PDE5 INHIBITORS

Frequently Asked Questions

What are PDE5 inhibitors?
Phosphodiesterase type 5 (PDE5) inhibitors are compounds that can be used for treatment of erectile dysfunction. Certain PDE5 inhibitors are approved drugs and are currently prescribed under brand names such as Viagra®, Cialis® or Levitra®.

If they are FDA approved and currently prescribed, what is the problem?
When PDE5 inhibitors are present in non-prescription, over-the-counter supplements, they are not labeled as such. Often, these products are labeled as natural remedies. Without knowledge of the presence of PDE5 inhibitors, the user is at risk for drug interactions or counter-indications. Also, many adulterated products have been found to contain analogues of the approved PDE5 inhibitors, in which case the health risks are mostly unknown. As well, when an ingredient is manufactured for use as an unlabeled adulterant, the manufacturing practices used in production often are not monitored properly or are at a level acceptable for standards.

How often does PDE5 inhibitor adulteration occur in over-the-counter sexual enhancement supplements?
A 2013 study reported 81% of 58 different products with no claims of synthetic substances were found to contain synthetic PDE5 inhibitor drugs. Another study in 2009 reported that 77% of the sexual enhancement products seized in Singapore contained PDE5 inhibitor adulterants.

What are the health risks of PDE5 inhibitor adulterants?
Adulteration with PDE5 inhibitors can be dangerous and even lethal. FDA-approved PDE5 inhibitor drugs have many reported side effects, as well as life-threatening drug interactions. Counterfeit drugs or unapproved analogues can have unknown side effects, drug interactions and manufacturing standards. Consumers can unknowingly risk their health by using over-the-counter sexual enhancement products without proper safety warnings.

What types of products may contain PDE5 inhibitor adulterants?
Dietary supplement ingredients and end products with sexual enhancement claims may contain PDE5 inhibitor adulterants to increase user experience of label claims.

Who should test for PDE5 inhibitors?
Dietary supplement manufacturers should test ingredients from their suppliers as part of an ongoing vendor verification and management program. Retailers should engage in a statistically sound testing program of all dietary supplement products sold in stores as part of an ongoing quality, safety and brand protection program.
Which PDE5 inhibitors does the Covance method detect?

Our method is based on non-targeted data acquisition using liquid chromatography coupled to accurate-mass/high-resolution mass spectrometry, which can detect and identify PDE5 inhibitors such as avanafil, lodenafil carbonate, mirodenafil, sildenafil, tadalafil, udenafil or vardenafil and their unapproved known and novel analogues in various sexual enhancement dietary supplements and ingredients including botanical powders, solid and liquid botanical extracts, tablets, capsules, softgels and drinks. Our method was accepted by AOAC INTERNATIONAL as the new First Action Official Method™ for PDE5 inhibitor analysis for screening, identification and quantitation of PDE5 inhibitors.

What is the next step if I would like to set up a testing program to include the detection of PDE5 inhibitors?

To start the conversation, simply contact your Customer Service Associate or call us at 1-800-675-8375.

References