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(54) Title **Pharmaceutical formulations containing dapagliflozin propylene glycol hydrate**

(56) References Cited:

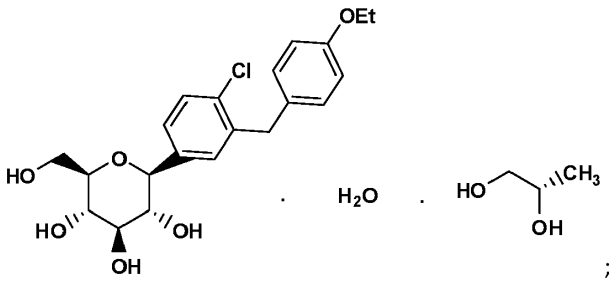
WO-A-03/099836
WO-A-2008/002824
MENG WEI ET AL: "Discovery of dapagliflozin: A potent, selective renal sodium-dependent glucose cotransporter 2 (SGLT2) inhibitor for the treatment of type 2 diabetes", JOURNAL OF MEDICINAL CHEMISTRY, vol. 51, no. 5, March 2008 (2008-03), pages 1145-1149, XP002491733, ISSN: 0022-2623

Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (http://worldwide.espacenet.com) or via the search engine on our website here: https://search.patentstyret.no/

Patentkrav

1. Farmasøytisk formulering med umiddelbar frigjøring, i form av et rågranulat som skal fylles i kapsler eller danne tabletter, der rågranulatet omfatter:

a) 0,1 til 40 % (m/m) dapagliflozin-propylenglykolhydrat som har formelen



;

b) 0 til 50 % (m/m) vannfri laktose;

c) 1 til 15 % (m/m) krospovidon;

d) 0 til 6 % (m/m) silisiumdioksid;

e) 0 til 4,0 % (m/m) magnesiumstearat; og

f) mikrokrystallinsk cellulose i en mengde som gjør rågranulatsammensetningen 100 % (m/m).

2. Rågranulat ifølge krav 1, som omfatter 10 til 30 % (m/m) vannfri laktose, 3 til 10 % (m/m) krospovidon; 0,5 til 4 % (m/m) silisiumdioksid, 0,5 til 2,0 % (m/m) magnesiumstearat og mikrokrystallinsk cellulose.

3. Tablett eller kapsel som omfatter et rågranulat ifølge et foregående krav.

4. Tablett eller kapsel ifølge krav 3, der dosen med dapagliflozin er fra 0,1 mg til 50 mg.