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Example- 2

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Objective: To conduct invalidation search for US Patent 8039009

Search Strategy:

Comprehensive searches were conducted to retrieve information before 17, June, 2004

Key features:

- Search for patents and non-patent literature for Memantine + Hydroxy propyl methyl cellulose (HPMC) + once a day dose with sustained /modified release
- To Search for patents & non- patent literature for Memantine as single dose or once a day dose
- Search for patent & non – patent literature for HPMC used as polymer in sustained release

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Patent Number	US 6194000 B1
Title	Analgesic immediate and controlled release pharmaceutical composition
Assignee	F.H. Faulding & Co., Limited
Status	Published

Claims

A method of preparing an analgesic pharmaceutical composition for the administration of an NMDA receptor antagonist to a human or animal subject for the treatment of pain, comprising: providing a matrix or coated core containing an NMDA receptor antagonist to provide sustained release of a NMDA receptor antagonist;providinga mixture containing a NMDA receptor antagonist to provide an immediate release of a NMDA receptor antagonist; andcombiningthe matrix or coated core with the mixture,theimmediate release form and **sustained release** form being present in sufficient amounts to diminish or abolish wind-up.

The method of claims 1 wherein the coated core is a core of NMDA receptor antagonist coated with a pharmaceutically acceptable polymer including diffusion barrier polymers with or without porosity enhancers selected from the group consisting of ethyl cellulose, cellulose acetate butyrate, cellulose acetates, polymethacrylatescontaining quaternary ammonium groups, polyethylene glycol, hydroxypropylcellulose, **hydroxypropylmethyl cellulose**, polyvinylpyrrolidone, polyvinyl alcohol, and monomeric materials, sugars, lactose, sucrose, fructose and mannitol, salts, sodium chloride, potassium chloride, organic acids, fumaricacid, succinic acid, lactic acid and tartaric acid and mixiresthereof, enteric polymers, hydroxypropylcelluose, **hydroxypropylmethyl cellulose**, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, shellac, zein, and polymethacrylatescontaining carboxyl groups.

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Patent Number	EP 1169024
Title	PREGELATINIZED STARCH IN A CONTROLLED RELEASE FORMULATION
Assigne / Inventor	Janssen Pharmaceutica N.V.
Status	Published
Description	The present invention concerns the use of pregelatinized starch to prevent dose- dumping from a hydrophilic **controlled release formulation**. It also concerns a **hydrophilic controlled release formulation, more in particular a hydrophilic controlled release matrix formulation**, and solid dosage forms prepared therefrom, preferably for once daily oral administration. The hydrophilic controlled release formulation comprises pregelatinized starch, one or more active ingredients, one or more viscous hydrophilic polymers and optionally pharmaceutically acceptable formulating agents. Preferred hydrophilic polymers include hydroxypropyl cellulose and **hydroxypropyl methylcellulose.** WO 96/14070 discloses an extended release formulation for oral administration comprising cisapride-(L)-tartrate as the active ingredient embedded in a matrix of two hydrophilic viscous polymers, in particular hydroxypropyl cellulose and **hydroxypropyl methylcellulose**. These hydrophilic polymers swell upon contact with water, thereby forming a gellayer from which the active ingredient is gradually released.

Non-patent Literature information

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HPMC used as sustained/modified release polymer in tablets

Colombo P1, BettiniR, PeppasNA.Observationof swelling process and diffusion front position during swelling in hydroxypropylmethyl cellulose (HPMC) matrices containing a soluble drug. J Control Release. 1999 Aug 27;61(1-2):83-91.

Abstract :The behavior of gel layer thickness in **swellable hydroxypropyl methyl cellulose** matrices loaded with increasing amounts of soluble and colored drug and exhibiting swelling, diffusion and erosion fronts, was studied using a colorimetric technique. The effect of the drug loading on the front position in the gel layer, in particular, on the presence of a diffusion front and its movement, was investigated. In addition, the swelling, diffusion and erosion front positions at different releasing times were measured and a theoretical analysis of the overall process was provided. It was found that the diffusion front was visible in systems with more than 30% drug, due to the presence of an undissolved drug layer. The physical analysis of such systems clearly showed the importance of drug solubility and loading in the observation of the diffusion front.