Implantable drug delivery systems are currently based on three basic mechanisms, swelling control, osmotic pumping and diffusion system. Based on these mechanisms five different types of pump systems like infusion pump, peristaltic pump, osmotic pump, positive displacement pump and controlled release micro-pumps have been marketed worldwide. Currently marketed osmotic implantable pumps have cost around 450-500$. This limits the applications of such type of devices for effective sustainable drug delivery at research level and development of novel mechanical pressurized pump having similar features like currently available implanted pumps would serve as a better and cost effective alternative.

The proposed mechanical pressurize implantable pump (MPI Pump) will be made up of polyetheretherketone (PEEK) material. The inner layer or drug reservoir of the device lined with PEEK material would serve as a movable chamber, with functionally controlled movement of diaphragm or piston at sustained pressure. Drug chamber would be designed to have connection with connector to control the out flow of the fluid. The developed MPI Pump will be characterized for delivery of all types of injectable conventional formulations like solutions, suspensions and emulsions. The characterization of formulation will be done on the basis of *In vivo* compatibility of MPI Pump, *In Vitro* pumping efficiently, Start-Up time, Pumping duration/rate and reproducibility. The MPI Pump will be beneficial for cost effective way in research, and may be further useful clinically for powerless sustain release formulation delivery based drug development.

Poster No.: 094

Exploring novel design and evaluation of Mechanical Pressurize Implantable Pump (MPI Pump) for delivery of sustained release formulation*

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Introduction

- Currently implantable drug delivery pump work on: swelling, osmosis and diffusion system.
- The marketed osmotic implantable pumps have cost around 3000/piece INR.
- The MPI Pump work on different mechanism from currently marketed pump.
- MPI Pump, development and characterization having similar features like currently available implanted pumps would serve as a better and cost effective alternative.

Objective of Research

Novel design structure and characterize the Implantable pressurize pump for sustain release formulation

Methodology

MPI Pump Components		
1. Pump Body Materials ***Length*** (overall) 1.5 cm ***Outer Diameter*** 0.6 cm ***Weight*** (overall) 2 g ***Material*** polyamide/ polyetheretherketone	**2. Flow Moderator** ***Length*** (overall) 1.2 cm ***Gauge*** (tube) 21 ***Outer Diameter*** 0.08 cm ***Internal Diameter*** 0.05 cm ***Weight*** (overall) 0.05 g ***Material*** (tube) stainless steel/Polyethylene	**3. Drug reservoir** ***Length*** (tube only) 1.0cm ***Gauge*** (tube only) 27 ***Internal Diameter*** 0.4 cm ***Material*** polyamide/ polyetheretherketone
4. Pressurize unit Specific stainless steel Spring	**5. Diaphragm** ***Length*** 0.01cm ***Diameter*** *0.4cm* ***Material*** *P*olyamide/PEEK	

Start-Up Time

- If an MPI Pump is loaded with drug solution the pumping rate will reach steady state within 1-2 minutes.

Delivery/Pumping Rate

- To calculate the average pumping rate, the difference between the amount of drug initially loaded and the residual amount in the pump is divided by the elapsed time.

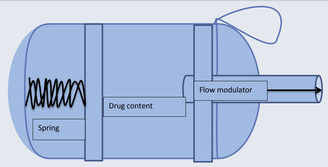
Duration of Administration

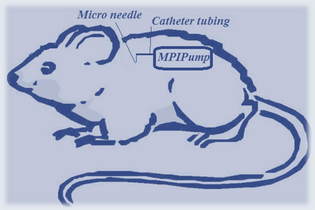
- The nominal durations for MPIP range will be more than 30 days , it will be set up depends on spring characteristic.
- MPI Pump will be deliver content longer than the nominal duration also there is no need of Priming required.

$$D = (V/Q)\ (0.95)$$

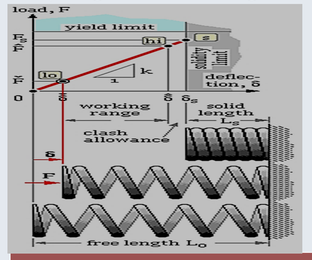
In this equation, D is duration in hours, V is the pump's reservoir volume in µl and Q is pumping rate in (µl/hr).

* Applied for Provisional Patent application





Spring Tensile strength



Dose characterization

Following equation to determine the daily dose delivered by a pump:

$K = C \times Q$ K = compound delivered per hour, in µg
C = concentration of solution, in µg/µl
Q = release rate of pump, in µl/hr

Solvent or Agent Compatibility With MPI Pump

Because of its mechanism of operation and used material MPI Pump may be well suited for administering a wide range of compounds regardless of their molecular weight.

MPI Pump Advantages

- Superior drug content delivery kinetics will provide.
- Convenient method for the chronic dosing of laboratory animals
- Minimize unwanted experimental variables and ensure reproducible, consistent results
- Eliminate the need for night time or weekend dosing
- Reduce handling and stress to laboratory animals
- Small enough for use in mice or very young rats
- Allow for targeted delivery of agents to virtually any tissue
- Cost effective research tool

Mechanical pressurize Implantable Pump (MPI Pump)	Alzet Osmotic pump
1 No need of Priming	1 Need of Priming (Tedious)
2 Start-Up Time will be reach steady state within 1-2 minutes	2 Required startup time to reach steady state
3 No dependent on physiological condition	3 For proper work dependent on physiological condition
4 No residual content will be left	4 Allow residual content (5%)
5 Commonly compatible with wide range of delivery content	5 Commonly compatible with wide range of content but have certain limitation
6 Temperature and osmolarity will be not affect the rate of duration	6 Temperature and osmolarity does affect the rate of duration
7 Will be very cheap and cost effective research tool	7 Costly research tool
8 Multiple use will be possible	8 Single use only

References:

1. Solanki HK, Thakkar JH, Jani GK. Recent advances in implantable drug delivery. 2010; 4(3).
2. http://www.alzet.com/products/guide_to_use/pump_selection.html