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COMMUNICATION

Ranitidine HCl: Tablet Film Coating Acidity and Discoloration

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ABSTRACT

The presence of citric acid in the film coating of ranitidine hydrochloride tablets decreased discoloration.

INTRODUCTION

Ranitidine hydrochloride is prone to discoloration in pharmaceutical dosage forms; this is accelerated by heat, moisture, and light (1). A patented film coating method employing triacetin (triacetyl glycerin) as a plasticizer is claimed to minimize discoloration of ranitidine HCl in tablets due to low solubility of the drug in it (2). Apart from this, no data on this subject appear to have been published in the pharmaceutical literature.

This communication presents evidence that the discoloration of ranitidine HCl in tablets is pH dependent and may be reduced by adding a small quantity of citric acid to the film coating.

MATERIALS AND METHODS

All raw materials employed were of pharmacopeial (EP) quality. Granulation was performed in an intensive mixer (Gral-25, Collette, Belgium), tablet compression in a rotary tableting machine (Manesty B3B, Manesty, UK), and film coating in a perforated rotary coating pan (Accela-Cota 10, Manesty, UK).

EXPERIMENTAL

Three lots of ranitidine tablets, batch size 6 kg, were prepared by wet granulation, followed by drying, sizing, mixing with magnesium stearate, and compaction to a target tablet mass of 600 mg and strength of 300 mg (ranitidine). The main excipient was microcrystalline cellulose. The tablet cores were coated with an aqueous film coating suspension containing hydroxypropylmethylcellulose (HPMC) as the film former, polyethylene glycol 6000 (33% relative to HPMC) as the plasticizer, titanium dioxide, and talc. One of the tablet batches was coated with the unaltered coating suspension; the other two batches also contained 0.3% and 3.3% (relative to HPMC), respectively, of citric acid monohydrate. The amount of applied coating (mass increase of cores) was approximately 3% in all cases. The tablets were packaged into brown plastic capped glass bottles and put on stability trial at 40°C/75% relative humidity for 3 months.

RESULTS

Visual examination of the tablets after 1 month revealed that the tablets coated with the plain suspension

were yellow; those containing citric acid remained almost white. After 3 months, the plain tablets had turned brown, but the others exhibited a faint yellowish tint only. There was no pronounced color difference between the two coatings containing different concentrations of citric acid.

DISCUSSION AND CONCLUSIONS

Judging from the results described above, there seems little doubt that the discoloration of ranitidine HCl tablets is pH dependent since inclusion of citric acid in the film coating retarded the appearance of discoloration. Recently, the surface acidity of citric acid was shown to be very high, with pH_{eq} of 1.45 (3). Bearing in mind that triacetin may be expected to furnish acetic acid on decomposition in film coatings, its discoloration diminishing effect on ranitidine may also be due to microenvironmental lowering of pH.

REFERENCES

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