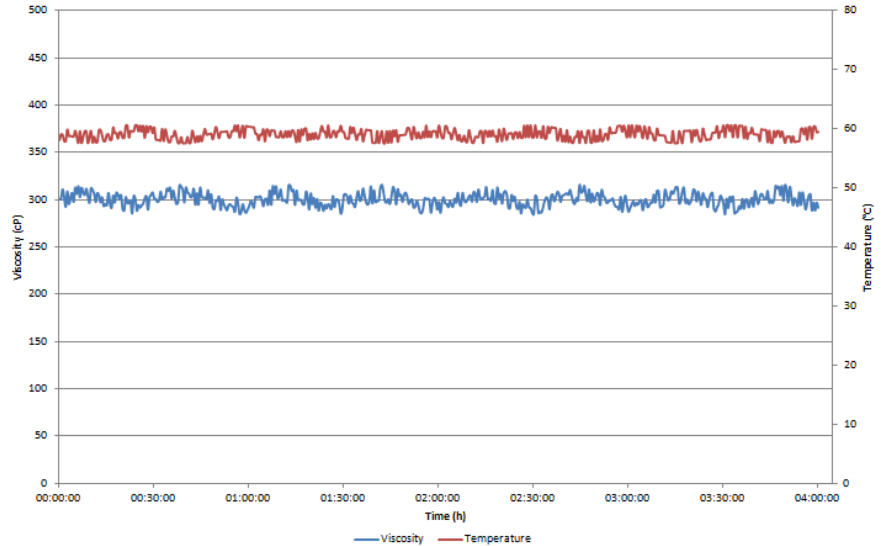
Solution

The installation of one MIVI sensor on the gelatin preparation tank provides continuous and stable viscosity values during the banding operation where temperature and viscosity conditions are optimized for perfect sealing. The MIVI viscometer and associated electronics guarantee zero default in viscosity deposit during the process' banding step.

Installation

Gelatin supply comes from the filling machine or a reactor. In the latter, the gelatin is produced prior to application and its viscosity is directly controlled in the reactor. The MIVI sensor (on the reactor) and the associated electronics allow precise temperature control, which permits the gelatin to be deposited according to pre-set banding operation parameters.

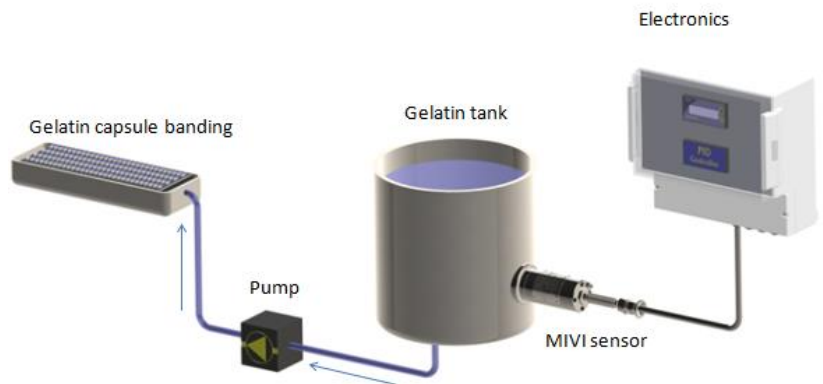
MIVI viscosity and temperature records on a gelatin tank



MIVI Installation on a gelatin tank



Gelatin deposit operation diagram



Key product characteristics:

- Repeatabile and reliable for permanent efficiency
- Small and compact size for easy machine integration
- Designed for sanitary environment (design according to 3A specifications and IP67 protection)
- Easy to install and to use
- Rugged
- No drift
- No maintenance