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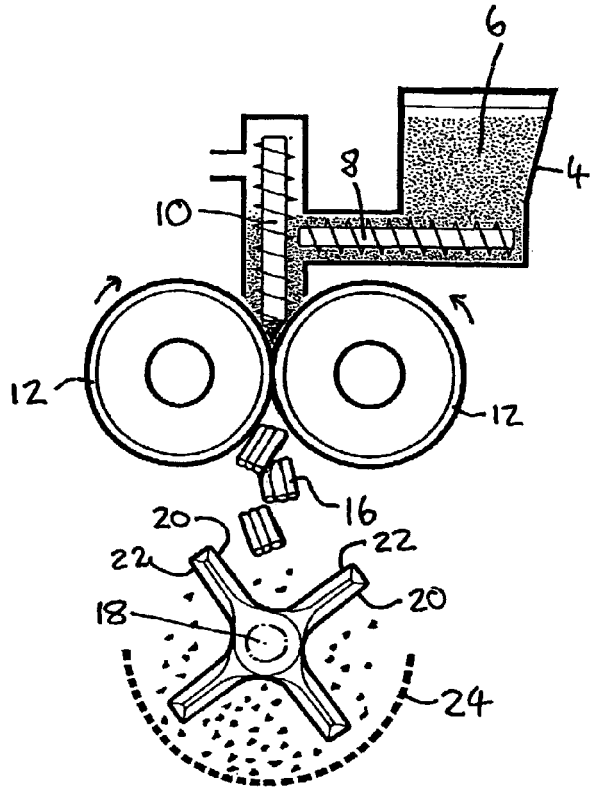
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(54) Title: PHARMACEUTICAL COMPOSITION COMPRISING N- ((1-N-BUTYL-4-PIPERIDINYL) METHYL)-3, 4-DIHYDRO-2H- (1, 3) OXAZINO (3, 2-A) INDOLE-10-CARBOXAMIDE OR SALT AND PROCESS THEREFOR COMPRISING DRY GRANULATION



(57) Abstract: The invention provides a process for preparing a pharmaceutical composition comprising N-[1-[n]butyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide (SB 207266) (piboserod) or a pharmaceutically acceptable salt thereof in combination with one or more pharmaceutically acceptable excipients, the process comprising forming part or all of the SB 207266 or the salt thereof into granules by a dry granulation process. The process is preferably a roller compaction process, preferably followed by milling to a suitable particle size. The granules are usually of increased particle size and/or compacted compared to the SB 207266 or the salt thereof. Preferably, the SB 207266 or the salt thereof is present in the composition and/or in the granules in at least 4 weight % and/or up to 60 weight % by weight of the composition and/or by weight of the granules respectively. An intragranular lubricant, filler (e.g. $CaHPO_4$), and/or compression aid (e.g. microcrystalline cellulose) are usually used. The invention also provides a pharmaceutical composition obtainable by the dry granulation process and/or which has been prepared by the dry granulation process.

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