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(54) Title: PHARMACEUTICAL COMPOSITION COMPRISING BUDESONIDE FOR TREATING IGA NEPHROPATHY

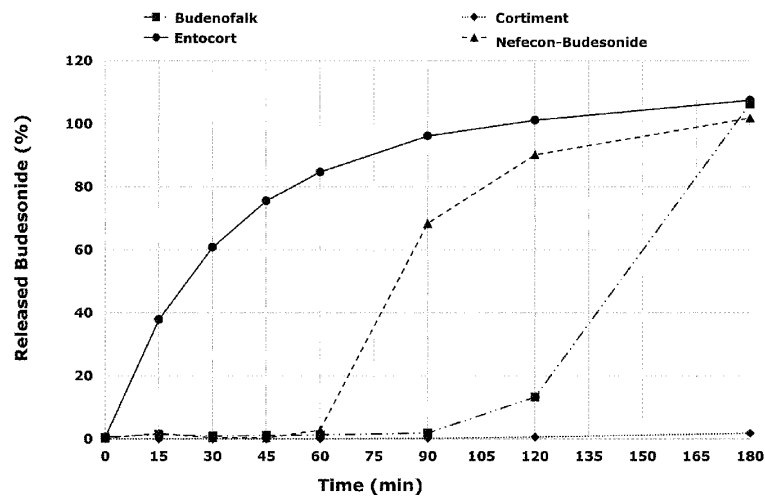


Figure 5

(57) Abstract: The present invention provides for a method of treatment of IgA nephropathy, which method comprises: (i) Identifying a pharmaceutically acceptable composition intended to treat IgA nephropathy comprising budesonide and one or more pharmaceutically-acceptable excipients that provide for a modified release of said budesonide after administration to the gastrointestinal tract, which composition fulfils the following requirements in a standard in vitro USP<711>/Ph.Eur. 2.9.3 dissolution test using a dissolution apparatus according to Apparatus 2 (Paddle Apparatus) of said test; (a) the composition fulfils the requirement that no more than about 10% of the budesonide is released into the dissolution medium within about 120 minutes, when the dissolution medium is aqueous and has a pH of about 1.2; (b) the composition fulfils the requirement that no more than about 10% of the budesonide is released into the dissolution medium within about 30 minutes, when the dissolution medium is aqueous and has a pH of about 6.8; and (c) the composi-

[Continued on next page]

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tion fulfils the requirement that at least about 70% of the budesonide is released into the dissolution medium within about 120 minutes, when the dissolution medium is aqueous and has a pH of about 6.8; (ii) wherein the method comprises the step of administering said composition to a patient with IgA nephropathy in need of said treatment.