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(54) Title: SPRAYING DEVICE COMPRISING AQUEOUS BUDESONIDE COMPOSITION

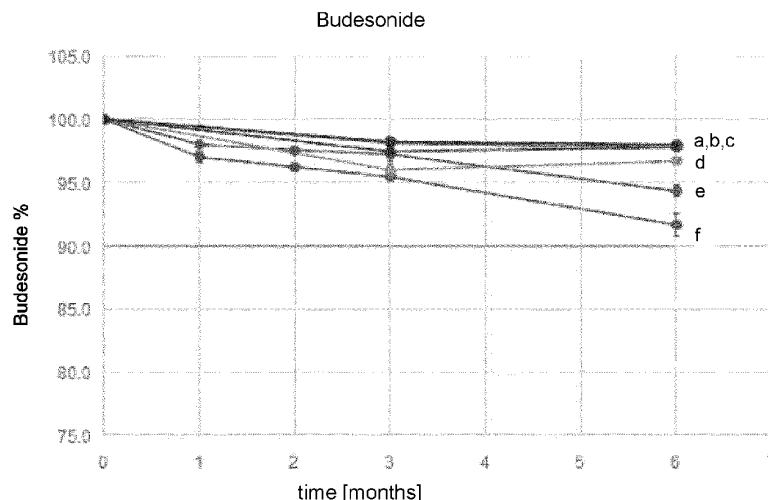


FIG. 9B

(57) Abstract: Disclosed is a spraying device for nasal or buccal delivery of a buffered aqueous composition comprising solubilized budesonide, which has improved long-term storage stability and reduced amounts of impurities, the buffer adjusted to pH 4 to 5, wherein budesonide is dissolved at a concentration of at least 100 µg/mL, wherein the composition is free of metal ions and packed into a metal-free first containment closed with a spray pump system packaged into a sealed oxygen-impermeable, oxygen-free second containment, and wherein the composition after storage at 25 °C over a period of 12 months contains at least 90%, preferably at least 95 %, of the nominal starting concentration of solubilized budesonide, and no more than 1 %, relative to the budesonide concentration, of total impurities. The invention further relates to the composition for use as a medicament in the treatment of inflammatory diseases or conditions.

[Continued on next page]

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