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(54) Title: MESALAMINE SUPPOSITORY

(57) Abstract: The present invention relates to a mesalamine rectal suppository designed to provide improved comfort of use. One embodiment of the invention is a mesalamine rectal suppository comprising mesalamine and one or more pharmaceutically acceptable excipients, wherein the drug load of the suppository ranges from 35% to 50%. Yet another embodiment of the invention is a mesalamine rectal suppository comprising mesalamine having a tap density ranging from about 600 to about 800 g/L (as measured by USP <616>) and a hard fat having an ascending melting point of 32 to 35.5° C. Yet another embodiment is a mesalamine rectal suppository comprising mesalamine particles and one or more pharmaceutically acceptable excipients, where the mesalamine particles have a surface area of from about 0.1 m<sup>2</sup>/g to about 2.8 m<sup>2</sup>/g (e.g., from about 0.1 m<sup>2</sup>/g to about 1.3 m<sup>2</sup>/g). Methods of preparing and methods of treatment with mesalamine suppositories are also provided. The invention further provides a method of determining a dissolution parameter (such as dissolution rate) of a mesalamine rectal suppository, such as a 1 g mesalamine suppository, by measuring its dissolution with USP Apparatus #2 at 40° C and a paddle rotation speed of 125 rpm in 0.2 M phosphate buffer at a pH of 7.5.

