Docket No.: 241957.000596
(TRACK 1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: William H. McKenna et al.	Customer No. 06980
Application No.: 14/729,660	Confirmation No.: 2426
Filed: June 3, 2015	Art Unit: 1642
For: TAMPER RESISTANT DOSAGE FORMS	Examiner: AKHOON, KAUSER M.

AMENDMENT AFTER FINAL

MS Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Please amend this U.S. patent application as follows.

Amendments to the Claims begin on page 2 of this paper.

Remarks/arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all previous claims, and listings of claims, in the application.

1-169. (Cancelled)

170. (Currently Amended) A method of treating pain comprising administering to a patient in need thereof a pharmaceutical tablet comprising:

(1) at least a first compression shaped and then air cured matrix, wherein said curing is without compression by heated air having a temperature of at least about 62 ^{o} C for a duration of at least about 5 minutes, said matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight selected from the group consisting of 4,000,000, 7,000,000, and a combination thereof, and optionally further comprising at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000;

(2) optionally a second air cured matrix comprising oxycodone or a pharmaceutically acceptable salt thereof in combination with at least one low molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of less than 1,000,000; and

(3) optionally a coating,

wherein in said tablet:

(i) said oxycodone or pharmaceutically acceptable salt thereof is provided in a dose selected from the group consisting of 10 mg, 15, mg, 20 mg, and 30 mg;

the total combined weight of said low molecular weight polyethylene oxide, if present, and said high molecular weight polyethylene oxide is at least 79 % by weight of the total weight of said tablet, excluding the weight of any coatings; and

said low molecular weight polyethylene oxide, if present, is at least10% by weight of the total weight of said uncoated tablet, excluding the weight of any coatings;or

(ii) said oxycodone or pharmaceutically acceptable salt thereof is provided in a dose selected from the group consisting of 40 mg, 60 mg, and 80 mg;

the total combined weight of said low molecular weight polyethylene oxide, if present, and said high molecular weight polyethylene oxide is at least 65 % by weight of the total weight of said tablet, excluding the weight of any coatings; and

said low molecular weight polyethylene oxide, if present, is at least 10 % by weight of the total weight of said tablet, excluding the weight of any coatings; and

said tablet provides a dosage form for twice-daily extended release administration of oxycodone or pharmaceutically acceptable salt thereof.

171. (Previously Presented) A method as defined in claim 170, wherein said oxycodone or pharmaceutical salt thereof comprises at least 5% by weight, based upon the total weight of said uncoated tablet.

172. (Previously Presented) A method as defined in claim 170, wherein each shaped and cured matrix has been cured by heated air having a temperature of about 62° C to about 90 ° C for a duration of about 15 minutes to about 10 hours, and then is subsequently cooled.

173. (Previously Presented) A method as defined in claim 172, wherein said heated air temperature is from about 65° C to about 90° C, said duration is about 15 minutes to about 8 hours, and said cooling comprises exposure to an air temperature of less than about 62 ° C.

174. (Previously Presented) A method as defined in claim 170, wherein said shaped tablet is coated at least one of before or after being cured.

175. (Previously Presented) A method as defined in claim 173, wherein one or both of said first matrix and second matrix further comprise a coating.

176. (Previously Presented) A method as defined in claim 170, wherein, said second matrix is not present, the dosage amount of oxycodone is selected from 10 mg, 15, mg, 20 mg, and 30 mg, and the total combined weight of said high and low molecular weight polyethylene oxide is at least 79 % by weight of the total weight of said uncoated tablet.

177. (Previously Presented) A method as defined in claim 170, wherein, said second matrix is not present, the dosage amount of oxycodone is selected from 40 mg, 60 mg, and 80 mg, and the total combined weight of said high and low molecular weight polyethylene oxide is at least 65 % by weight of the total weight of said uncoated tablet.

178. (Previously Presented) A method as defined in claim 176, wherein said low molecular weight polyethylene oxide is not present.

179. (Previously Presented) A method as defined in claim 177, wherein said low molecular weight polyethylene oxide is not present.

180. (Previously Presented) A method as defined in claim 174, wherein the total combined weight of said high and low molecular weight polyethylene oxide is at least 65 % by weight, based upon the total weight of said uncoated tablet.

181. (Previously Presented) A method as defined in claim 174, wherein the total combined weight of said high and low molecular weight polyethylene oxide is at least 80 % by weight, based upon the total weight of said uncoated tablet.

182. (Previously Presented) A method as defined in claim 174, wherein the total combined weight of said high and low molecular weight polyethylene oxide is at least 85 % by weight, based upon the total weight of said uncoated tablet.

183. (Previously Presented) A method as defined in claim 174, wherein the total combined weight of said high and low molecular weight polyethylene oxide is at least 90 % by weight, based upon the total weight of said uncoated tablet.

184. (Previously Presented) A method as defined in claim 174, wherein said tablet further comprises magnesium stearate.

185. (Previously Presented) A method as defined in claim 184, wherein said tablet further comprises butylated hydroxytoluene.

186. (Previously Presented) A method as defined in claim 184, wherein said tablet further comprises at least one of lactose, microcrystalline cellulose and hydroxypropyl cellulose.

187. (Previously Presented) A method as defined in claim 170, wherein said tablet, when subjected to an indentation test, has at least one of (i) a cracking force of at least 110 N; and (ii) a penetration depth to crack distance of at least 1.0 mm.

188. (Previously Presented) A method as defined in claim 170, wherein said tablet can be flattened to a thickness that is no more than about 60% of the initial tablet thickness without breaking; and said flattened tablet swells upon exposure to water or ethanol.

189. (Previously Presented) A method according to claim 170, wherein, after a plurality of at least 100 of the same tablets are stored at 40° C and 75% relative humidity for at least 3 months, a set of at least ten of said stored tablets, on average, when measured in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37 ° C., in the absence of an added stabilizer, release an amount of said oxycodone or pharmaceutical salt thereof, after 1 hour, 4 hours, and 12 hours, that deviates from an initial dosage amount of said oxycodone or pharmaceutical salt thereof by no more than about 10% points.

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