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(54) Title **SUSTAINED RELEASE FORMULATIONS USING NON-AQUEOUS CARRIERS**

(56) References
Cited: WO-A1-2005/102293, US-A1- 2004 224 030, US-A1- 2008 146 490, WO-A2-2007/024700
JAIN R A ET AL: "Controlled release of drugs from injectable in situ formed biodegradable PLGA
microspheres: effect of various formulation variables", EUROPEAN JOURNAL OF
PHARMACEUTICS AND BIOPHARMACEUTICS, ELSEVIER SCIENCE PUBLISHERS B.V.,
AMSTERDAM, NL, vol. 50, no. 2, 1 September 2000 (2000-09-01), pages 257-262,
XP004257199, ISSN: 0939-6411, DOI: 10.1016/S0939-6411(00)00062-X

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:

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Patentkrav

1. En fremstilt forblandet formulering for injeksjon som hovedsakelig består av en suspensjon av:

- (i) en farmasøytisk akseptabel bærer som omfatter ett eller flere triglyserider av C₆ -C₁₂ fettsyrer; og
 - (ii) mikrosfærer som hovedsakelig består av en poly(laktid-ko-glykolid) polymer med dispergert deri ca. 5 % (vekt/vekt) eksenatid som aktiv farmasøytisk ingrediens og ca. 2 % (vekt/vekt) sukrose; hvori forholdet mellom laktid:glykolid i polymeren er omtrent 1:1
- hvor den farmasøytisk akseptable ikke-vandige bæreren består av en eller flere triglyserider av C₆ -C₁₂ fettsyrer,
hvor triglyseridene omfatter 0 til 2 vekt% C₆ fettsyre, 50 til 65 vekt% C₈ fettsyre, 30 til 45 vekt% C₁₀ fettsyre, og 0 til 2 vekt% C₁₂ fettsyre.