LETTER TO THE EDITOR

In-vitro dissolution testing of 5-aminosalicylic acid release from pH dependent mesalazine formulations

Dear Sir,

We have read with interest the abstract presented at the last ECCO Congress by Tenjarla & Abinusawa. While we agree with the authors’ final statement that ‘consideration of the potential release profiles [of 5-ASA] may be a useful tool in choosing the most appropriate treatment’, we question the findings on Salofalk granules, i.e., that Salofalk 1.5 g granules release only approximately 20% of its total amount of 5-aminosalicylic acid in different dissolution experiments.

In contrast to the conclusions on the poster of Tenjarla & Abinusawa that ‘Salofalk granules may fail to release the majority of their 5-ASA load at colonic pH values’, several studies published as full articles in established journals have shown the favourable release profile of Salofalk granules. To further elucidate these contradicting data, replication of the dissolution experiments was initiated. Strictly following the methods as used by Tenjarla & Abinusawa, we found an in-vitro release of 5-ASA of more than 90% after 4 h in Experiment A and after 7 h in Experiment B (see Figs. 1 and 2), which is in line with earlier published data on Salofalk granules, but in strong contradiction to Tenjarla & Abinusawa.

The in-vitro release profiles of Mezavant 1200 mg under both experimental designs as described by Tenjarla & Abinusawa could be confirmed (see Figs. 1 and 2). Salofalk granules have not only been shown to exert a favourable release profile for 5-ASA, but a number of well designed, randomised, double-blind, controlled pivotal phase III studies clearly demonstrate significant therapeutically efficacy both for active ulcerative colitis and for maintenance of remission in ulcerative colitis. Moreover, recently a pooled analysis of several clinical studies has demonstrated a very high efficacy of Salofalk granules in active UC confined to the distal part of the colon, which again points to a sufficient release of 5-ASA from Salofalk granules, and thus confirms the suitability of this formulation to target colonic inflammation.

References


Figure 1 Experiment A: dissolution of Salofalk 1.5 g granules (batch no. 10F18833L) and Mezavant 1200 mg (batch no. VB032) at pH 6.8 (n=6).

Figure 2 Experiment B: dissolution of Salofalk 1.5 g granules (batch no. 10F18833L) and Mezavant 1200 mg (batch no VB032) at sequential pH 1.0, 6.0, and 6.8 (n=6).


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