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PATENTABILITY SEARCH

Submitted to:

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Client Reference No:

Date: 08-Jun-2016

Patent Number: US8728519

Title: Soft gelatin capsules

Features to Search

E1: A soft gelatine capsule consisting of a shell enclosing a filling material. The shell contains a cyclodextrin which is maintained separated from the active ingredient in the filling materia.The shell of the capsule is prepared from a mix containing, by weight:

from 0.7 to 20% of hydroxypropyl-β-cyclodextrin or β-cyclodextrin,
from 20 to 50% by weight of gelatine, from 1 to 25% by weight of a
plasticizer, from 20 to 50% by weight of water.

E2: The filling material consists of a solution of a poorly water-soluble or water-insoluble active ingredient in an oily solvent/phase.

E3: The active ingredient is selected from the group consisting of progesterone ranging from 10 to 200 mg, liposoluble vitamins as single vitamins or in mixture with other vitamins ranging from 0.001 to 20 mg, and acetylsalicylic acid ranging from 50 to 300 mg.

Search Strategy

Database: AcclaimIP, USPTO, Patentscope, Espacenet, Google Patents.

Keywords:

Set 1	Gelatin, Soft Gelatin, Shell, Soft shell
Set 2	Capsules, Soft Capsules, Soft Gelatin Capsules
Set 3	Drug, Active Ingredient, Lipo soluble Drug.

US Classification Codes with definitions

424/455: Containing emulsions, dispersions, or solutions

424/456: Gelatin

International Classification Codes with definitions

A61K9/48: Preparations in capsules, e.g. of gelatin, of chocolate;

A61K9/4816: Wall or shell material

A61K9/4825: Proteins, e.g. gelatin

A61K9/4891: Coated capsules; Multilayered drug free capsule shells

A61K47/40: Cyclodextrins; Derivatives thereof

Search Results 1

Patent/Publication Number: US6759395

Title: Soft-gelatin capsule comprising S-adenosylmethionine and a method for producing the same

Assignee/Applicant: Orchid Chemicals and Pharmaceuticals Ltd

Filing Date: 18-Dec-2001

Priority Date: 18-Dec-2000

Also Published as: US2002164369

Relevant Excerpt for E1	Claims:
	1. An enteric-coated soft gelatin capsule. said fill material being disposed within a soft gelatin film. 26.A capsule as claimed in claim 1 wherein the soft gelatin capsule is enteric coated with a coating agent selected from the group consisting of hydroxypropylmethyl cellulose phthalate (HPMCP), hydroxypropylmethyl cellulose succinate (HPMCS), carboxymethyl cellulose (CMEC) and methylacrylic acid copolymer. Description: **Col. 5, Lines 45-49;** A plasticiZer such as PEG 400, or a non-crystalliZing solution of sorbitol may be used. If sorbitol is used alone as plasticiZer, the amount may be 10 to 20%. If used in combination With other plasticiZers, or if any other plasti ciZers are opted for, the amount may be 8 % to 10% W/W.

Relevant Excerpt for E2	Claims: 1. said salt being coated with lipophilic material, an oily matrix, antioxidants and preservatives.
Relevant Excerpt for E3	Description: **Col. 13, Table 4;** Discloses the presence of Vitamins in the nutritional analysis data.

Search Results 2

Patent/Publication Number: US20100178335

Title: Formulations of acetylsalicylic acid or its derivatives in soft capsules, exhibiting high stability

Assignee/Applicant: Angel Mateo Echanagorria, Maurizio Marchiorri, Giorgio Zoppetti

Filing Date: 30-Aug-2007 **Priority**

Date: 01-Sep-2006

Also Published as:

JP2010501632,WO2008025819,ITMI20061672,EP2066330,CN101511370,CA2662178

Relevant Excerpt for E1	Claims: 56. Pharmaceutical formulation of acetylsalicylic acid or its pharmaceutically acceptable derivatives in a soft capsule made of an outer shell and an inner liquid or semi-liquid oil phase wherein the acetylsalicylic acid or its derivative is partly dissolved and partly suspended in the said liquid or semi-liquid oil phase, a compound of the cyclodextrin class being suspended in the said liquid or semi-liquid oil phase, and/or contained in said shell, in order to provide stability to the formulation. 57. Formulation as claimed in claim 1 wherein the cyclodextrin is suspended in the liquid or semi-liquid oil phase in a substoichiometric quantity with respect to the quantity of acetylsalicylic acid or its pharmaceutically acceptable derivative. 62. Formulation as claimed in claim 1 wherein the said shell comprises gelatin and/or modified gelatin and/or a suitable substitute gelling compound, water and/or a plasticizer and optionally one or more excipients.

	67. Formulation as claimed in claim 1 wherein the said compound of the cyclodextrin class is chosen in the group consisting of natural cyclodextrins such as alpha-, beta- or gamma-cyclodextrins, and modified cyclodextrins such as methyl-beta-cyclodextrin, sulfobutyl-beta-cyclodextrin, hydroxypropyl-gamma-cyclodextrin and hydroxypropyl-betacyclodextrin. Description: [0025] A first aspect of the present invention concerns the use of a compound of the cyclodextrin class for stabilizing formulations of acetylsalicylic acid or its pharmaceutically acceptable derivatives in soft capsules,
Relevant Excerpt for E2	Claims: 69. Formulation as claimed in claim 1, wherein the acetylsalicylic acid or its derivative is partly dissolved and partly suspended in the said oil phase, wherein a compound of the cyclodextrin class is contained in the soft capsule shell and in the said oil phase the content of EPA or DHA, or EPA and DHA together, is at least 5% by weight, calculated as free acids. Description: [0025] in which the acetylsalicylic acid (or its pharmaceutically acceptable derivatives) is partly dissolved and partly suspended in a liquid or semi-liquid oil phase contained within the soft capsule.
Relevant Excerpt for E3	Description:

	[0015] For example aqueoushormone formulations have long been proposed in Which cyclodextrins act as excipients Which solubiliZe the lipophilic hormone in aqueous environments.

Search Results 3

Patent/Publication Number: WO1997040823 **Title:** Oral pharmaceutical compositions containing sex hormones **Assignee/Applicant:** R.P. Scherer Limited **Filing Date:** 28-Apr-1997 **Priority** **Date:** 26-Apr-1996 **Also Published as:** AT207346,AU2707497,DE69707669,DK0904064,EP0904064,ES2164339,JP2000510458,JP5088804,PT904064,ZA9703653	
Relevant Excerpt for E1	Claims: 24. A hard or soft capsule filled with a pharmaceutical composition as claimed in any preceding Claim.
Relevant Excerpt for E2	Description: A suspension of micronised progesterone in oil encapsulated in a softgel has recently been available but, as for solid dosage forms, dissolution is still required in vivo and limits the rate of absorption, particularly as the aqueous solubility of progesterone is very low.

	The blend of digestible oil and surfactants used in the invention provides good solubilisation of the hydrophobic
	drug.

Relevant Excerpt for E3	Claims: 2. A pharmaceutical composition as claimed in Claim 1 in which the hydrophobic drug is dissolved and is selected from progesterone, oestradiol, testosterone and mixture of progesterone and oestradiol. 3. A pharmaceutical composition comprising: at least 5% by weight of progesterone. 25. A softgel capsule as claimed in Claim 24 comprising a capsule of size 12 oblong containing 50mg of progesterone. 27. A softgel capsule as claimed in Claim 25 or Claim 26 in which the capsule additionally contains from 0.25 to 2mg of oestradiol. 28. A softgel capsule as claimed in Claim 24 containing from 20 to 80τng testosterone. Description: In order to achieve a dose of 50mg of progesterone completely dissolved in the formulation in a softgel capsule it is necessary to employ a large (20 oblong) capsule size or divide the dose into two smaller capsules.