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(54) Title: FORMULATIONS OF ATORVASTATIN STABILIZED WITH ALKALI METAL ADDITIONS

(57) Abstract: A pharmaceutical formulation having improved bioavailability and bioequivalence includes particles of amorphous and/or crystalline atorvastatin that have a particle size (d90) less than 150 m and a mean particle size (d50) of the atorvastatin particles that is between approximately 5 and 50 m. The atorvastatin can be one or more of atorvastatin calcium, atorvastatin magnesium, atorvastatin aluminum, atorvastatin iron, and atorvastatin zinc. The formulations of atorvastatin can be stabilized by mixing atorvastatin with an alkali metal salt additive at between approximately 1.2% and less than 5% w/w of the formulation. The alkali metal salt additive may be one or more of sodium carbonate, sodium bicarbonate, sodium hydroxide, sodium silicate, disodium hydrogen orthophosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium phosphate, sodium aluminate, calcium carbonate, calcium hydroxide, magnesium carbonate, magnesium hydroxide, magnesium silicate, magnesium aluminate, and aluminum magnesium hydroxide. The atorvastatin formulations can be used to treat medical conditions, including primary hypercholesterolemia, dysbetalipoproteinemia, and homozygous familial hypercholesterolemia.