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(71) Applicant *(for all designated States except US)*: **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).

(71) Applicant *(for MG only)*: **SMITHKLINE BEECHAM CORPORATION** [US/US]; One Franklin Plaza, PO Box 7929, Philadelphia, PA 19101 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **NEWMAN, Stephen** [GB/GB]; c/o GlaxoSmithKline, Park Road, Ware Hertfordshire SG12 0DP (GB).

(74) Agents: **DADSWELL, Charles** et al.; GlaxoSmithKLine, Corporate Intellectual Property Dept., Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US).

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(54) **Title:** PROCESSES FOR MAKING LACTOSE UTILIZING PRE-CLASSIFICATION TECHNIQUES AND PHARMACEUTICAL FORMULATIONS FORMED THEREFROM

(57) **Abstract:** A process for forming lactose suitable for use in a pharmaceutical formulation comprises providing a plurality of lactose particles containing no more than 10% w/w of lactose particles having a volume average particle size of about 70 microns or less; milling the plurality of lactose particles to yield a plurality of milled lactose particles with an average particle size, (D50), ranging from about 50 microns to about 100 microns; and classifying the plurality of milled lactose particles into at least two fractions comprising a fine fraction and a coarse fraction wherein the fine fraction has an average particle size, (D50), ranging from about 3 microns to about 50 microns, and the coarse fraction has an average particle size, (D50), ranging from about 40 microns to about 250 microns.

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