Tecnologie Tradizionali ed Innovative nella Fabbricazione di Forme di Dosaggio a Combinazione Fissa

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The Module Assembling Technology

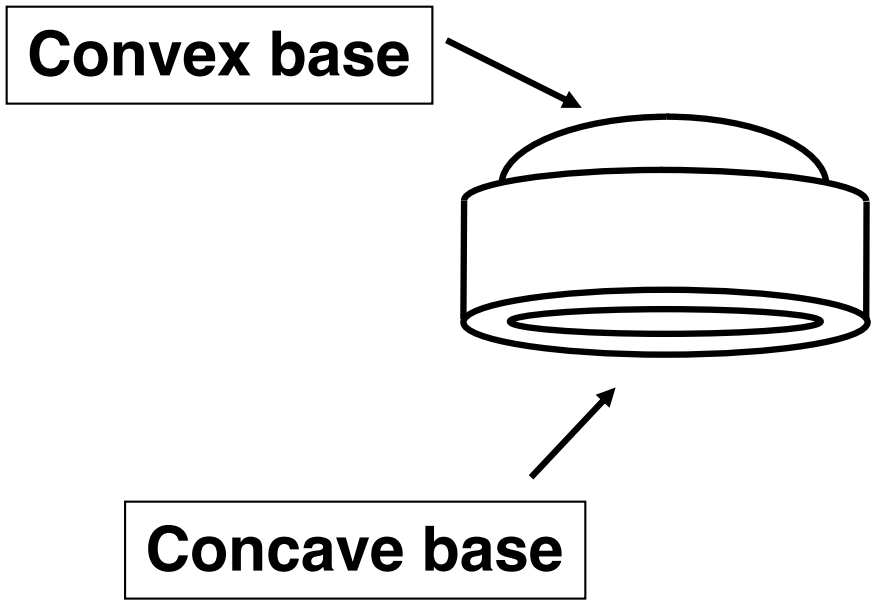
DRUG DELIVERY MODULE

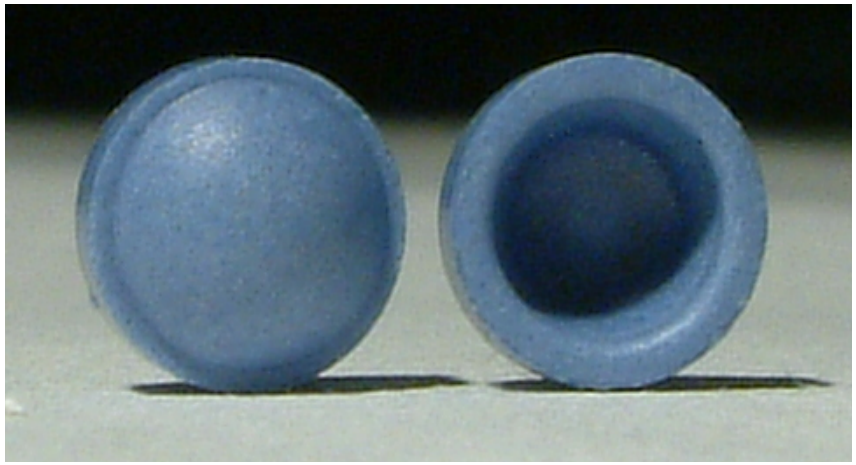
release unit exhibiting its own individual drug delivery program

MODULE ASSEMBLED DDS

two or more modules stuck together to form one-piece delivery system able to perform different time and/or site release, not only in dependence on modules' composition, but also on how the modules have been assembled

Delivery Module: disk-shaped tablet or matrix having one concave and one convex base

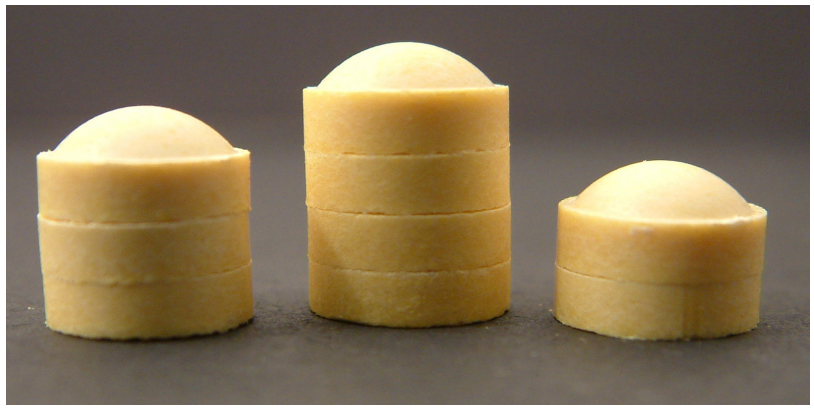


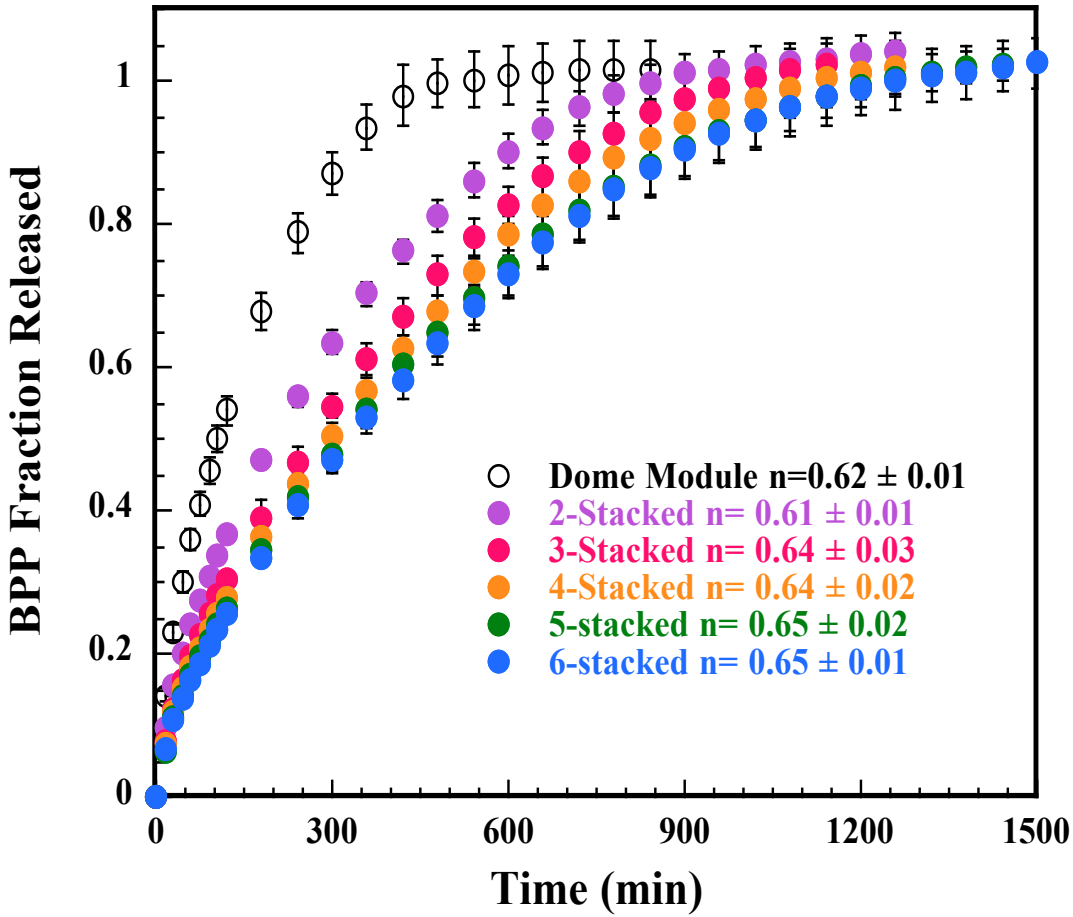


STACKED CONFIGURATION

Concave face over convex

Increasing pile length increases the dose with a **geometric effect** on release kinetics

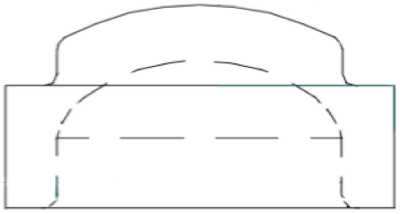




Click Technology: module assembling by friction interlocking

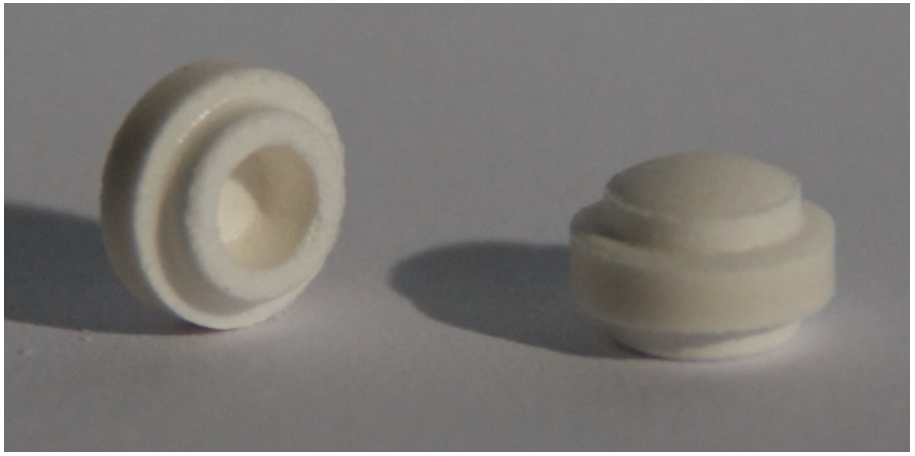
Female module

Protruded Convex Base

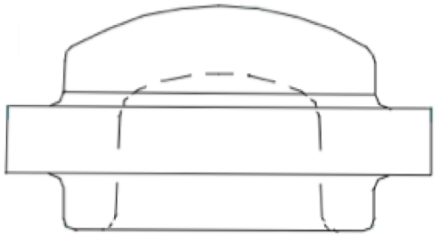


Concave Base

Male module

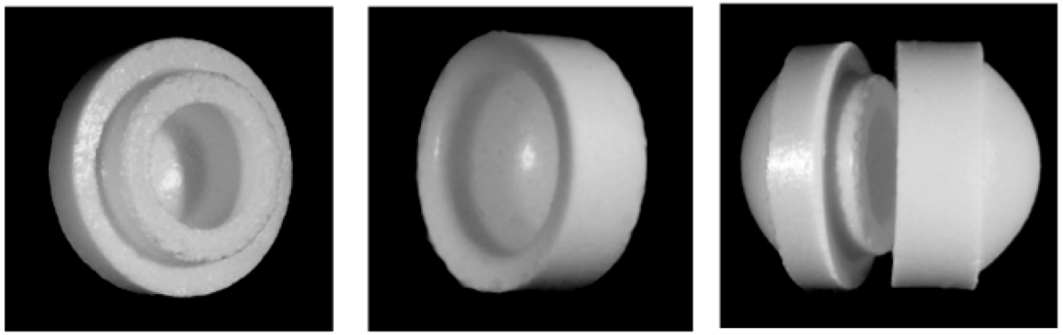


Protruded Convex Base

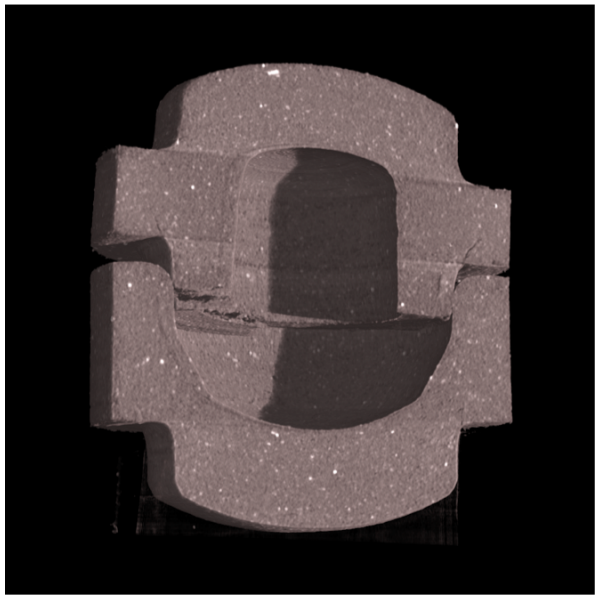


Concave Base with Annular Protrusion

Void Clicked Modules

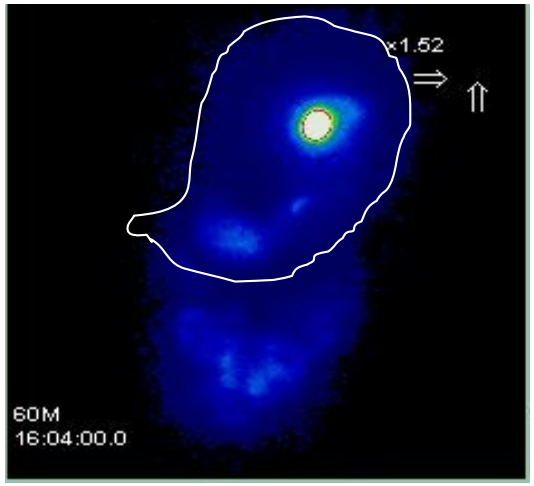


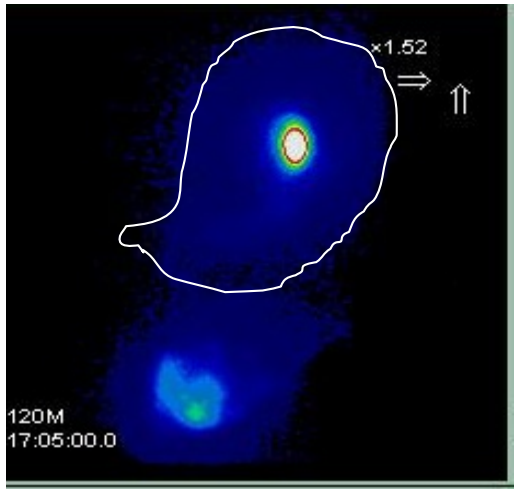
(a) (b) (c)

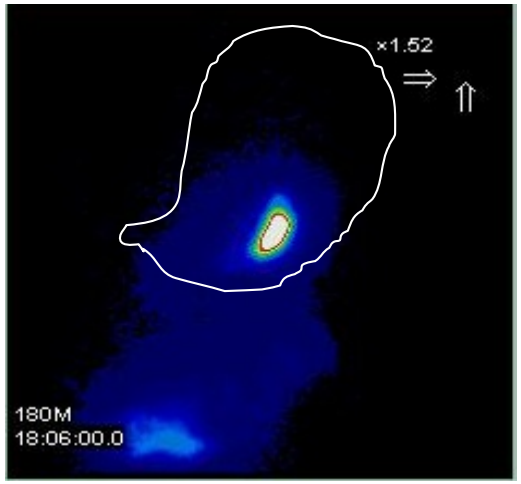


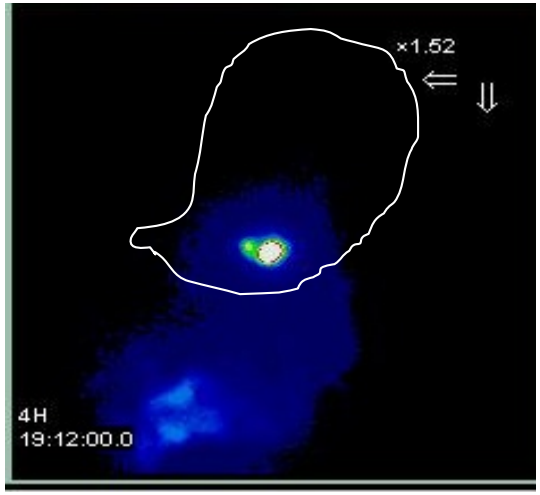
γ Scintigraphy Void System in Humans

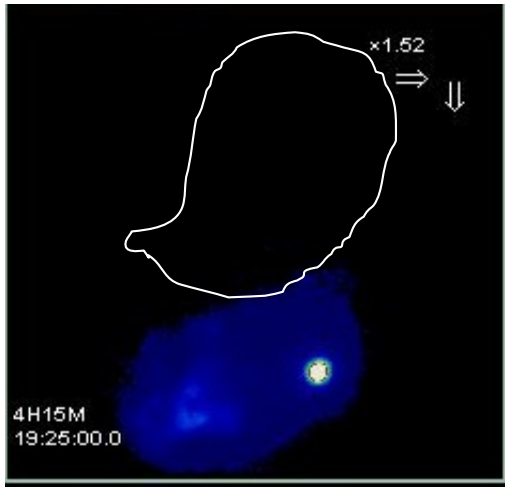
10 healthy subjects (5 male, 5 female), standard meal (1000Kcal) + 150 mL water. Void assemblage, Tc-99 labeled inside cavity + system soaked in radioactive liquid (to illuminate anatomical structures). Total activity: 15 MBq











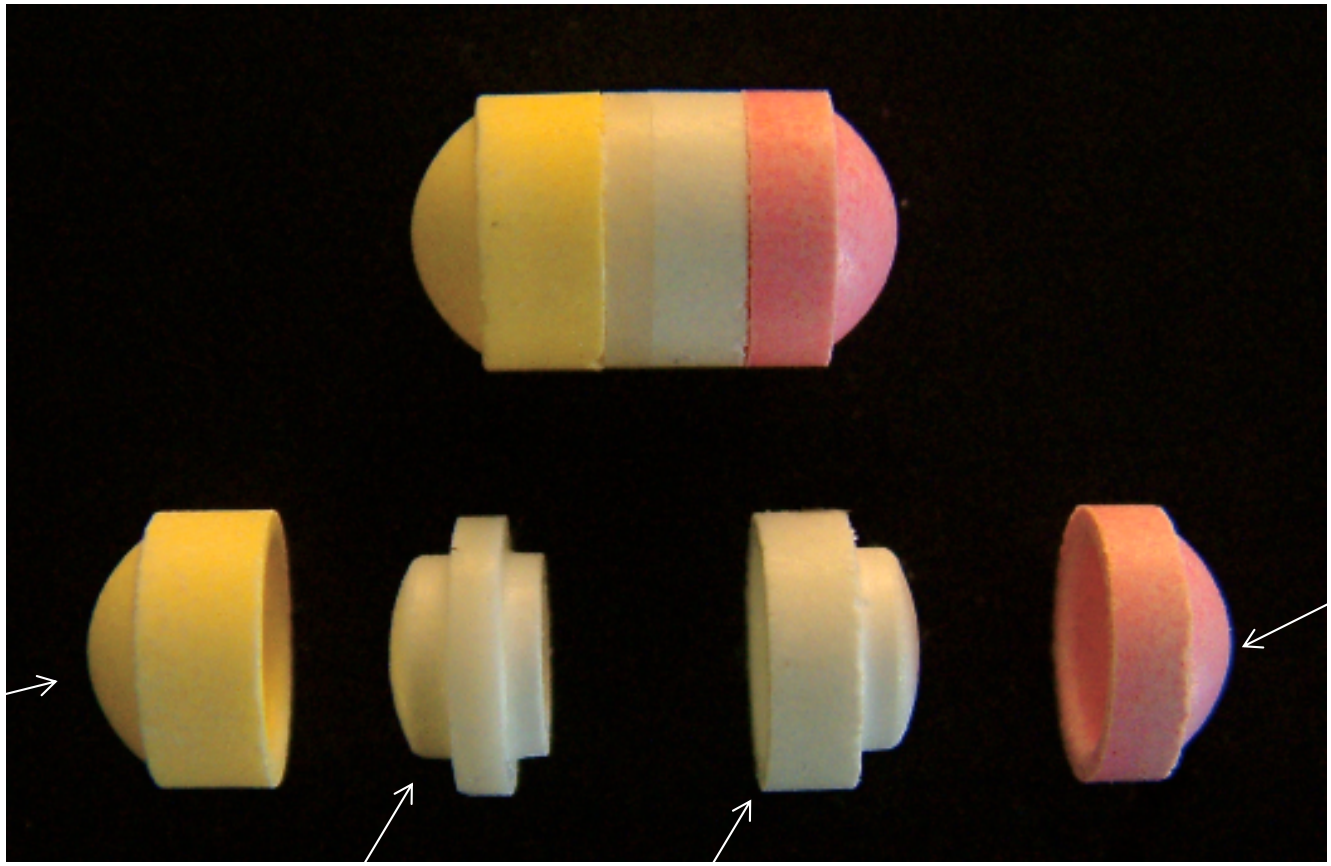
Gastro Retention Time

Men	2:30 (0:11) h
Women	4:09 (0:13) h

Pedro Coehlo UFP, personal communication

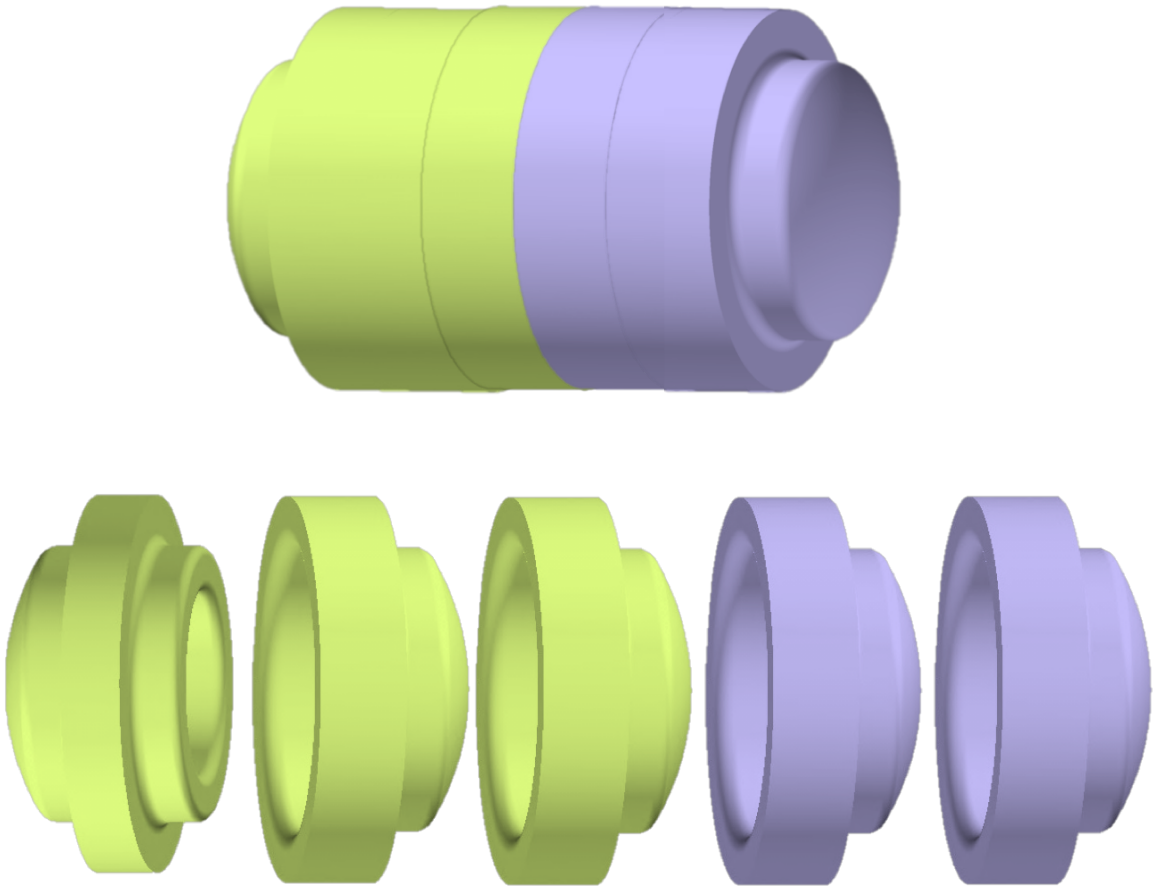
4 MODULES, 3 KINETICS, 2 DRUGS, 1 ASSEMBLED UNIT: POLYPHARMACY FOR MALARIA

Clindamycin 240 mg; Artesunate 50 mg

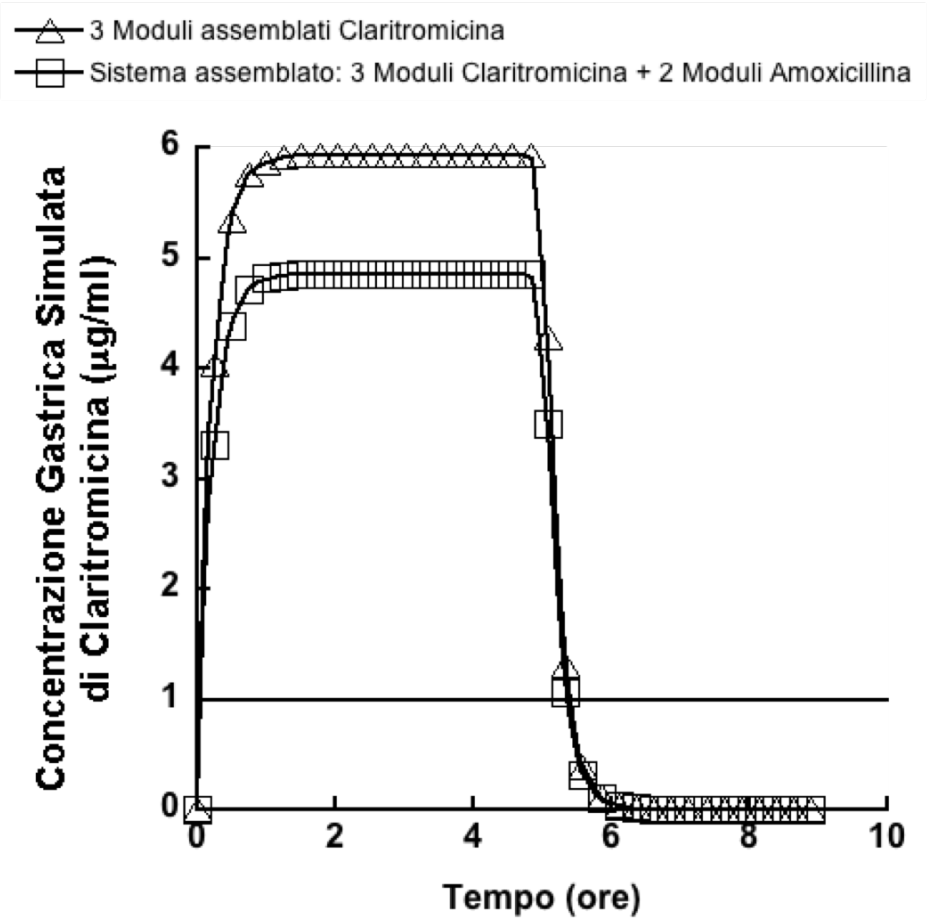


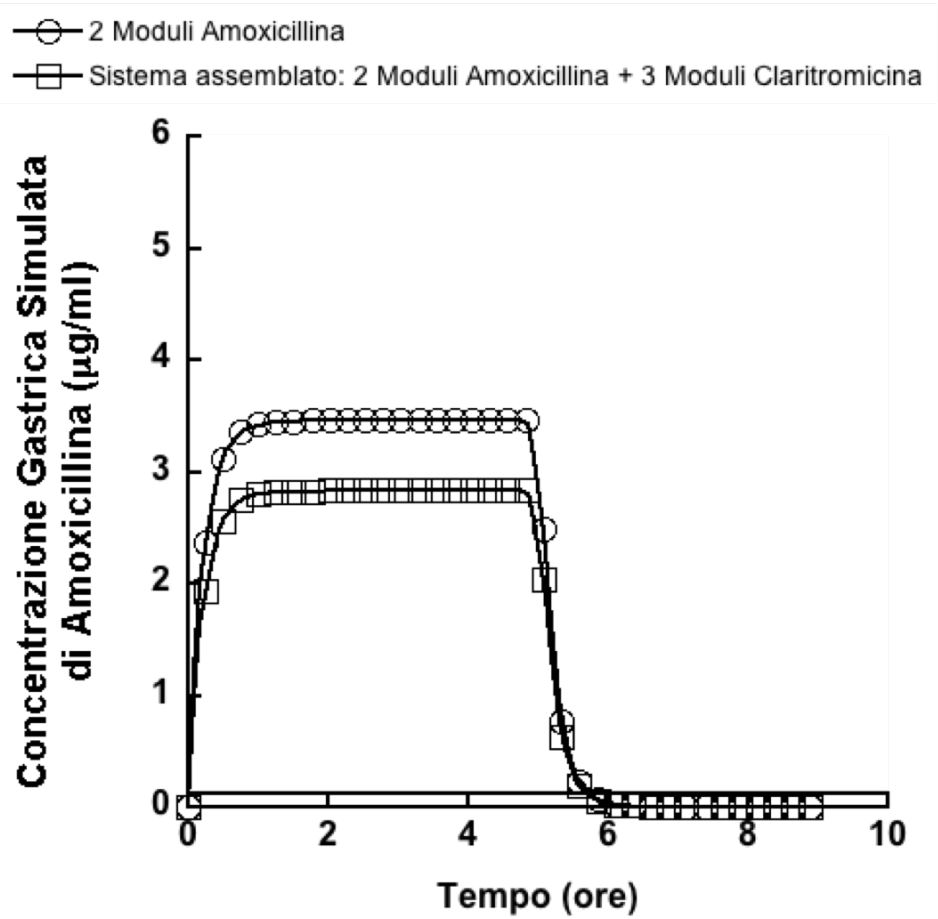
POLYPHARMACY FOR *HELICOBACTER PYLORI*
2 DRUGS, 1 KINETICS, 5 MODULES, 1 ASSEMBLY

Modified release modules for
Claritromicina 300 mg and Amoxicillina 200 mg

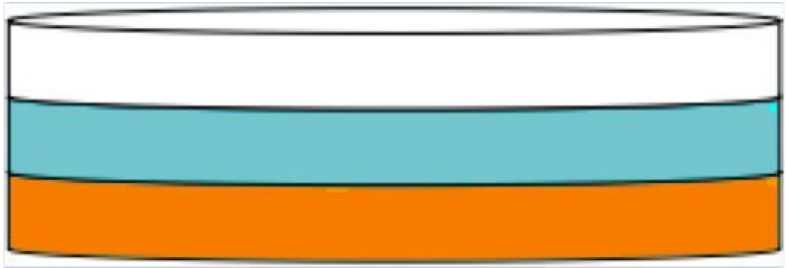


Simulated Gastric Concentration Amoxicillin e Clarithromycin





Multi-layer Tablets for Drugs and Release Combination



A. Gabapentin 300 mg
white hydrophilic matrix
gastro-retentive

B. Gabapentin 75 mg
blue immediate disintegrating

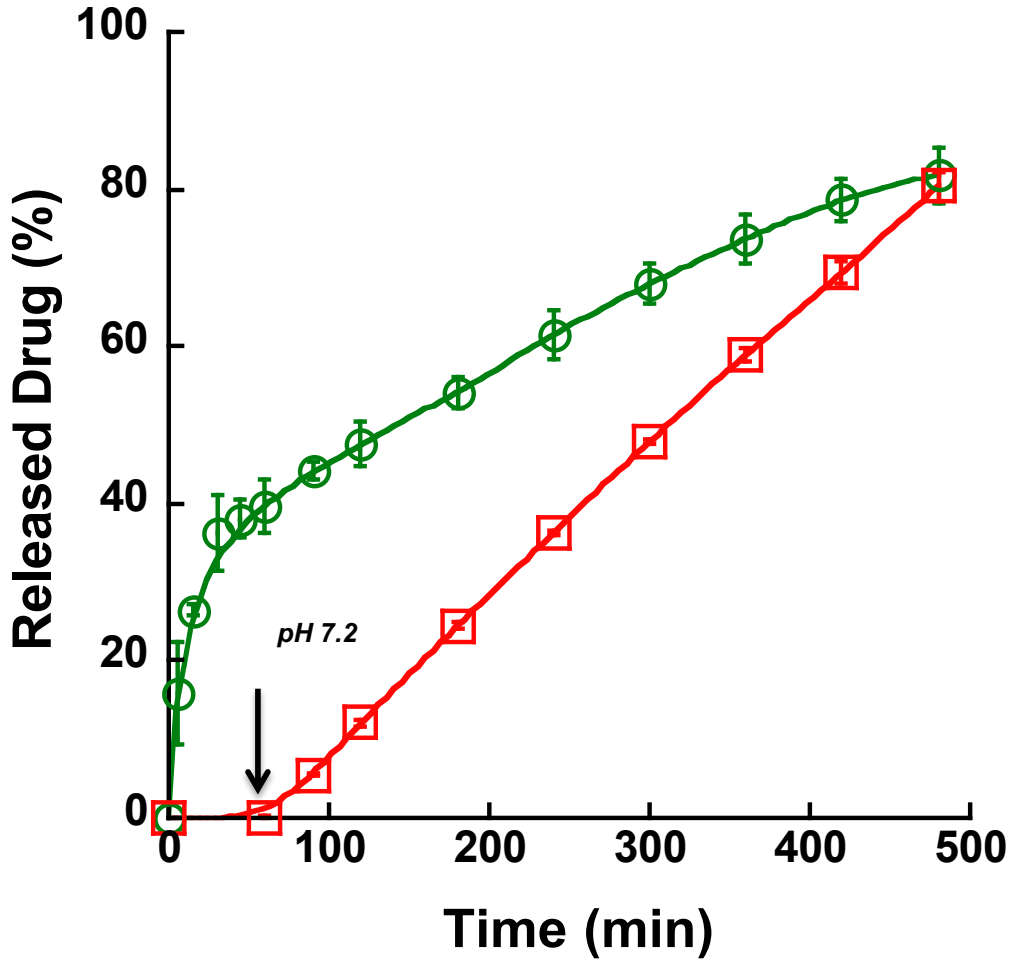
C. Flurbiprofen 37.5 mg
orange hydrophilic matrix
delayed prolonged release

Three-layer DDS in SGF pH 1.2

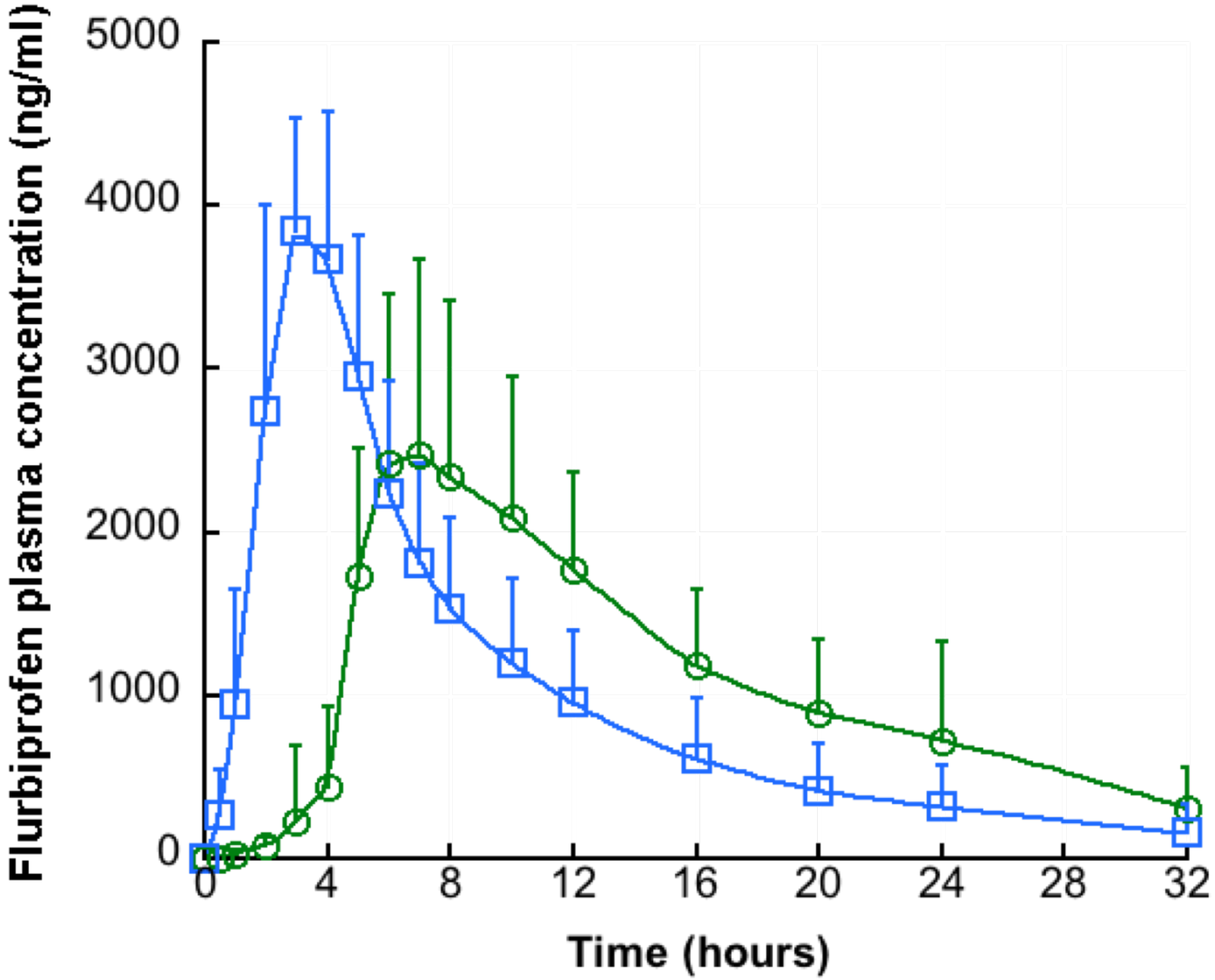
- The three layer tablet sinks in the medium.
- Layer B (blue layer) disintegrated provoking the separation of the layers A and C.
- Layer A (white layer) develops CO_2 bubbles entrapped into the gel formed in contact with aqueous medium.
- After the tablet splitting Layer A floats.
- Layer C (orange layer) remained in the bottom for intestinal transit.

In vitro release profiles at pH 1.2 of gabapentin (HPMC in Layer A) and flurbiprofen

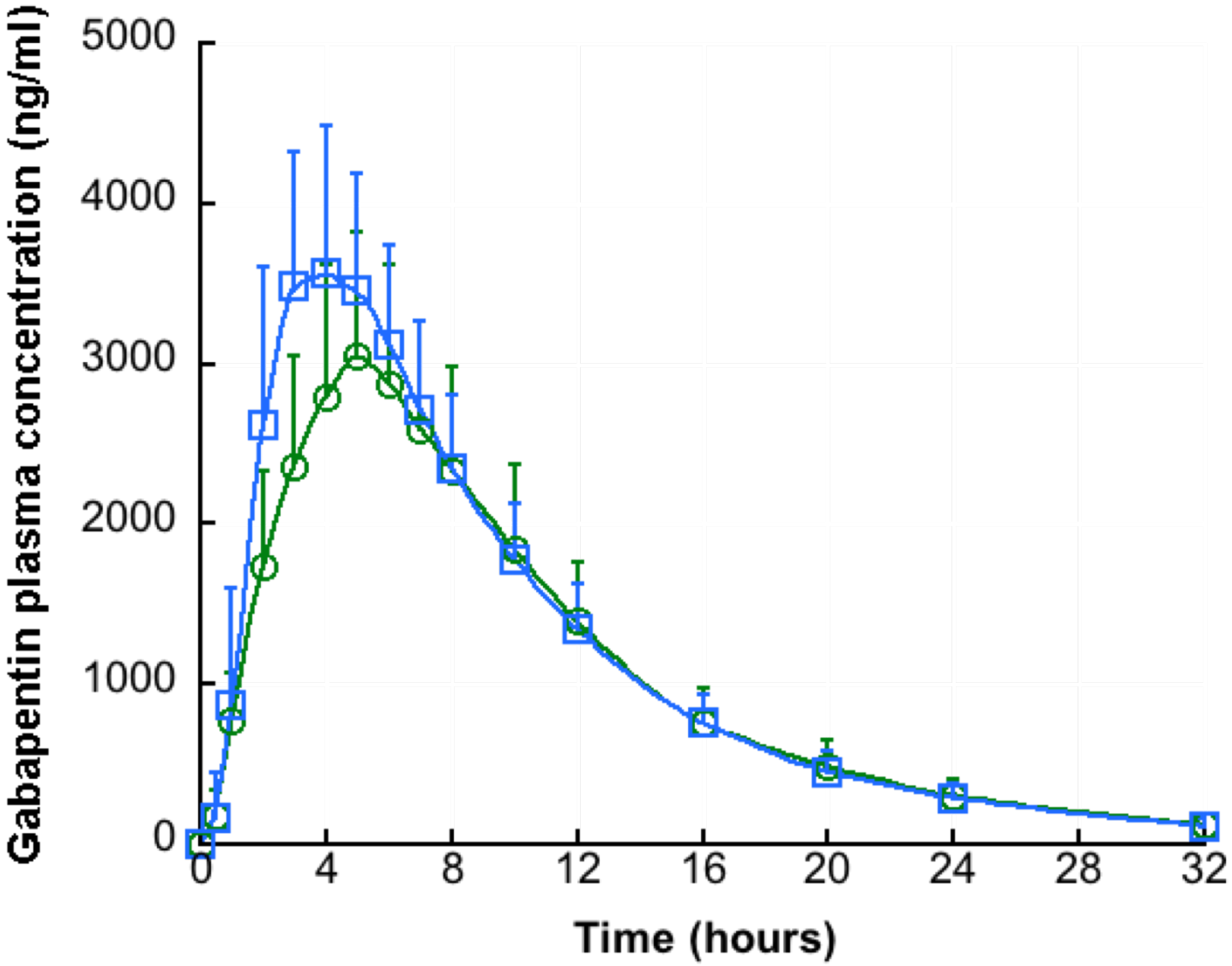
(pH to 7.2 after 60 min)



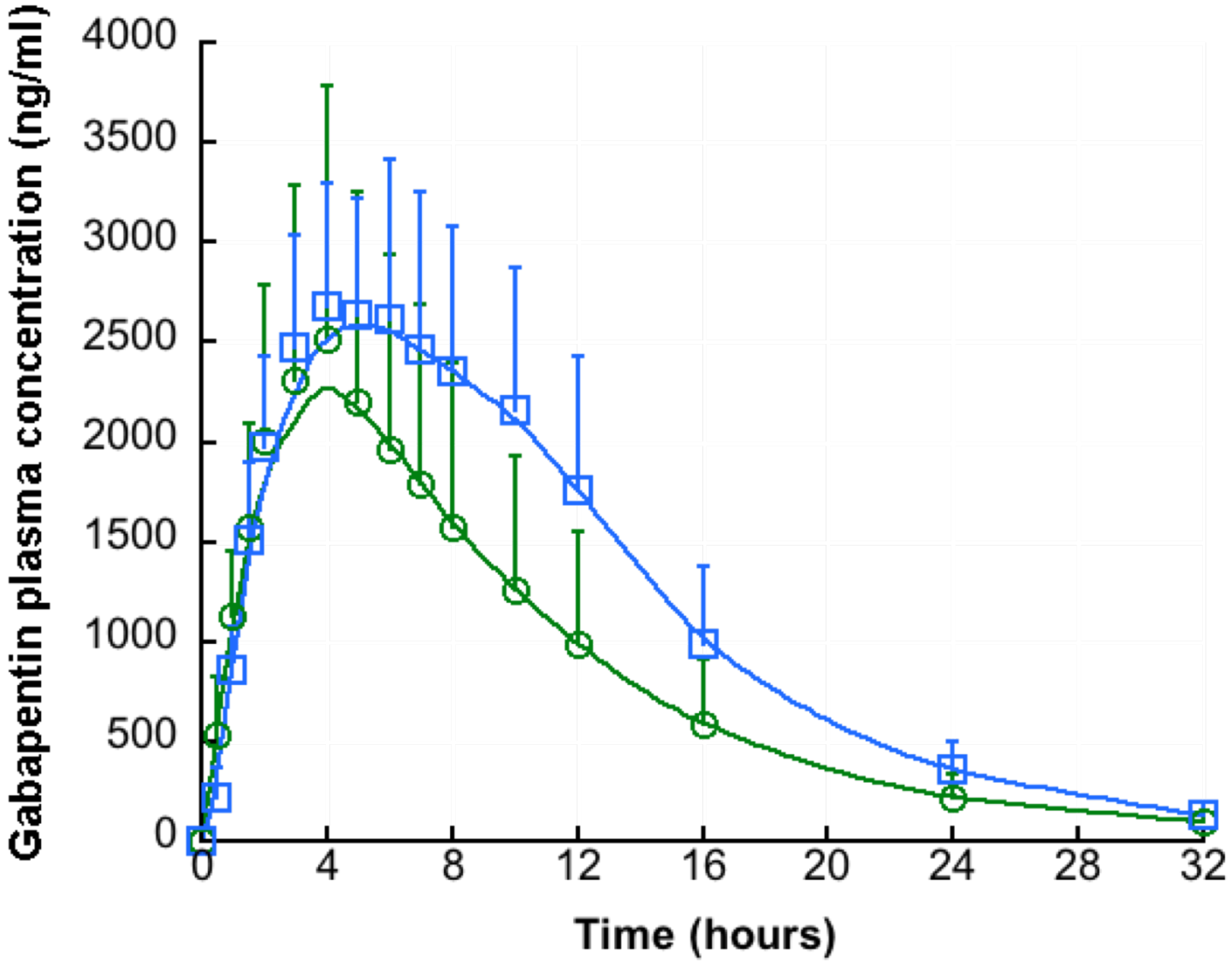
Flurbiprofen mean plasma levels from the FDC and IR formulations (n = 23)



Gabapentin mean plasma levels from the FDC and IR formulations (n = 23)



Gabapentin mean plasma levels in fasting and fed conditions (n = 24)



Combination Products

Two or more regulated components produced as a single entity

Combination products incorporating cutting edge, novel technologies hold great promises for advancing patient care

Innovative drug delivery devices have the potential to make treatments safer and more effective, or more convenient or acceptable to patients

Drug delivery systems are typically combination products since one component (polymer) is functional to the availability of the other (drug)

Tomorrow Dosage Forms

drug/drug combi novel products
oral multifunction delivery systems
personalized medicines