

Title (en)

WET GRANULATION FORMULATION OF A GROWTH HORMONE SECRETAGOGUE

Title (de)

NASSGRANULATIONSFORMULIERUNG EINES WACHSTUMSHORMONSEKRETIONSFÖRDERERS

Title (fr)

FORMULATION DE SECRETAGOGUE STIMULANT LA SECRETION DE L'HORMONE DE CROISSANCE, DESTINEE A ETRE GRANULEE PAR VOIE HUMIDE

Publication

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Application

EP 96937761 A 19961023

Priority

- GB 9603238 A 19960216
- GB 9603834 A 19960223
- US 9617196 W 19961023
- US 589795 P 19951027
- US 590195 P 19951027

Abstract (en)

[origin: WO9715191A1] The present invention relates to a pharmaceutical composition and a process for the preparation of a tablet containing a growth hormone secretagogue as the active ingredient. The tablet is prepared by forming a powder blend of the active ingredient N-[1(R)-[(1,2-dihydro-1-methanesulfonyl-spiro[3H-indole-3,4'-piperidin]-1'-yl)carbonyl]-2-(phenylmethyl-oxy)ethyl]-2-amino-2-methyl-propanamide, or a pharmaceutically acceptable salt thereof, in particular the methanesulfonate salt, with a binder/diluent, a first diluent, a second diluent, a first portion of a disintegrant, and a lubricant; wet granulating the powder blend with a solution of ethanol/water to form granules; drying the granules to remove the ethanol/water; adding a second portion of a disintegrant; lubricating the granules; and compressing the dried granules into the desired tablet form. The present invention further relates to a novel amorphous form of the compound N-[1(R)-[(1,2-dihydro-1-methanesulfonyl-spiro[3H-indole-3,4'-piperidin]-1'-yl)carbonyl]-2-(phenylmethyl-oxy)ethyl]-2-amino-2-methylpropanamide methanesulfonate which is produced directly as a result of the process of tablet formulation.

IPC 1-7

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IPC 8 full level

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CPC (source: EP)

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- [X] WO 9511029 A1 19950427 - MERCK & CO INC [US], et al
- See references of WO 9715191A1

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