ABSTRACT

SUSTAINED RELEASE COMPOSITIONS AND A METHOD OF PREPARING PHARMACEUTICAL COMPOSITIONS

In order to provide a sustained release pharmaceutical formulation containing morphine which is suitable for administration on a once daily basis, in a first aspect, an orally administrable sustained release dosage unit form contains morphine, or a pharmaceutically acceptable salt thereof, as active ingredient, which formulation gives a peak plasma level at 1.0 to 6 hours after administration. In a second aspect, the formulation contains an effective amount of morphine or a pharmaceutically acceptable salt thereof, characterised by a W_{50} for the M-6-G metabolite or for morphine of between 4 and 12 hours. In a third aspect, the pharmaceutical dosage unit form is obtainable by compressing multiparticulates comprising a pharmaceutically active substance in a matrix of hydrophobic fusible material having a melting point of from 35 to 150°C, the dosage form optionally containing conventional tabletting excipients. In a further aspect of the invention, sustained release multiparticulates containing morphine or a pharmaceutically acceptable salt thereof are produced by mechanically working in a high-speed mixer a mixture of particulate morphine or a pharmaceutically acceptable salt thereof and a particulate, hydrophobic fusible carrier or diluent having a melting point from 35 to 150°C and optionally a release control component comprising a water soluble fusible material or a particulate soluble or insoluble organic or inorganic material at a speed and energy input which allows the carrier or diluent to melt or soften whereby it agglomerates, and breaking down the agglomerates to give controlled release particles.

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