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(54) **Title:** PHARMACEUTICAL COMPOSITIONS OF DEXLANSOPRAZOLE

(57) **Abstract:** The present invention relates to the Pharmaceutical capsule comprising the tablet, pellets or granules comprising (i) a core ii) the first drug layer comprising 30-90% of Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules iii) a first sub coating layer iv) an extended release layer comprising the pH dependently soluble polymer or the combinations thereof, said polymeric substance is soluble in the pH range of 6.0 to 7.5. v) a second sub coating on the extended release layer vi) the second drug layer comprising 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules vii) a third sub coating layer on the second drug layer viii) an enteric coating layer comprising the enteric coating polymer such that the 10-70% of the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0.



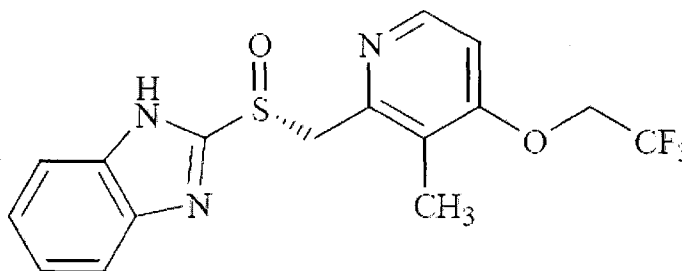
Pharmaceutical Compositions of Dexlansoprazole

FIELD OF THE INVENTION

- 5 The present invention relates to the Pharmaceutical composition of Dexlansoprazole and process for the preparation thereof.

BACKGROUND OF THE INVENTION

- 10 Dexlansoprazole is the R-enantiomer of Lansoprazole (a racemic mixture of the R- & S- isomers). Dexlansoprazole is represented by the chemical formula as (+)-2-[(R)-{[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methyl}sulfinyl]-1H-benzimidazole, with the structure as follows



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- Dexlansoprazole is available in United States with the trade mark DEXILANT in the dosage form of delayed release capsules sold by Takeda Pharmaceutical America, Inc, for the treatment of symptomatic non-erosive gastro esophageal reflux disease-heart burn associated with gastro esophageal reflux disease (GERD) and erosive esophagitis. The inactive excipients of DEXILANT include sugar spheres, magnesium carbonate, sucrose, low substituted hydroxy propyl cellulose, titanium dioxide, hydroxy propyl cellulose, hypromellose 2910, talc, methacrylic acid copolymer, polyethylene glycol 8000, Triethyl citrate, polysorbate 80, and colloidal silicon dioxide. The capsule shell is made of hypromellose, carrageenan and
- 20

potassium chloride. Based on the capsule shell color, blue contains FD&C Blue No.2 and Aluminum lake, grey contains ferric oxide and Aluminum lake and both contains titanium dioxide.

- 5 US Patents 6,462,058 and 6,664,256 disclose crystalline forms of Dexlansoprazole or a salt thereof. US Patent 7,790,755 discloses a capsule comprising two kinds of tablet, granule or fine granule as (i) a granule, tablet or pellet in which a release of the active ingredient is controlled and the said pellet comprising the Dexlansoprazole as the active ingredient and a pH dependently soluble release- controlled coating layer
10 which comprises one kind of polymeric substances soluble in the pH range of 6.0 to 7.5 and composition of (ii) a pellet, granule or a tablet comprising a core particle containing the active ingredient and enteric coat such that the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0. This patent further disclose the capsule comprising the two types of pellets in which or granules having
15 dual delayed release of Dexlansoprazole wherein the first portion of the pellets are coated with the extended release coating layer and the second portion of the pellets are coated with the delayed release coating layer.

- Therefore there is a need to develop a stable capsule comprising the Dexlansoprazole
20 filled with one type of pellets, tablet or granule comprising both the extended release portion and the Delayed release portion.

SUMMARY OF THE INVENTION

- 25 The present invention Provides

1. A Pharmaceutical capsule comprising the tablet, Pellets or granules comprising (i) a core ii) the first drug layer comprising 30-90% of

Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules iii) a first sub coating layer iv) an extended release layer comprising the pH dependently soluble polymer or the combinations thereof, said polymeric substance is soluble in the pH range of 6.0 to 7.5. v) a second sub coating on the extended release layer vi) the second drug layer comprising 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules vii) a second sub coating layer onto the second drug layer viii) an enteric coating layer comprising the enteric coating polymer such that the 10-70% of the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0.

2. The capsule according to above mentioned (1) wherein the core composition is 5-15% of the total weight of the pellets or granules filled into the capsule.
3. The capsule according to the above mentioned (1) wherein the first drug layer comprises the 30-90% of Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules.
4. The capsule according to the above mentioned (3) wherein the first drug layer composition is 5-15% of the total weight of the pellets or granules filled into the capsule.
5. The capsule according to the above mentioned (1) wherein the first sub coating layer composition is 5-10% of the total weight of the pellets or granules filled into the capsule.
6. The capsule according to the above mentioned (1) wherein the extended release layer is 5-10% of the total weight of the granules filled into the capsules.

7. The capsule according to the above mentioned (1) wherein the extended release layer comprises the pH dependent soluble release polymer.
- 5 8. The capsule according to any of the above mentioned (1), (7) wherein the pH dependent release soluble polymer is selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, carboxymethyl ethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methyl methacrylate-ethyl acrylate copolymer, hydroxy propyl acetate succinate and polyvinyl acetate phthalate.
- 10
9. The capsule according to the above mentioned (1) wherein the second sub coating layer 4-8% of the total weight of the pellets or granules filled into the capsule.
- 15
10. The capsule according to the above mentioned (1) wherein the second drug layer comprises 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules.
- 20
11. The capsule according to the above mentioned (1) wherein the second drug layer is 4-6% of the total weight of the granules filled into the capsules.
12. The capsule according to the above mentioned (1) wherein the third sub coating layer is 2-6% of the total weight of the pellets or granules filled into the capsules.
- 25

13. The capsule according to the above mentioned (1) comprises the basic inorganic salt as a stabilizer.
- 5 14. The capsule according to the above mentioned (1) wherein the enteric coating layer comprises the enteric polymer that releases the second layer of the Dexlansoprazole in the pH range of no less than 5.0 to no more than 6.0.
- 10 15. The capsules according to the above mentioned (7) wherein the enteric polymer is the methacrylic acid-ethyl acrylate polymer.
16. The capsule according to the above mentioned (1) wherein the enteric coating layer is 10-20% of the total weight of the granules filled into the capsules.
- 15 17. The capsule according to the above mentioned (1) wherein the size of the capsule to fill the granules is 0el.

DETAILED DESCRIPTION OF THE INVENTION

- 20 The present invention relates to a pharmaceutical capsule comprising the tablet, Pellet or granules comprising (i) a core ii) the first drug layer comprising 30-90% of Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules iii) a first sub coating layer iv) an extended release layer comprising the pH dependently soluble polymer or the combinations thereof, said polymeric substance is
- 25 soluble in the pH range of 6.0 to 7.5. v) a second sub coating on the extended release layer vi) the second drug layer comprising 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules vii) a third sub coating layer onto the second drug layer viii) an enteric coating layer comprising the enteric

coating polymer such that the 10-70% of the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0.

The core particles used for the drug layering is the inactive carrier such as NON-PARIEL (NONPARIEL-101 (particle diameter- 850 μ m-710 μ m, 710-500 μ m and 500-355 μ m), NONPARIEL-103 (particle diameter- 850 μ m-710 μ m, 710-500 μ m and 500-355 μ m), NONPARIEL-105 (particle diameter- 850 μ m-710 μ m, 710-500 μ m and 300-180 μ m); and Celphere (CP-507 (Particle diameter-500-710 μ m) and CP-305 (Particle diameter 300-500 μ m)). When an inactive carrier core is not used, a core particle can be produced by granulating excipient such as lactose, white sugar, mannitol, corn starch and crystalline cellulose and Dexlansoprazole, using binders such as hydroxy propyl methyl cellulose, hydroxy propyl cellulose, methyl cellulose, a poly vinyl alcohol, Macrogol, gum Arabic, gelatin and starch. Particles having a particle size of 50 μ m to 5mm preferably 100 μ m to 2mm are used. The core particles composition is 5-15% of the total weight of the granules filled into the capsule.

The first drug layer comprises 30-90% of total amount of the Dexlansoprazole filled into the capsule formulation. The drug layering material is obtained by appropriately compounding the Dexlansoprazole Active ingredient with the polymeric substances such as low substituted hydroxy propyl cellulose, hydroxy propyl cellulose, hydroxy propyl methyl cellulose, poly vinyl pyrrolidinone, poly vinyl alcohol, methyl cellulose. The first drug layer composition is 10-15% of the total weight of the granules filled into the capsule.

The coating material for the first sub coating layer include those obtained by appropriately compounding polymeric materials such as low substituted hydroxy propyl cellulose, hydroxy propyl methyl cellulose, poly vinyl pyrrolidone, poly vinyl alcohol, methyl cellulose. The excipients such as titanium dioxide and talc may be

suitably added to the Sub coating layer. The first sub coating layer composition is 1-10% of the total weight of the granules filled into the capsule.

The pH dependent soluble polymer is preferably a substance which is dissolved at the higher pH (preferably a pH of 6.0 or above and 7.5 or below, and more preferably a pH of 6.5 or above and below 7.2). As a coating material for controlling the pH dependent release the Dextranoprazole polymers such as hydroxy propyl methyl cellulose phthalate, Cellulose acetate phthalate, carboxy methyl ethyl cellulose, methyl- methacrylate methacrylic acid copolymer (Eudragit L 100 (methacrylic acid copolymer L), or Eudragit S 100 (methacrylic acid copolymer S)) methacrylic acid-ethyl acrylate polymer (Eudragit L100-55 (dried methacrylic acid copolymer LD) or Eudragit L30D-55 (methacrylic acid copolymer LD), methacrylic acid-methyl acrylate-methyl methacrylate copolymer (Eudragit FS30D), hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac are used. The polymer as the above mentioned coating material may be used alone or at least two or more kinds of polymers may used to coat in combination, or at least two or more kinds of polymers may be coated sequentially to prepare multiple layers.

The extended release layer composition is 5-10% of the total weight of the pellets or granules filled into the capsule.

The second sub coating on the extended release layer can be obtained by compounding polymeric materials such as low substituted hydroxy propyl cellulose, hydroxy propyl methyl cellulose, poly vinyl pyrrolidinone, poly vinyl alcohol, methyl cellulose. The excipients such as titanium dioxide and talc may be suitably added to the Seal coating layer. The second sub coating composition is 4-8% of the total weight of the pellets or granules filled into the capsule.

The second drug coating layer encompassing the second sub coat comprises 10-70% of total amount of the Dextranoprazole filled into the capsule formulation. The drug

layering material is obtained by appropriately compounding the Dexlansoprazole Active ingredient with the polymeric substances such as low substituted hydroxy propyl cellulose, hydroxy propyl cellulose, hydroxy propyl methyl cellulose, poly vinyl pyrrolidinone, poly vinyl alcohol, methyl cellulose. The second drug layer composition is 2-6% of the total weight of the granules filled into the capsule.

The coating for the second sub coating layer include those obtained by appropriately compounding polymeric materials such as low substituted hydroxy propyl cellulose, hydroxy propyl methyl cellulose, poly vinyl pyrrolidinone, poly vinyl alcohol, methyl cellulose. The excipients such as titanium dioxide and talc may be suitably added to the Sub coating layer. The third sub coating layer composition is 12-10% of the total weight of the granules filled into the capsule.

The enteric coating layer comprises the methacrylic acid-ethyl acrylate polymer (Eudragit L100-55 (dried methacrylic acid copolymer LD) or Eudragit L30D-55 (methacrylic acid copolymer LD) that releases the 10-70% of the Dexlansoprazole in the pH range of no less than 5.0 to no more than 6.0. The enteric coating layer composition is 20-25% of the total weight of the granules filled into the capsule.

The present invention is further illustrated by the following examples which are provided merely to be exemplary of invention and don't limit the scope of the invention. Certain modifications and equivalents will be apparent to those skilled in the art and are intended to be apparent to those skilled in the art and are intended to be included within the scope of the present invention.

Example :

Table-1 provides the composition of batches of present invention.

Table-1

S.No	Ingredient	Mg/cap
Core		
1	Sugar spheres 50/60#	75.0
2	Hypromellose 5cps	6.25
3	Talc	1.25
4	Purified water	q.s.
First Drug Loading- 75%		
5	Dexlansoprazole	45.0
6	Light Magnesium Carbonate	22.5
7	Hydroxypropyl cellulose	22.5
8	Purified water	q.s.
Sub Coating-I		
9	Hypromellose 15 cps	35.92
10	Talc	7.18
11	Purified water	q.s.
Extended release layer coating		
12	Eudragit S100	89.6
13	Triethyl citrate	8.96
14	Talc	8.96
15	Purified water	q.s.
Sub coating -II		
16	Hypromellose 5cps	53.85
17	Talc	10.77
18	Purified water	q.s.
Second Drug Loading-25%		
19	Dexlansoprazole	15
20	Light Magnesium Carbonate	7.5
21	Hydroxypropyl cellulose/L-HPC	7.5
22	Purified water	q.s.
Sub Coating-III		
23	Hypromellose 5cps	69.6
24	Talc	13.9
25	Purified water	q.s.
Enteric coating layer coating		
26	Eudragit L30 D55	92.10
27	Poly Vinyl Alcohol 4-88	39.20
28	Triethyl citrate	9.8
29	Talc	9.8

30	Isopropyl Alcohol	q.s.
31	Purified water	q.s.
Total fill weight of the capsules		652.1

Procedure:

- 5 **1. Core:** Hypromellose and talc are added to the solvent Purified water and the stirred suspension obtained is coated on to the sugar spheres using fluid bed processer.
- 10 **2. Drug Loading-I :** To the purified water hydroxy propyl cellulose, magnesium carbonate and about 75% of total weight of the Dexlansoprazole to be filled into each capsule are added and homogenized. The coating solution prepared as above is coated onto the seal coated pellets using fluid bed processer.
- 15 **3. Sub coat-I:** Hypromellose and talc are added to the solvent purified water and stirred till a homogenous suspension is formed. Suspension obtained is coated onto the drug loaded pellets using the fluid bed processer.
- 20 **4. Extended release coating:** Extended release polymer Eudragit S 100, Triethyl citrate and talc are added to the purified water under stirring. Enteric coating suspension formed as above is coated onto the sub coated pellets.
- 25 **5. Seal coating:** Hypromellose and talc are added to the purified water and stirred till a homogenous suspension is obtained. Suspension thus obtained is coated onto the extended release layer coated pellets as obtained in the step no 4.
- 6. Drug Loading- II:** To the purified water hydroxy propyl cellulose, magnesium carbonate and 25% of the total weight of the Dexlansoprazole

filled into capsules are added and homogenized. The drug coating solution prepared as above is coated onto the sub coated-II pellets obtained in step no.5.

- 5 **7. Sub Coating II:** Hypromellose and talc are added to purified water and stirred a homogenous suspension is obtained. Suspension obtained as above is coated onto the drug loaded II pellets obtained in the step no. 6 using the fluidized bed processor.
- 10 **8. Enteric coating:** Purified water is divided into portions. To the first portion of purified water Glycerol monostearate and Polysorbate 80 is added and stirred followed by the addition of Triethyl citrate and stirring for 10 minutes. To the second portion of the purified water poly vinyl alcohol is added and stirred. Both the above two portions prepared above are added to the Eudragit
- 15 L30 D55 dispersion under stirring conditions and coated onto the sub coated III pellets of step no.7 by using the fluid bed processor.
9. Finally the above enteric coated pellets prepared as of step no 8 are filled into the Oel capsules.

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We Claim:

1. A Pharmaceutical capsule comprising tablet, pellets or granules comprising (i) a core ii) a first drug layer comprising 30-90% of Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules iii) a first sub coating layer iv) an extended release layer comprising the pH dependently soluble polymer or the combinations thereof, said polymeric substance is soluble in the pH range of 6.0 to 7.5. v) a second sub coating on the extended release layer vi) a second drug layer comprising 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules vii) an enteric coating layer comprising the enteric coating polymer such that the 10-70% of the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0.
2. A pharmaceutical capsule as claim 1 wherein the core composition is 5-15% of total weight of granules filled into capsule
3. A pharmaceutical capsule as claim 1 wherein the first drug layer comprises about 30-90% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules.
4. a pharmaceutical capsule as claim 1 wherein the first drug layer composition is 5-10% of the total weight of the granules filled into the capsule
5. A pharmaceutical capsule as claim 1 wherein the extended release layer composition is 5-10% of the total weight of the granules filled into the capsule

6. A pharmaceutical capsule as claim 1 wherein the second drug layer comprises about 10-70% of the Dexlansoprazole of the total weight of the Dexlansoprazole filled into the capsules.
7. A pharmaceutical composition as claim 1 wherein the second drug layer composition is 2-6% of the total weight of the granules filled into capsule
8. A pharmaceutical capsule as claim 1 wherein the enteric coating layer composition is 10-20% of the total weight of the Dexlansoprazole filled into the capsules.
9. A pharmaceutical capsule as claim 1 wherein the size of the capsule is 0el

INTERNATIONAL SEARCH REPORT

International application No

PCT/IN2012/000097

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61K9/50 A61K31/4439
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	WO 2010/117756 A2 (REDDYS LAB LTD DR [IN]; REDDYS LAB INC DR [US]; LAD VISHAL [IN]; SHARE) 14 October 2010 (2010-10-14) examples 1-2 claims 1,7,9,17	1-9
Y	WO 2006/049565 A1 (ASTRAZENECA AB [SE]; CLEMMENSEN NICLAS [SE]; LOEFROTH JAN-ERIK [SE]; S) 11 May 2006 (2006-05-11) page 5, line 29 - page 6, line 3 example 4 claim 2	1-9
	----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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INTERNATIONAL SEARCH REPORT

International application No

PCT/IN2012/000097

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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