

Research and Development

16 Products Launched

Brands

Tussicaps®
PENNSAID®
Exalgo®
Gablofen®
Pre-filled Syringe

Generics

Methylphenidate ER Tablets (Concerta)
Oxycodone ER (Oxycontin)
Fentanyl Lozenge (Actiq)
Fentanyl Patch (Duragesic)
Oxymorphone IR Tablets (Opana IR)
Morphine Sulfate Oral Solution

Imaging

Sestamibi (Cardiolite Generic)
Pre-Filled Syringe Replacement Resin
Germanium-68

API

Hydromorphone HCl
Buprenorphine HCl
Buprenorphine Base

7 Products Filed Awaiting Approval:

Business	Product	Approval Type	Approval Target
Brand	MNK -395 (PENNSAID® 2% Pump)	NDA(505(b)(2))	Q4 FY13/Q1 FY14
Brand	MNK-795	NDA(505(b)(2))	Q2/Q3 FY14
Generic	Methylphenidate ER Capsules (Metadate CD)	ANDA	Q4 FY14
Generic	Intrathecal Morphine Sulfate (Mitigo)	ANDA	Q1 FY14
Generic	Oxymorphone ER Tablets (Opana ER)	ANDA	Q3 FY14
Generic	Methylphenidate ER Tablet 18 mg (Concerta)	PAS to ANDA	Q2 FY15
Generic	Fentanyl Transdermal Patch 12.5 mcg/hr	PAS to ANDA	Q3 FY14

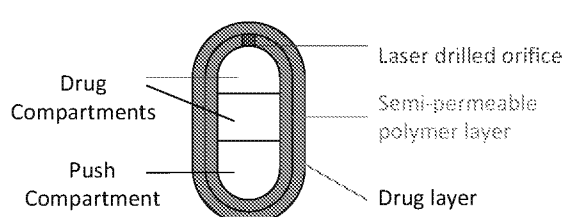
2 Brand NDAs
3 Generic ANDAs
2 PAS to an ANDA

Generic Version of **CONCERTA®** from Mallinckrodt (27, 36, and 54 mg dosage strengths) – First To File

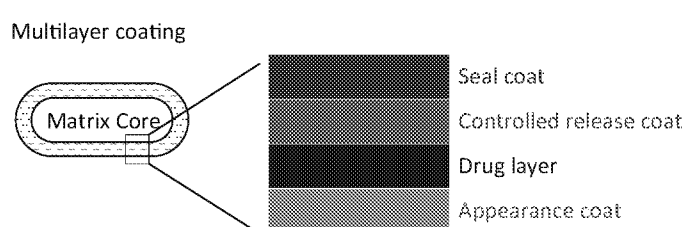
- First to file
- Partial-area bioequivalent
- Non-infringing

CONCERTA: Product Comparison

Innovator
Concerta®

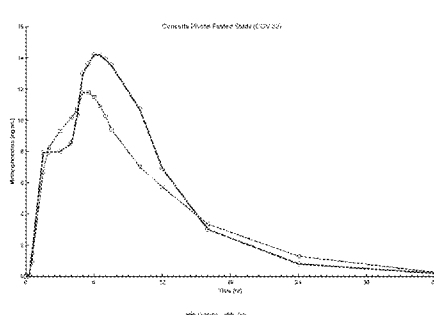


Covidien's
generic

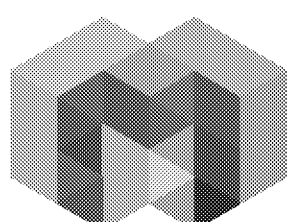
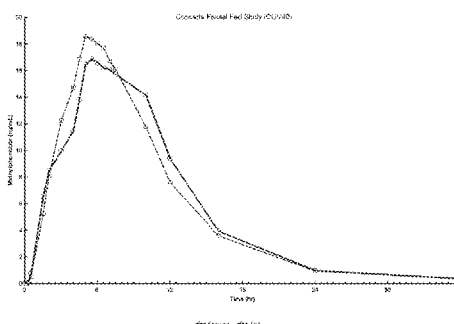


Bioequivalence Results

Fasted



Fed



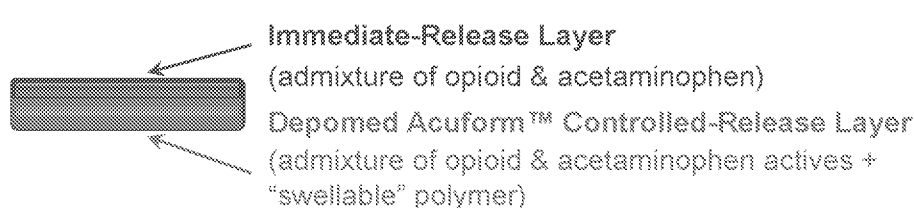
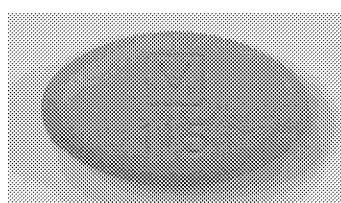
Mallinckrodt
Pharmaceuticals

Research and Development

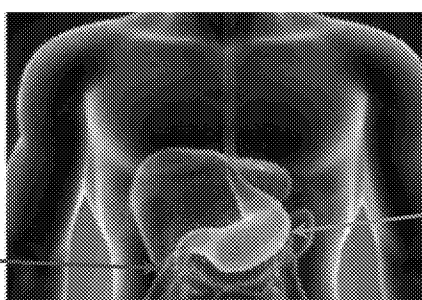
MNK795 - Ruby

- Acute moderate to severe pain
- Bilayer tablet: *Immediate-Release Layer* + *Controlled-Release Layer*
- Controlled-release 12-hr formulation
- Significant abuse-deterrent properties

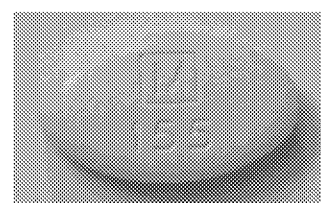
7.5 mg Oxycodone Hydrochloride / 325 mg Acetaminophen Tablet



Immediate-Release Layer quickly dissolves and can exit stomach



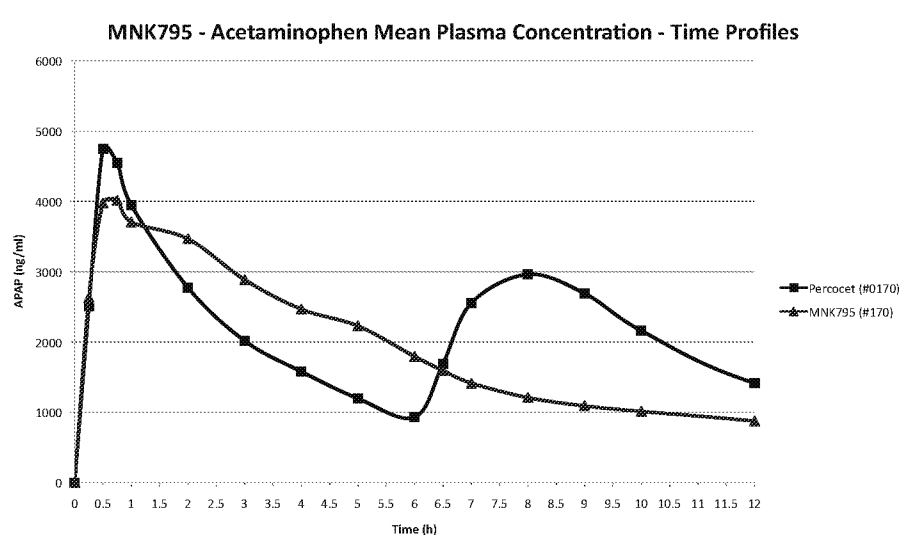
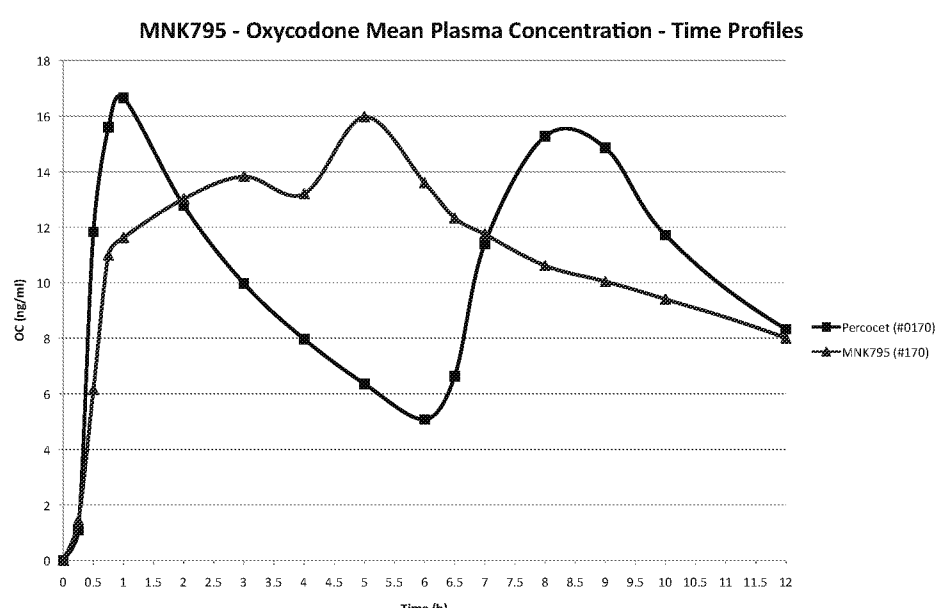
...while the Controlled-Release Layer swells and remains



MNK155 - Zircon

- Acute moderate to severe pain
- Bilayer tablet: *Immediate-Release Layer* + *Controlled-Release Layer*
- Controlled-release 12-hr formulation
- Significant abuse-deterrent properties

7.5 mg Hydrocodone Bitartrate / 325 mg Acetaminophen Tablet



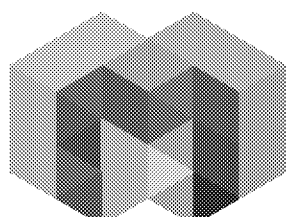
MNK795 Characteristics

Product Design

- Rapid onset of relief from immediate-release layer
- Sustained relief from gastroretentive extended-release layer
- Oxycodone blood levels at the beginning and end of the dosing interval mirror Percocet
- Acetaminophen blood levels rise rapidly to provide quick relief and absorption is complete early to allow approximately one half life with no first pass metabolism

Abuse Deterrence Features

- Difficult to extract opioid due to rapidly hydrating polymers that form gels
- Difficult to snort due to low dose of opioid in large tablet mass
- When ground powder from extended-release layer mixes with powder from immediate-release layer impeding manipulation



Mallinckrodt
Pharmaceuticals