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Formulation and Evaluation of Controlled Porosity Osmotic Pump Tablet of Nateglinide

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Abstract

The present work studied the effect of concentration of polymer that was HPMC on the drug release and the effect of different concentration of osmogens on the drug release. In each formulation the drug and the polymer were weight, mix and then granules was prepared by wet granulation method. After the compression the tablet it was coated with the help of coating agent and pore forming agent are incorporated in the coating solution for the development of pore when they are come in coated with the GIT fluid and solvents are used as a vehicle for the preparation of coating solution. And then the dried blends are compressed with the help of excipients. Then the tablet was evaluated for the hardness, thickness, drug content uniformity, in vitro drug release for 16 hrs. And it observed that F6 formulation was the best formulation

Keywords: Nateglinide, Formulation, Polymer, Evaluation

Introduction

In oral route the drug is placed in mouth and then swallowed. After oral administration of drug the absorption of drug begins in mouth and stomach and most of the drugs are usually absorbed from the small intestine. Oral route is the most preferable route for the administration of most of the therapeutic agents. Systemic effects and local effects both are effectively achieved by this route. Oral route is the most convenient route for the administration of various drugs because of ease of administration and low cost. Liver and intestinal wall chemically alter or metabolize drugs and due to that decreasing the amount of drug that reaches in the blood. The amount and rate of absorption is affected by food and other drugs present in the digestive tract. Tablets, capsules, liquid etc type of dosage form are administered by the oral route. Almost 90% of drugs which used for the systemic effect are administered by the oral route.

Nateglinide is one type of amino acid derivative, Nateglinide (2R)-2-({hydroxy[(1r,4r)-4- (propan-2-yl)cyclohexyl]methylidene}amino)-3-phenylpropanoic acid that compound having a antidiabetic property. Glipizide has administered orally in the tablet form containing a dose of about 60-240mg three times a day.[1-3]

Nateglinide has a biological half life is about 1.5hrs. Hence ,it required 3-4 times in a day. Therefore nateglinde is suitable for the development of osmotically release dosage form.

Adverse effect which are shown by that drug are hypoglycaemia, and some other adverse reactions like drowsiness, dizziness, weakness, fast heartbeat etc. And this adverse effect may be avoided by using the sustained release dosage form.

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Material and Methods[4-7]

The drug was identified by FTIR.

Preparation of core tablet:-The core tablet was prepared by drug, HPMC LV 50, Nacl, Kcl, PVP K-30, Colloidal silicon dioxide and with other addatives and role of that ingredients are listed below:

Table 1: Composition of core tablet

	Name of the ingredient	Batch Code					
		CT1	CT2	CT3	CT4	CT5	CT6
1	Drug	120	120	120	120	120	120
2	HPMC	25	30	35	25	30	35
3	PVP K 30	40	40	40	40	40	40
4	Lactose	20	20	20	20	20	20
5	Kcl	35	30	25	-	-	-
6	Nacl	-	-	-	35	30	25
7	Colloidal Silicon Dioxide	5	5	5	5	5	5
8	Magnesium Stearate	5	5	5	5	5	5
9	IPA	q.s	q.s	q.s	q.s	q.s	q.s

All the ingredients which are mentioned in the table were weighted accurately. Then the drug and the remaining excipients except lubricant and glidant are passed through sieve no. 30. And the lubricant and glidant are passed through sieve no.80. Then drug, osmogens, polymer and solubilising agent are blended homogenously in the pestle mortar. Then the IPA(isopropyl alcohol) was added in the mixture of all ingredient. Then the prepared mass was passed through the sieve number 40. And granules were dried in hot air oven at 60^0c for 3-4 hours. Then the dried granules were blended with glidant (talc) and lubricant magnesium stearate. The granules were compressed into 10 stations tablet punching machine. The coating of tablet was prepared by using the Ethyl cellulose, polyethylene glycol 400 and dibutylpthalate and acetone is used as a solvent.

Table 2: Formulation of coating solution

S.No	Ingredient	Formulation			
		CT1	CT2	CT3	CT4
1	Ethyl Cellulose	1gm	2gm	3gm	4gm
2	PEG 400	3gm	3gm	3gm	3gm
3	Dibutylpthalate	2.5ml	2.5ml	2.5ml	2.5ml
4	Acetone	100ml	100ml	100ml	100ml

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The tablet was evaluated as per standard protocol.

Results and Discussion

The IR spectrum of the nateglinide is hown below: .

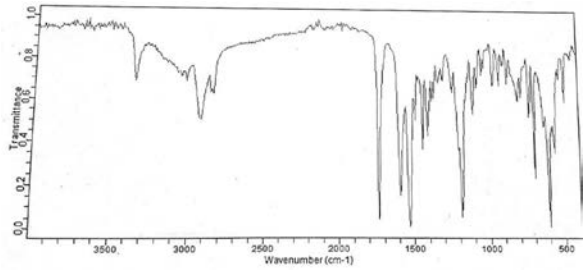

Fig. 1: IR spectra of Pure drug

The results of tablet evaluation are shown in table 2.

Table 2:Result of post compression study of Tablets

S.no	Formu -lation Code	Thickness (mm)	Weight variation(gm)	Hardness (Kg/cm2)	Friability (%)	Drugcontent uniformity (%)
1	F1	4.97±0.05	267±0.16	7±0.46	0.48±0.43	95.30±0.32
2	F2	4.89±0.05	265±0.16	6.8±0.47	0.58±0.39	97.34±0.32
3	F3	4.92±0.05	264±0.16	7.5±0.45	0.72±0.35	96.32±0.32
4	F4	4.81±0.05	265±0.16	6±0.50	0.40±0.47	98±0.32
5	F5	4.89±0.05	267±0.16	6.9±0.47	0.51±0.41	96.2±0.32
6	F6	4.84±0.05	266±.16	7.5±0.45	0.73±0.34	99.40±0.32

* values expressed as mean ± SD (n=3)

Table 3: Dissolution profile (0.1 N HCL and 6.8 pH buffer)

Time	F1	F2	F3	F4	F5	F6
0	0.07±0.05	0.04±0.01	0.03±0.04	0.04±0.02	0.08±0.01	0.05±002
30	2.54±0.13	3.05±1.34	4.17±1.78	7.16±0.86	11.54±2.13	14.65±2.13
1	7.91±0.57	10.54±1.82	13.78±2.34	15.6±1.53	21.68±1.32	27.65±0.54
2	14.51±1.51	19.51±1.15	30.19±1.87	31.1±1.15	34.55±1.54	48.65±2.17
4	21.56±1.50	29.56±1.34	41.74±2.34	45.2±2.13	55.22±0.76	63.75±0.65
8	48.54±2.81	51.32±2.23	64.65±1.45	61.22±0.54	62.05±0.87	77.81±1.89
12	58.11±2.30	60.21±1.16	79.85±2.53	74.5±1.95	71.85±1.53	82.7±1.45
16	67.15±0.57	70.11±1.87	80.2±1.58	82.19±1.71	84.61±1.65	92.2±1.76

Conclusion

The CPOP tablet of Nateglinide were prepared using different concentration of osmotic agent and poreforming agent. Controlled porosity osmotic tablet of Nateglinide were prepared using a hydrophilic and swellable type polymer. Polymer used were HPMC LV 50. The drug release from the formulation is in controlled manner. And the HPMC is widely used for the formulation of controlled release formulations because of its non toxic nature, High level of drug loading capacity and its non-pH dependence. The in vitro study of these tablets suggested that the CPOP tablets of Nateglinide perform therapeutically much better than the commercial conventional dosage forms for the treatment of pre and post prandial diabetes.

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