

Coloured Granules for Compression Coating

R. C. Shah

A. R. Shah

Mac Laboratories (P) Ltd.

Kirol, Bombay-400 086
(India)

It is now well established that mottling in coloured tablets is caused by migration of dyes with the granulating fluid during drying. The various factors contributing to mottling of coloured tablets have been fully dealt with in recent two articles (1, 2). In an attempt to prepare coloured granules for coating tablets by compression, it was concluded that the factors responsible for migration of the dye were the nature of the dye, excipients and the granulating agent.

During extensive trials for developing yellow, orange, blue and red granules for Compression Coating, the formulation consisting of 40% lactose, 40% amylum and 20% microcrystalline cellulose, wet granulated with 50% W/W of 10% amylum paste coloured with 0.1% to 0.4% W/W of the appropriate dye, gave highly satisfactory results. The wet mass was passed through No. 8 sieve and tray dried for about 16 hours at 60°C. The dried granules were passed through No. 20 mesh, treated with 1% magnesium stearate and used as coating granules for dry cota compression. The use of microcrystalline cel-

lulose prevented migration of the colour to a very large extent. This formulation was highly satisfactory for tartrazine yellow and sunset yellow. With indigo carmine and FDC Red No. 3, there was appreciable migration and the tablets were mottled with the result that the formulation which was suitable for preparing yellow and orange coloured granules failed to yield uniform blue and red coloured granules. This proved that the nature of the dye played a very important part in colour migration. Substituting the aluminium lakes of indigo carmine and FDC Red No. 3 for the respective soluble dyes, gave uniformly coloured granules which could be compressed into tablets without any mottling. There was no stripping of either the blue or the red dye from the aluminium lakes by the excipients. In order to have comparable shades, it was necessary to use 2% to 3% of the aluminium lakes instead of 0.1% to 0.4% of the corresponding dyes. This was found to be expensive and hence several combinations of excipients and granulating agents were tried.

40% tricalcium phosphate, 40% amylum and 20% microcrystalline cellulose granulated with 90% W/W of coloured 5% of methanolic solution of shellac gave uniformly coloured granules without any migration of the blue and red dyes. Both indigo carmine and FDC Red No. 3 were soluble in methanol to the extent of giving reasonably deep shades. The wet mass was passed through No. 20 sieve, treated with 1% magnesium stearate and used for compression. The use of coloured 5% methanolic solution of PVP as granulating agent for the above excipients resulted in perceptible migration of both the blue and red dyes.

All the above four formulations gave uniformly coloured dry cota tablets with good hardness, rapid disintegration and strong adhesion to the core.

- 1) N. A. Armstrong and G. A. March,
J. Pharm. Sci., 65, 198 (1976)
- 2) N. A. Armstrong and G. A. March,
J. Pharm. Sci. 65, 200 (1976)