ANALYTICAL PROCEDURE
DRY PREMIX FOR WHITE-COLOUR COATING 37781 RBC
(E000658-013)

The methods and reagents R referred to in this technique are described in the European Pharmacopoeia.

Mixture of coating excipients to be dispersed in water before use.

Percentage composition (% *m/m*) is the following:

Glycerol	4.50
Hypromellose	74.80
Macrogol 6000	1.80
Magnesium stearate	4.50
Titanium dioxide (E 171)	14.40

1. CHARACTERS

White coloured granules or powder.

2. IDENTIFICATION

Dissolve the residue obtained during the "Total ash" test in a mixture of 8 ml of concentrated sulfuric acid *R* and 2 ml phosphoric acid *R*. Heat until the mixture boils. Centrifuge or filter. Pour 1 ml of the clear solution into 5 ml of water to which is added several drops of a solution of hydrogen peroxide *R*. A yellow to yellow-orange coloration develops.

3. TEST

3.1. Suspension S

Prepare a bubble-free homogeneous aqueous suspension containing 15 per cent *m/m* of the substance to be examined.

3.2. Viscosity *(2.2.10)*

300 mPa.s to 900 mPa.s, determined on the suspension S with a rotating viscometer (Brookfield-type LVT) at 20 °C.

3.3. Dispersion

Allow 665 g of the suspension S to pass through a tared sieve with a mesh size of 150 µm. Rinse several times with water then dry and weigh the sieve. The mass of the residue on the sieve does not exceed 0.5 g (0.5 per cent *m/m*).

3.4. Film formation

Spread out part of the suspension used during the "Dispersion" test on a metallic or glass plate. A white film is formed after drying.

3.5. Loss on drying *(2.2.32)*

Not more than 6.0 per cent, determined on 1.5 g by drying in an oven at 100 °C to 105 °C for 3 h.

3.6. Total ash *(2.4.16)*

12.0 per cent to 17.0 per cent, determined on 1.5 g at a maximum temperature of 800 °C ± 25 °C.

3.7. Microbial contamination (If tested)

Total aerobic microbial count (TAMC) *(2.6.12)* not more than 10^3 CFU/g and total combined yeasts/moulds count (TYMC) not more than 10^2 CFU/g. It complies with the test for Escherichia coli *(2.6.13)*.

4. STORAGE

Store in a well-closed container.