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(54)	Title	METHOD FOR CONTROLLING IMPURITY OF CYCLOSPORIN IN AN EYE GEL
(56)	References Cited:	BONIFACIO F N ET AL: "Development and validation of HPLC method for the determination of Cyclosporin A and its impurities in Neoral(R) capsules and its generic versions", JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS, vol. 49, no. 2, 20 February 2009 (2009-02-20), pages 540-546, XP027282464, NEW YORK, NY, US ISSN: 0731-7085 [retrieved on 2008-11-27], HUSEK A ED - CHANKVETADZE B ET AL: "High-performance liquid chromatographic analysis of cyclosporin A and its oral solutions", JOURNAL OF CHROMATOGRAPHY A, vol. 759, no. 1, 24 January 1997 (1997-01-24), pages 217-224, XP004049990, AMSTERDAM, NL ISSN: 0021-9673, DOI: 10.1016/S0021-9673(96)00770-4 JAIN DEEPTI ET AL: "Forced degradation and impurity profiling: Recent trends in analytical perspectives", JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS, vol. 86, 31 July 2013 (2013-07-31), - 31 July 2013 (2013-07-31), pages 11-35, XP028734549, NEW YORK, NY, US ISSN: 0731-7085, DOI: 10.1016/J.JPBA.2013.07.013

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

- 5 **1.** En fremgangsmåte for å kontrollere urenheter i en cyklosporin A øyegel, som bestemmes ved høy-ytelses væskekromatografi, hvor de kromatografiske forholdene er som følger:
- deteksjonsbølgelengden er 210-230 nm;
- strømningshastigheten er 0,8-1 ml/min;
- den mobile fasen er: THF-vann-fosforsyre, den kromatografiske kolonnen har oktadecylsilan-bundet silikagel som fyllstoff, **karakterisert ved**
- 10 **at** kolonnetemperaturen er 60-68°C; og volumforholdet til mobilfasen THF-vann-fosforsyre er 400:600:1,58.
- 2.** Fremgangsmåten for å kontrollere urenheter ifølge krav 1, **karakterisert ved**
- 15 **at** kolonnetemperaturen er 65°C.
- 3.** Fremgangsmåten for å kontrollere urenheter ifølge krav 1, **karakterisert ved at** deteksjonsbølgelengden er 220 nm.
- 20 **4.** Fremgangsmåten for å kontrollere urenheter ifølge krav 1, **karakterisert ved** **at** kolonnen er en Waters-kolonne, en Thermo-kolonne, en Pheromone-kolonne eller en YMC-kolonne.
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