

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

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Application  
**EP 96937761 A 19961023**

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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'-piperdin]-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'-piperdin]-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.

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