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FORMULATION AND DISSOLUTION CHARACTERISTICS OF SODIUM SALICYLATE ENTERIC COATED TABLETS PREPARED BY VARIOUS POLYMERS

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Enteric coated formulation of sodium salicylate offers a viable solution to the problem of gastrointestinal distress caused by its tablets. The aim of this study was to evaluate the effect of acrylic resins (Eudragits L100, S100), shellac and cellulose acetate phthalate (CAP) on the release behaviours of sodium salicylate from enteric coated tablets prepared by these polymers.

The sodium salicylate granules were prepared, using 10% alcoholic solution of PVP as binder. Suitable size of dried granules mixed with microcrystalline cellulose (MCC). Lubricated mixture was compressed into tablet using an excenteric tablet machine (EKO, Erweka). Cores were coated by various pH dependent soluble polymers (Eudragits S100, L100, CAP and Shellac) by a conventional stainless steel coating pan. Coated cores were recoated with the mixture of polyethyleneglycols (PEG) 400+4000 (1:1) to improve the film coating behaviours of the polymers used. Different release characteristics can be devised by changing the amount of polymers used for film coating. Dissolution of sodium salicylate was studied using the basket method described in USP XXII. The dissolution medium (900 ml, at 37±0.5°C) was consisted of hydrochloric acid buffer pH 1.2 (SGF) for the first 1.5h and phosphate buffer pH 7.5 (SIF) for the remaining period of time (1h). The speed of rotation was 100 RPM. A spectrophotometric method (at 301 nm) was compared with USP XXII titrimetric procedure for investigation of drug release characteristics of enteric coated formulations. Although CAP showed a proper enteric coating properties however its dissolution profile above pH 6.0 is very fast. The $t_{50\%}$ of drug release patterns of all polymers used were compared statistically and were significantly different ($p < 0.05$). Furthermore, the consistency of drug release profiles of all polymers were improved when polyethylenglycols were utilized as second film coating in formulation processes. However, the release profiles of the coated cores with or without PEG were not significantly different at 95% confidence interval. Of the polymers used the mixture of Eudragits L100+S100 (1:1) exhibited a proper coating behaviours when used as enteric coating agents.