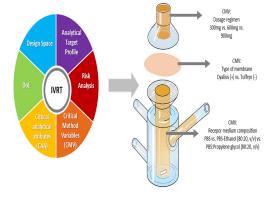
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 $\mathsf{CAA} \rightarrow \mathsf{IVRR} \mid \mathsf{Qi} \mid \mathsf{Qf} \mid \mathsf{Dose} \ \mathsf{Depletion}$

Key: In Vitro Relase testing (IVRT) | Design of Experiments (DoE) | Critical Method Variables (CMV) | Critical Analytical Atributes (CAA) | In Vitro Release rate (IVRR) | Cumulative amount released in an initial timepoint (Qi)] Cumulative Amount Released in final time (Qf)



PHARMAPEDIA PSGCP *E-News Letter*

VOL 1 / ISSUE 10 / JUNE 2019 - SEPTEMBER 2019

Research shows low-cost once a day combination pill can prevent heart disease and Stroke:



Research carried out by the collaboration of Tehran University Of Medical Science, Iran with the University of Birmingham,UK has shown a combination low-cost pill called a polypill containing four drugs is effective in preventing cardiovascular disease.

The Polypill included aspirin, a statin (atorvastatin), and two drugs to lower blood pressure (hydrochlorothiazide and enalapril).

Ref1:<u>https://www.birmingham.ac.uk/news/latest/2019/08/polypill-heart-disease-stroke-research.aspx</u>

Ref 2: https://www.bbc.com/news/health-49434337

aQbD as a platform for IVRT method development–A regulatory oriented approach:

The European Medical Agency draft guideline on quality and equivalence of topical products and the FDA non-binding product specific guidances release has encouraged the establishment of a regulatory background for *in vitro* release testing (IVRT). Herein, a novel framework applicable to the development of a discriminatory IVRT method is described, according to analytical quality by design (aQbD) principles. A commercially available diclofenac emulgel formulation was used as model product.

Through the definition of IVRT analytical target profile, a risk assessment analysis was carried out, in which the critical analytical attributes (*in vitro*release rate, cumulative amount released at an initial/final point and dose depletion) and critical method variables (medium, membrane and dosage regimen) were identified. Based on this information, a $3 \times 2 \times 3$ full factorial design was performed.

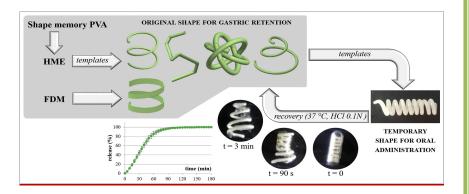
aQbD provided a comprehensive framework for developing a reliable and effective IVRT method. A thorough analysis of the new EMA draft guideline requirements revealed that some of the established criteria may be challenging to attain.

Ref: https://www.sciencedirect.com/science/article/pii/S0378517319307409

Important Health Days:
1 st Oct to 31 st Oct – Breast Cancer Awareness Month
10 th Oct – World Mental day
11 th Oct – World Obesity day
12 th Oct – World Arthritis day
15 th Oct – Global Handwashing day
16 th Oct – International Infection Prevention Week
20 th Oct – World Osteoporosis day
1 st Nov to 30 th Nov – Lung Cancer Awareness Month
13 th Nov to 19 th Nov – World Antibiotic Awareness week
14 th Nov – World Diabetes day
17 th Nov – World Prematurity day
20 th Nov – World COPD day
1 st Dec – World AIDS day
3 rd Dec – International day of Persons with Disabilities
31 st Jan – Anti-Leprosy day

Novel 4D Printed Tablet for Expandable Drug Delivery system for Gastric retention

Several diseases would benefit from prolonged drug release provided by systems retained in the stomach for extended time periods. Expandable gastroretentive devices are administered in a collapsed configuration enabling swallowing and regain *in situ* their native shape having larger spatial encumbrance, thus hindering voidance through the wide open pylorus. An expandable system for gastric retention was here proposed relying on the shape memory behavior of pharmaceutical-grade poly (vinyl alcohol). Release from the samples, although of relatively short duration, was independent of the original shape and processing undergone, and was noticeably slowed down by application of Eudragit RS/RL-based coatings.



Ref: https://www.sciencedirect.com/science/article/pii/S0378517319307458

PHARMA TEASER!!!!!

- 1. What does DVOM stand for?
- 2. The first Inhaler is also called as?
- 3. In 2019 which Pharma company launches Infugem Injection for treatment
- of cancer in US?
- 4. _____ is the first and only one-dose oral medicine approved to treat flu?
- 5. Prithvi Shaw received eight months backdated ban for ingesting which prohibited

substance according to the World Anti - Doping Agency in 2019?

Send your correct answers to psgcp.ceutics@gmail.com .

The first three participants with correct answers will be acknowledged in the next issue.

In 1892, Parisian Pharmacist Jules Bengue, M.D., launched liquid ethyl chloride in tubes quipped with his patented spray nozzles.



Historical Perspective:

In *May 14, 1796*, Edward Jenner beginning with an attempted to using matter from Nelms' lesions, he inoculated an 8-year-old boy, James Phipps.

James Blundell gave his first report of a blood transfusion from man to man in a paper to the Medico-Chirurgical Society of London presented on *22 December 1818*.

William T.G. Morton made history by being first in the world to publicly and successfully demonstrate the use of ether anesthesia for surgery on **October 16, 1846 ("Ether day").**

Sales - Giron introduced first portable nebulizer to the Academy of Medicine in Paris on *May 20, 1856.*

On December 18, 1866, Jules – Auguste Beclard presented the earliest documented Jet Injector at the Imperial Academy of Medicine in Paris.

The US Patent office recognizes **December 1**, **1885**, as the first time Dr Pepper (Soft Drink) was served.

Alexander Fleming returned to his laboratory on **September 28, 1928** to find a Petri dish containing **Staphylococcus** bacteria, but that dish had become contaminated with blue-green mold called **Penicillium notatum**.

Banaras Hindu University (BHU): First Indian university to introduced Pharmacy course in **1932.** The establishment of a separate college of Technology comprising the Department of Industrial Chemistry and Pharmaceutics in **1939.**

National Institute of Pharmaceutical Education & Research (NIPER): NIPER was declared as an "Institute of National Importance" under the Act of Parliament on 26th June 1998.

PUBLISHER:

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