Materials — Hydroxypropyl cellulose (HPC, Klucel® LF; Eigenmann & Veronelli); Hydroxypropyl methylcellulose (HPMC, Methocel® E5 Premium LW, Dow); polyethylene glycol (PEG) 1500 and 6000 (Clariant Masterbatches); colloid grade Avicel® 50 and microcrystal cellulosic (SMC S.p.A.); acetylated gelatin (AAP) fine powder (Atabay) and granules (Comp® Coarse; Mallinkrodt); sodium 3,3-dimethyl-1-(4-pyridyl)propenyl (DDL). 

**METHODS**

**Injection-molding process** — A mixture of HPC 90% and PEG 1500 10% was added in Turbula (type T2C, WAB), dried in a vibrated oven for 24 h at 40°C and then transferred into the injection-molding press (Baby Plast mod. 61/9P, Cronogest, Rambaldi S.R.L.) equipped with a cap mold with two layers in order for the manufacturing of matching cap and body items of 600 μm nominal thickness. The conditions and results are reported in Table 1.

**RESULTS**

The feasibility of injection molding (IM) in the preparation of a shell device (Chronocap®) for oral pulsatile delivery and/or time-dependent colonic release has previously been demonstrated (1,2). Capsule devices based on hydroxypropyl cellulose (HPC) produced by means of a prototype mold showed the ability to delay, both in vitro and in vivo, the release of a tracer drug as a function of the wall thickness and polymeric composition of the shell. By evaluating the thermal, rheological and mechanical characteristics of the polymer, a new purposely-designed mold was recently developed and capsular with improved technological characteristics (e.g. homogeneity of the shell thickness and relevant consistency with the nominal value of 600 μm) were obtained (Figure 1) [3,4]. Moreover, the rate of production and automation extent of the manufacturing process were also enhanced.

**CONCLUSIONS**

- Molded HPC-based capsules were similar in diameter to gelatin and HPMC ones, but about 7mm shorter in length (Table 2). The weight of HPC devices was noticeably higher, mainly due to the shell thickness (610±20μm).
- HPC-based capsules appeared more tightly closed than conventional gelatin and HPMC ones (Figure 2), thus suggesting that the sealing step could be avoided.
- HPC-based capsules filled with AAP powder showed a lag time roughly 30 minutes longer than conventional capsules (Figure 3). Moreover, the time elapsed from the onset to completion of the release process was comparable (approximately 5 min).
- When HPC-based capsules were filled with the other selected formulations, some minor differences were found in the release parameters, in particular extended lag and pulse times of capsules filled with pellets or the solid dispersion; an analogous trend for gelatin and HPMC-based dosage forms with the same contents (Table 3) was observed.
- The lag time of HPC-based and HPMC capsules tested at pH 1.2 and 6.8 increased when the closing system was sealed (Table 4).
- A slight increase in the lag time of HPC-based capsules at pH 6.8 was noticed (Table 4).