

Simplifying Complex Molecules

Buprenorphine Buccal Film Phase I study for USFDA Submission



Buprenorphine is a schedule III opioid with unique pharmacodynamic and pharmacokinetic properties that contribute to effective analgesia. Buprenorphine buccal film is a small, bilayered dissolving polymer film that adheres to the buccal mucosa, which enhances bioavailability compared with other routes of administration and facilitates a unidirectional flow of the drug. Buprenorphine buccal film has advantages over the transdermal formulation and is considered by many practitioners to be a preferential treatment option over schedule II opioids.

Phase of the Study:

Single dose bioequivalence study of test formulations of Buprenorphine Buccal film, 900 mcg and Belbuca (Buprenorphine Buccal film) 900 mcg in healthy adult human subjects under fasting conditions.

Dosing Method:

Buprenorphine Buccal film 900 mcg was placed in right/left cheek pouch (the area between the cheek and gums) of each subject's mouth until dissolution.

Major Challenges:



Respiratory Depression as buprenorphine is a partial agonist of opioid receptors, it carries a risk of respiratory depression, particularly at higher doses or in opioid-naïve individuals. concurrent oral Naltrexone was administered to reduce adverse events (AEs).

Multiparametric (multipara) monitoring is essential for assessing safety, pharmacodynamics, and tolerability, especially considering the risks associated with opioid administration.

Dosing , application, and monitoring for correct film adherence and retention, dose absorption variability and patient compliance.

Managing Phase I clinical studies of complex molecules such as Buprenorphine demands a CRO partner with specialized expertise and proven experience to navigate the challenges inherent in such trials.

Cliantha Research, a full-service global CRO, offers a distinctive approach to clinical development, making it ideally equipped to handle some of the industry's most intricate and challenging Phase I molecules.

Our Phase I Infrastructure



Well-equipped Phase I units at Ahmedabad (20 bedded) & Vadodara (16 bedded)

- The silent features of Phase I set up includes:
 - 1) Infusion pumps for continuous and precise IV infusion
 - 2) Bedside oxygen supply with a dedicated oxygen unit
 - 3) Cardiac monitors with centralized cardiac monitoring system
 - 4) Defibrillators, suction machine and all the medications to manage any kind of adverse event
- ICU on wheel ambulance is available on site for 24*7 to transfer the subject to tertiary care hospital in case of emergency.

For more information

 info@cliantha.com