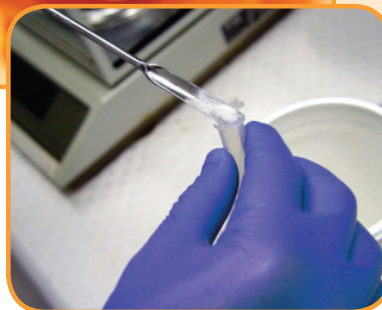


# Drug Diversion & Product Safety Studies for the pharmaceutical industry

With so much riding on the development of your new drug, any setback with the FDA can be costly. This is especially true for compounds with abuse potential. The FDA now requires drug manufacturers to submit a Risk Evaluation and Mitigation Strategy (REMS) prior to approval<sup>1</sup>. NMS Labs can help – by expertly designing and conducting your REMS study and providing a report that is sound, clear and FDA-ready – from a trusted and unbiased third party.

Our extensive experience conducting these kinds of studies has given us a unique understanding of the drug diversion methods, latest techniques and "kitchen-type" lab set-up required to simulate real-world environments and accurately evaluate abuse potential.



## Common Products Studied

- Diversion resistant opioid products containing oxycodone, hydrocodone, oxymorphone, morphine or hydromorphone
- Over-the-counter pseudoephedrine products
- Transdermal devices

## Why Look to NMS Labs for Your Next Drug Diversion Study?

### Features we offer:

- ✓ Compare your product to competitor products
- ✓ Customized protocols and analysis
- ✓ Experiments in "kitchen chemistry" environments
- ✓ Quantitative testing by LC-MS/MS
- ✓ Comprehensive, non-biased third-party reports
- ✓ GLP-like protocols
- ✓ Expert services support
- ✓ Diversion for oral/I.V. abuse

### Benefits you can count on:

- ✓ Scientists with experience in these kinds of studies
- ✓ Data that fits with other information submitted to the FDA; present with confidence
- ✓ Objective, non-biased opinions and conclusions
- ✓ Credibility from established experts in REMS, FDA submissions, DEA expectations and drug delivery mechanisms

## A Partner You Can Trust

**Experienced:** Our highly-trained team is well versed in formulation development and has supported many FDA submissions.

**Independent:** We provide unbiased assessments, objective opinions and GLP-like protocols to assure credibility with the FDA and other agencies.

**Confidential:** Complete confidentiality is assured.

## Replicating Diversion Techniques

We perform a wide range of "kitchen-type" experiments to challenge drug delivery devices to their limits and compare to currently available formulations. We then take the outcomes and quantitate by LC-MS/MS to measure, evaluate and report detailed and scientifically backed conclusions.

NMS Labs drug diversion studies are typically conducted in comparison to similar products currently on the market. Although each project is unique, evaluations tend to take on similar structures with multiple variables applied to each set of experiments, including:

- Number of replicates
- Use of intact and/or crushed products
- Comparators
- Degree of agitation
- Solvents
- Continually-heated extractions
- Time-points
- Room temperature and heated experiments

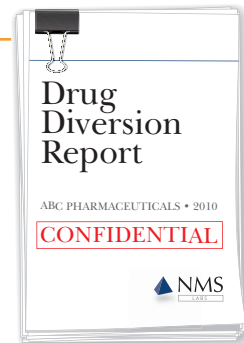
## Detailed and Easy-to-Read Reports

- Ready for FDA and other regulatory agencies submittal
- Includes a well-organized table of contents followed by detailed sections and subsections
- Data presented in detailed tables with easy-to-comprehend summary charts

## Focused Study Protocols

Study protocols address the priority concerns of the FDA:

- How will DEA and FDA view the risk and abuse of this product?
- How easy is it to abuse this product?
- How can "street dealers" profit from this product?
- How can the active ingredients be extracted and available for abuse?



### Report Details:

- > Table of Contents
- > Introduction
- > Materials / Method
- > Detail / Observations
- > Data / QC Results
- > Photographs
- > Conclusions

## Facts About Prescription Drug Diversion & Abuse\*

- ✓ Unintentional overdose deaths involving prescription opioids increased 114% between 2001 and 2005.
- ✓ The estimated annual cost of diversion and abuse of controlled prescription drugs to the public and insurers is \$72.5 billion.
- ✓ Pain relievers are by far the most widely abused – more than sedatives and tranquilizers combined – primarily by those age 12-25.

For more information contact an NMS Labs Representative today at (800) 522-6671 or [researchstudies@nmslabs.com](mailto:researchstudies@nmslabs.com).



<sup>1</sup> FDA Amendments Act of 2007

\* US Department of Justice 2009 National Prescription Drug Threat Assessment (NPDTA) (Reference: [www.usdoj.gov/ndic/](http://www.usdoj.gov/ndic/))