

A NEW LEVEL OF BRAND PROTECTION

Covance Develops Non-Targeted Analysis for Adulterants in Sexual Enhancement Supplements

The adulteration of dietary supplements with synthetic phosphodiesterase type 5 (PDE5) inhibitors can cause serious adverse health risks. Covance has introduced a new non-targeted analysis method using liquid chromatography-high resolution mass spectrometry (LC-HRMS) for screening and identification of known and novel PDE5 inhibitors in dietary ingredients and supplements, leading the industry and our clients to a new level of brand protection.

PDE5 Inhibitor Adulterants Are Common and Can Pose a Serious Health Risk

PDE5 inhibitor adulteration of dietary supplements is a serious problem. Over 150 known analogues currently exist outside of the four FDA-approved PDE5 inhibitor drugs. In a 2013 study, 81% of 91 herbal products with no claims of synthetic substances were found to contain synthetic PDE5 inhibitor drugs or analogues.¹ A previous study also reported that 77% of 175 illegal sexual enhancement products seized in Singapore contained PDE5 inhibitor adulterants.²

Adulteration of supplements with PDE5 inhibitors can prove dangerous for consumers. When FDA-approved PDE5 inhibitor drugs are prescribed, known drug interactions and side effects are managed by skilled medical care, and manufacturing standards are upheld due to regulation. Consumers who purchase adulterated over-the-counter sexual enhancement supplements, however, are unknowingly at risk since the manufacturing process, side effects or drug interactions are not managed or regulated.

Covance Pioneers Non-Targeted PDE5 Inhibitor Analysis

To address growing concerns about PDE5 inhibitor adulterants, AOAC International issued a call for methods to screen for these compounds in dietary supplements and ingredients.

Covance took action on this issue by responding to the AOAC International call for methods. We have now developed and validated a method using liquid chromatography-high resolution mass spectrometry (LC-HRMS) for non-targeted screening and identification of known and novel PDE5 inhibitors. Accepted by AOAC International as the new First Action Official MethodSM for PDE5 inhibitor analysis in dietary supplements and ingredients, this new testing helps assure the products you market, manufacture or sell uphold your high brand standards.

Experience a New Level of Brand Protection

To discover more about this new offering, contact us today at 1-800-675-8375. Let's start this important conversation.

References

1. Campbell, N., Clark, J.P., Stecher, V.J., Thomas, J.W., Callanan, A.C., Donnelly, B.F., Goldstein, I., & Kaminetsky, J.C. (2013) Adulteration of purported herbal and natural sexual performance enhancement dietary supplements with synthetic phosphodiesterase type 5 inhibitors, *J. Sex Med.* 10(7), 1842-18492.
2. Low, M.Y., Zeng, Y., Li, L., Ge, X.W., Lee, R., et al. (2009) Safety and quality assessment of 175 illegal sexual enhancement products seized in red-light districts in Singapore, *Drug Saf.* 32, 1141-1146.

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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.¹ Another study in 2009 reported that 77% of the sexual enhancement products seized in Singapore contained PDE5 inhibitor adulterants.²

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 both known and novel PDE5 inhibitors. Our method was accepted by AOAC International as the new First Action Official MethodSM 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

1. Campbell, N., Clark, J.P., Stecher, V.J., Thomas, J.W., Callanan, A.C., Donnelly, B.F., Goldstein, I., & Kaminetsky, J.C. (2013) Adulteration of purported herbal and natural sexual performance enhancement dietary supplements with synthetic phosphodiesterase type 5 inhibitors, J. Sex Med. 10(7), 1842-18492.
2. Low, M.Y., Zeng, Y., Li, L., Ge, X.W., Lee, R., et al. (2009) Safety and quality assessment of 175 illegal sexual enhancement products seized in red-light districts in Singapore, Drug Saf. 32, 1141-1146.

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