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(54) Title: DIRECT COMPRESSION FORMULATION AND PROCESS

(57) Abstract: Dipeptidylpeptidase IV inhibitor (herein referred to as DPP-IV) that may be 98.5-100% pure is a high-dose drug capable of being directly compressed with specific excipients into sold form dosage forms, such as tablets and capsules having desired, hardness, disintegrating ability and acceptable dissolution characteristics. DPP-IV is not inherently compressible and thus presents formulation problems. Excipients used in the formulation enhance the flow and compaction properties of the drug and tableting mix. Optimal flow contributes to uniform die fill and weight control. The binder used ensures sufficient cohesive properties that allow DPP-IV to be compressed using the direct compression method. The tablets produced provide an acceptable *in vitro* dissolution profile.

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