PLASTICIZATION OF CELLULOSE ETHERS USED IN THE FILM COATING OF TABLETS - THE EFFECT OF PLASTICIZER MOLECULAR WEIGHT

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Film formers such as the cellulose ethers, ethyl cellulose and hydroxypropyl methylcellulose are now used extensively in the film coating of solid dosage forms. Plasticizers are often added to these polymers in order to change their physical properties and enhance their film forming characteristics. To be effective, a plasticizer must interpose itself between the polymer chains and interact with the forces holding the chains together thereby extending and softening the polymer matrix. It would be expected, therefore, that within an homologous series of plasticizers there should be an optimum molecular weight when there is maximum location of the interacting groups in relation to each other. This hypothesis has been tested in this study using the intrinsic viscosity measurements.

Intrinsic viscosities of ethyl cellulose (Grade N50 Hercules Powder Co. Ltd.) in a series of dialkyl phthalates and hydroxypropyl methylcellulose (Pharmacoat 606, Shinetsu Chemical Co. Ltd.) in a series of liquid glycols were measured using standard U tube viscometers at 25°C and substituting in equations derived by Rudin and Wagner (1975).

For both polymers there was a maximum in the intrinsic viscosity corresponding to diethyl phthalate for ethyl cellulose and polyethylene glycol 200 for hydroxypropyl methylcellulose. Some variation in the results was found for the hydroxypropyl methylcellulose when polyethylene glycols from varying sources were used probably due to the varying molecular weight distribution of these materials. It is interesting to note that diethyl phthalate also has a solubility parameter 20.5 MPa² closest to that of ethyl cellulose - 21.1 MPa² (Burrell, 1975). Similar results have been reported in the literature for polyvinyl chloride in a series of dialkyl phthalates where the maximum intrinsic viscosity occurred with dibutyl phthalate (Wurstlin and Klein, 1952).

If maximum interaction is related to maximum efficiency in films, as would seem to be the case for polyvinyl chloride where dibutyl phthalate has been shown to be the most efficient in lowering the torsional modulus of elasticity (Lawrence and McIntyre, 1949), then the implications of these results in film formulation are obvious.

Burrell, H. (1975). Polymer Handbook. 2nd Edition pp IV 337-360, Eds. Bandrup, J. and Immergut, E.H. Wiley Interscience.

Lawrence, R.L. and McIntyre, E.B. (1949). Ind. Engng. Chem., 41, 689-694.

Rudin, A. and Wagner, R.A. (1975). J.Appl. Polym. Sci., 19, 3361-3367.

Wurstlin, F.K. and Klein, H. (1952). Kunststoffe 42, 445-449.