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Review Article
International Journal of Pharmacy and Engineering (IJPE)
ISSN 2320-849X

A study on the Robotic Pills

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ABSTRACT:

The Robotic Pill is a type of pill which deliver an intestinal injection without exposing drugs into digestive enzymes. The patient takes what appears to be an ordinary capsule, "robotic" pill is a sophisticated device which incorporates a number of innovations, enabling it to navigate through the stomach and enter the small intestine. The robotic pill goes through a transformation and positions itself to inject the drug into the intestinal wall. This pill consists of dissolvable needle which helps to inject the drug into intestinal tract and helps to release the drug without any pain as there are no pain receptors in the intestine, rendering the injection painless. To ensure safety of the pill, US FDA-approved injectable and ingestible materials that are either safely absorbed or easily passed out of the body.

KEY WORDS: Robotic pill, embodiment capsules, tissue penetrating member.

Received: 22nd May, 2018, Revised: 29th May , 2018, Accepted:1ST June , 2018,

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1. Introduction:

The Robotic pill premise that injecting the drug into the intestinal wall would be ideal because there are no sharp-pain receptors in the intestine, rendering the injection painless. In addition, the intestinal wall is highly vascularised which means that the drug once delivered will be quickly absorbed. With deep experience in engineering and materials science, the Robotic Pills to ensure that the drug would stay protected within the pill until injected [1].

1.1 Working principle of the Robotic Pill:

The embodiments of the product provides a swallowable device as it is taken like a normal capsules, the preparation and method for delivering drugs and other therapeutic agents are

within the GI tract. The pill will automatically injects by the help of dissolvable needle into the GI tract which immediate release and absorption of drug through the blood as possible. The pill consists of solid dissolvable needle made up of sugar which is the main and primary way to carried out the drug. No patient will swallow metal spring, therefore pill was sophisticatedly invented in such a way where pill consist of inflatable balloon like structure that would supply the force to deliver the needle both side. Balloon inflation happens due to carbon dioxide is produced inside from a chemical reaction between citric acid and sodium bicarbonate that takes place inside the balloon, which creates pressure needed to inject the needle and thus dissolvable needle get absorb by the blood through vein [2].

1.2 Principle of the embodiment capsules:

The capsules wall is degradable by contact with liquids in the GI tract but also may include an outer coating or layer which only degrades in the higher pH's found in the small intestine and serves to protect degradation in the stomach before capsules reaches the small intestine at the point of drug delivery is initiated by degradation of the coating. Such material is used in the preparation of the embodiment capsules for the targeted delivery of a therapeutic agent in a selected portion of the intestinal tract such as the small intestine [3]. The outer coating of the capsules can include various enteric coating such as various co-polymer of Methacrylic Acid and Ethyl Acrylate. one or more portions of capsule 120 can be fabricated from various biocompatible polymers known in the art, including various biodegradable polymers which in a preferred embodiment can comprise cellulose, gelatin materials PGLA (polylactic-co-glycolic acid). Other suitable biodegradable materials include various enteric materials described herein as well as lactide, glycollide, lactic acid, glycolic acid, para-dioxanone, caprolactone, trimethylene carbonate, caprolactone, blends and copolymers.

1.3 Role of pH sensitivity action and balloon:

The preparation is configured in a swallowable capsule and operably coupled to an actuator expandable balloon or other device having a first configuration and a second configuration. The preparation is carried out within the capsule in the first configuration and advanced out of the capsule into the intestinal wall in the second configuration helps to deliver the therapeutic agent into intestinal wall.

The actuator is responsible for the condition in the small intestine such as pH so as to actuate delivery of the therapeutic agent preparation into the wall of small intestine. In specific embodiments, the actuator can comprise a release element or coating on the capsule which is degraded by a selected pH in the small intestine. Once degraded, the element or coating initiates delivery of the therapeutic agent preparation by one or more delivery means such as the by expansion of one or more balloons that are operably coupled to tissue penetrating members that contain the therapeutic agent preparation and are configured to penetrate and be advanced into the intestinal wall upon expansion of the balloon. Once the tissue penetrating members are in the intestinal wall, they degrade to release the therapeutic agent into the bloodstream [4].

1.4 Principle of C_{max} on therapeutic agent:

The time period on which the therapeutic agent is directly delivered into the wall of small intestine described as herein as C_{max} for achieving the maximum concentration of the therapeutic agent in the blood stream or other location in the body is shorter than a

corresponding time period for achieving such a maximum concentration when the therapeutic agent is non vascular injected into the body such as intramuscular or subconscious injection. In such embodiment the time period taken to achieving C_{max} by insertion of the therapeutic preparation into the intestinal wall using one or more embodiments of swallowable device can be 80%, 50%, 30%, 20%, or even 10% of the time period for achieving a C_{max} through the use of non-vascular injection of the therapeutic agent. The C_{max} can be achieved greater in case of swallowable therapeutic preparation rather than the C_{max} achieved by the therapeutic agent not inserted into the intestinal wall. Therefore, it is clear that the C_{max} should be shall be achieved in case of therapeutic preparation of swallowable invention can be 5,10,20,30,40,50,60,70 or even 100 times greater than the therapeutic agent delivered in the pill or other oral form. In other related embodiments, the composition can be configured to produce a long-term release of therapeutic agent with a selectable t1/2, that is the time period required for the concentration of the therapeutic agent in the bloodstream or other location in the body to reach half its original Cmax value after having reached $C_{max.}$

1.5 Process of penetration into intestinal wall:

Another embodiment of the capsule includes at least one guide tube, one or more tissue penetrating members positioned in the at least one guide tube, a delivery member and an actuating mechanism. The tissue penetrating member will typically comprise a hollow needle or other like structure and will have a lumen and a tissue penetrating end for penetrating a selectable depth into the intestinal wall. In these and related embodiments, the drug preparation can have a needle or dart-like structure configured to penetrate and be retained in the intestinal wall. embodiments having multiple tissue penetrating members, the tissue penetrating members can be symmetrically distributed around the perimeter of the capsule so as to anchor the capsule onto the intestinal wall during delivery of drug. [5]

1.6 Fabrication of the tissue penetrating member:

The tissue penetrating member can be fabricated from various biodegradable materials (e.g., PGLA (Polylactic-co-glycolic acid), maltose or other Sugar) so as to degrade within the Small intestine and thus provide a fail-safe mechanism for detaching the tissue penetrating member from the intestinal wall should this component become retained in the intestinal wall. Additionally, in theses and related embodiments, selectable portions of the capsule can be fabricated from such biodegradable materials so as to allow the entire device to controllably degrade into Smaller pieces. Such embodiments facilitate passage and excretion of the devices through GI tract. In particular embodiments, the capsule can include seams of biodegradable material which controllably degrade to produce capsule pieces of a selectable size and shape to facilitate passage through the GI tract. The seams can be pre-stressed, perforated or otherwise treated to accelerate degradation. The concept of using biodegradable seams to produce controlled degradation of a swallowable device in the GI tract can also be applied to other swallowable devices such as Swallowable cameras to facilitate passage through the GI tract and reduce the likelihood of a device becoming stuck in the GI tract.

2 Brief description of the drawing:

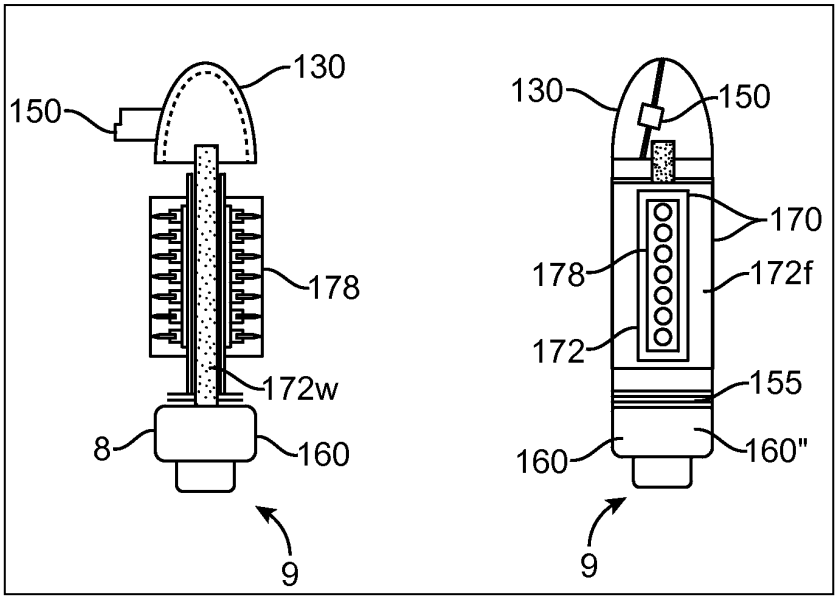

Figure 1: Mechanism of the Robotic Pill.

178: - Multiple drug delivery assemblies; 172w: - Balloon (deflate state); 160: - The deployable aligner; 150: - the degradable separation valve; 130: - The deployment balloon. A description will be provided of delivery mechanism 170. Typically, the mechanism will comprise a delivery assembly 178 (containing tissue penetrating members 140) that is attached to delivery balloon 172 as is shown in the embodiment of Figure 1. Inflation of the delivery balloon provides a mechanical force for engaging delivery assembly 172 outwards from the capsule and into the intestinal wall IW so as to insert tissue penetrating members 140 into the wall. In various embodiments, the delivery balloon 172 can have an elongated shape with two relatively flat faces 172f connected by an articulated accordion-like body 172b. The flat faces 172f can be configured to press against the intestinal wall (IW) upon expansion of the balloon 172 so as to insert the tissue penetrating members (TPMs) 140 into the intestinal wall. TPMS 140 (either by themselves or as part of a delivery assembly 178 described below) can be positioned on one or both faces 172f of balloon 172 to allow insertion of drug containing TPMs 40 on opposite sides of the intestinal wall. The faces 172f of balloon 172 may have sufficient surface area to allow for placement of a number of drug containing TPMS 140 on each face. [4,5].

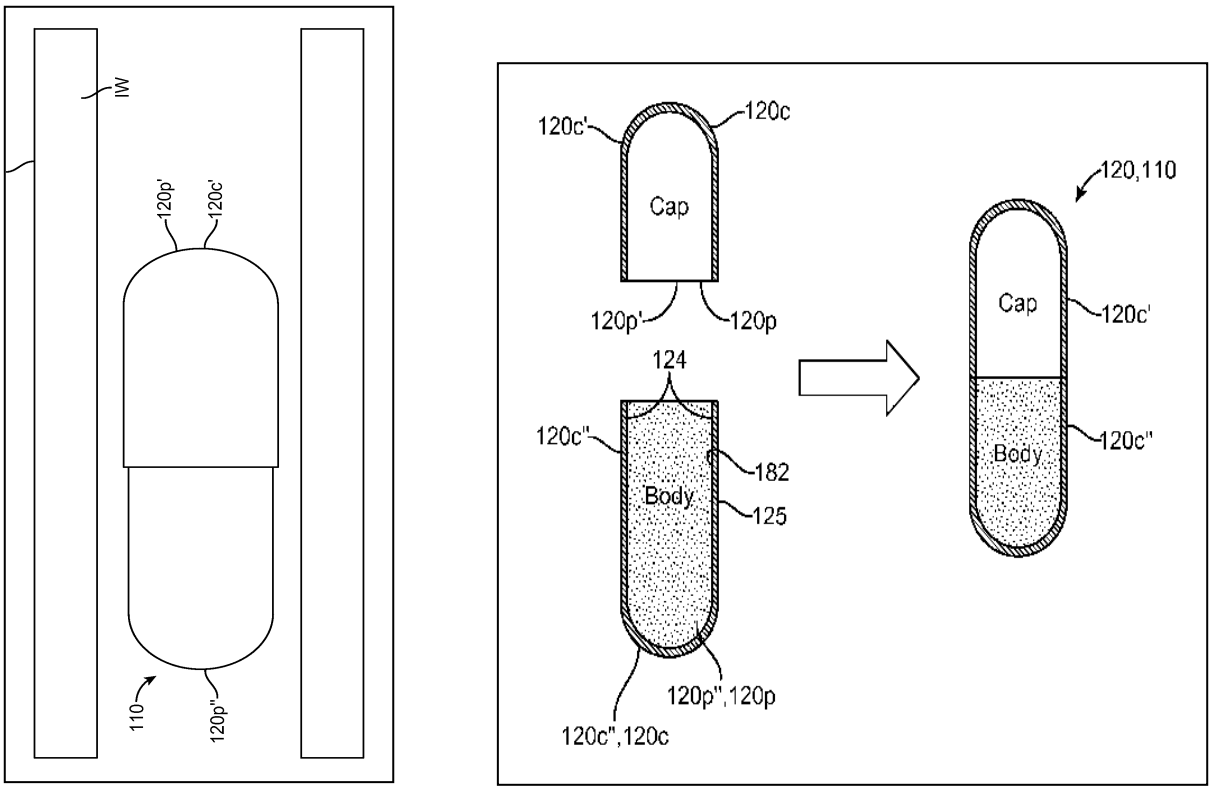

Figure 2: Ilustration provides a method of operation of swallowable device to deliver medication to the intestinal wall.

110: - Another embodiment device for the delivery medication; 120p (120p"): - This body portion is known as herein body; 120p': - Is known as herein cap, where the cap fits onto the body by sliding under the body. One of the portion such as the cap 120p' can include a first coating 120c' degrade above first pH (e.g, pH 5.5) and the second portion such as the body 120p" (herein body) can include second coating 120c" configured to degrade above a second higher pH (e.g. 6.5). Both the interior 124 and exterior 125 surfaces of capsule 120 are coated with coatings 120c and 120c" so that that either portion of the capsule will be sub stantially preserved until it contacts fluid having the selected pH. For the case of body 120p" this allows the structural integrity of the body 120p" to be maintained so as to keep balloon 172 inside the body portion and not deployed until balloon 130 has expanded. Coatings 120c' and 120c" can include various methacrylate and ethyl acrylate based coatings Such as those manufactured by Evonik Industries under the trade name EUDRAGIT. These and other dual coating configurations of the capsule 120 allows for mechanisms in one portion of capsule 120 to be actuated before those in the other portion of the capsule. This is due to the fact that intestinal fluids will first enter those portions where the lower pH coating has degraded thus actuating triggers which are responsive to Such fluids (e.g., degradable valves). In use, such dual coating embodiments for capsule 120 provide for targeted drug delivery to a particular location in the Small intestine (or other location in the GI tract), as well as improved reliability in the delivery process.[3]

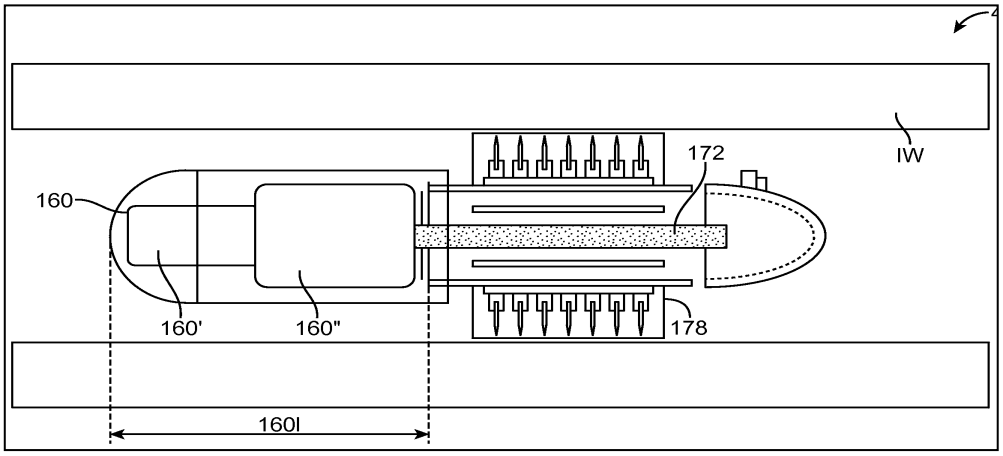

Figure 3: Mechanism of inflates of balloon and tissue penetrating membrane. IW: - It represents the intestinal wall; the balloon 172 continues to expand to now advance tissue penetrating membrane into intestinal tract as shown in figure 3.

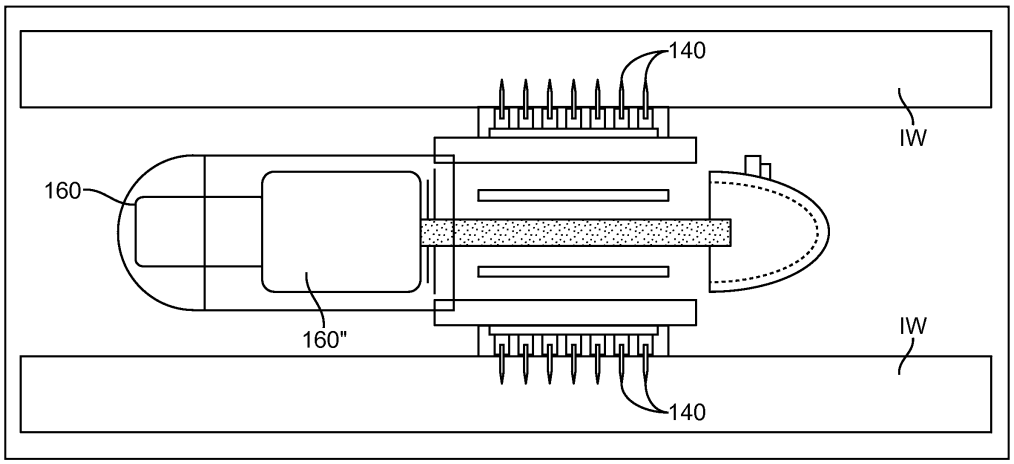

Figure 4: Tissue penetrating member. A tissue penetrating membrane consist of drug or desired medicaments. Balloon 172, (along with balloons 160 and 130) has deflated pulling back and leaving tissue penetrating members retained in the intestinal wall IW. Also, the body portion 120p" of the capsule has completely degraded (due to degradation of coating 120c") along with other biodegradable portions of device 110. Any portion not degraded is carried distally through the Small intestine by peristaltic contraction from digestion and is ultimately excreted. [2].

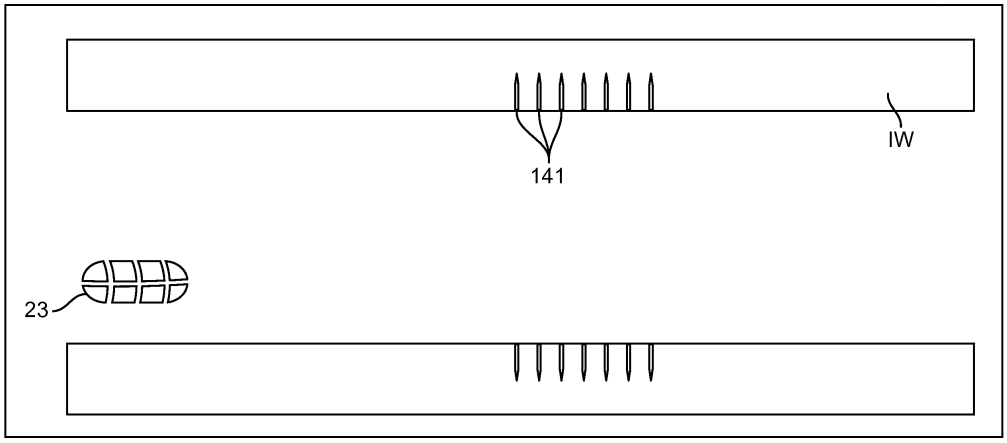

Figure 5: This figure provides a method of operation of swallowable device to deliver the medication to the intestinal wall. 23: - refers to the degradation of the various embodiments, capsules as it was made up of bio-degradable material which will degrade into pieces.

1. List of the dose and weight percent range for insulin and number of other drugs may be delivered by tissue penetrating member:

List of the dose and weight percent range for insulin is mention on the table. The table also mention the lists of weight percentage of drug in section.

Drugs	Dose Via Capsules	% Weight of Drug in the needle	% Weight of drug in pallet
Insulin	4-9 units, 5-30 units, 1-50 units	2-15%	10-75%
Exenatide	1-10 ug, 1-20 ug, 10ug	<1%, 0.1-1%	O.2-1%
Liraglutide	0.1-1 mg, 0.5-2mg, 0.6 mg	3-6%	25-40%
Pramlintide	15-120 ug	O.1-1%	O.5-6%
Growth Hormone	0.2-1 mg, 0.1-4 mg	2-10%	10-50%
Somatostatin and Analogs GnRH and Analogs	50-600 ug, 10-100 ug	O.3-8%	2-35%
Vasopressin PTH and Analogues	0.3-1.5 mg, 0.1-2 mg	2-15%	15-7596
Interferons and analogs	2-10 units	<1%, 0.1-1%	O.2-1%
	0.1 to 10 ug, 10-30 ug, 20 ug	1-2%	O.S-2%

Drugs	Dose Via Capsules	% Weight of Drug in the needle	% Weight of drug in pallet
1. For Multiple Sclerosis	0.03-0.25 mg	O.1-3%	1.5-1.5%
2. For Hep B and HepC	6-20 ug	O.O5-O.2%	O.2-1%
Adalimumab	1-5 mg, 2-4 mg	8-12%	70-90%
Infliximab	1-10, 5 mg	8-12%	70-90%
Etanercept	1-5 mg., 3 mg	8-12%	70-90%
Natalizumab	1-5 mg., 3 mg	8-12%	70-90%

3. Can Robotiic pills replace the injections:

The Robotic Pills is a novel approach for the oral delivery of large-molecule drugs such as basal insulin, which is currently delivered via injections. By replacing painful injections with a painless, easy-to-take pill, the technology has the potential to drastically improve the lives of millions of patients suffering from diabetes, osteoporosis, rheumatoid arthritis, multiple sclerosis, and many other chronic conditions.

4. Advantages on using robotic pills:

Effective - Bioavailability is on par or better than SC injections

Painless - No sharp-pain receptors in the intestine renders our resorbable needles painless

Efficient absorption - Delivered through the highly vascularized intestinal wall

Safe - FDA approved injectable and ingestible materials

Works for most drugs - Including small molecules, therapeutic peptides, proteins, antibodies and nucleotides

Strong patent position - More than 100 patents & patent applications, with more in progress

Low cost of goods - Lends itself to high volume manufacturing [2].

5. Conclusion of the Robotic Pills:

It is revolutionary idea and progress the future of pills for the patient having FDA approved injectable and ingestible materials, comparatively low cost rather than high premium insulin injections, no sharp pain receptor needle is being used or dissoluble injectors being used for painless treatment.

6. References:

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Received: 22nd May, 2018, Revised: 29th May , 2018, Accepted:1ST June , 2018,

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