Reference P005

MRL Clinical Study Report, Multicenter Study: A Randomized, Multicenter, Placebo-Controlled, 3-Period, Crossover Study to Assess the Glucose-Lowering Activity, Pharmacokinetics, and Safety and Tolerability of Single Oral Doses of MK-0431 in Patients with Type 2 Diabetes (Protocol 005)

| Reference P005 |
| --- |
| Reports of Human Pharmacokinetic (PK) Studies<br>Patient PK & Initial Tolerability Study Reports |

# CLINICAL STUDY REPORT

## MK-0431

## A RANDOMIZED, MULTICENTER, PLACEBO-CONTROLLED, 3-PERIOD, CROSSOVER STUDY TO ASSESS THE GLUCOSE-LOWERING ACTIVITY, PHARMACOKINETICS, AND SAFETY AND TOLERABILITY OF SINGLE ORAL DOSES OF MK-0431 IN PATIENTS WITH TYPE 2 DIABETES

| | |
| --- | --- |
| Generic Name: Generic Name | Protocol 005 |
| Dosage Form: Capsules | Phase I |
| Indication: Type 2 Diabetes | Study Design: Randomized, Placebo-Controlled, 3-Period Crossover Study |
| | |
| Sponsor Name: | Merck & Co., Inc. |
| Clinical Monitor: | Gary A. Herman |
| | |
| Study Initiation Date (FPI): | 14-Oct-2002 |
| Study Completion Date (LPO): | 07-Jan-2003 |
| | |
| Investigator Name/Affiliation: | Multicenter (6) |
| | |
| GCP Compliance: | Information regarding GCP compliance can be found in Sections 5.6 and 6.2 |
| | |
| Clinical Study Report Date: | 07-Nov-2005 |

# CLINICAL STUDY REPORT

## A Randomized, Multicenter, Placebo-Controlled, 3-Period, Crossover Study to Assess the Glucose-Lowering Activity, Pharmacokinetics, and Safety and Tolerability of Single Oral Doses of MK-0431 in Patients with Type 2 Diabetes (Protocol 005)

## TABLE OF CONTENTS

# TABLE OF CONTENTS (CONT.)

# TABLE OF CONTENTS (CONT.)

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.