

## Quality-by-design approach to analytical method development

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Quality-by-design was first described by Joseph M. Juran, is a systematic approach to drug development, which begins with pre-defined objectives, and uses science and risk management approaches to gain product and process understanding and ultimately process control. The FDA has recently begun to advocate the QbD methodology for the pharmaceutical sector. More companies in the pharmaceutical industry today are in the need of adopting the principles of Quality-by-design (QbD) to the development of analytical methods in addition to the development of manufacturing processes. As such, both industry and regulators recognize the benefits of adopting a QbD approach to drug-product development and manufacture, with key concepts described in the International Conference on Harmonization (ICH) guidelines, Q8 (R1) Pharmaceutical Development, Q9 Quality Risk Management, and Q10 Pharmaceutical Quality System. Drug development using the principles of QbD can be introduced as two key concepts that further aid in implementation. The first concept is the 'design space' that generally involves the identification of the critical attributes for the input materials, the process, and the final product. Another important concept is that of the 'control strategy' which is to ensure the final quality of the product. Some of the concepts are more applicable than others, and some have been advocated by many method development experts for some time, but modern technology has created an opportunity to revisit strategies for creation of chromatographic methods in particular, and it is certainly interesting to investigate the new opportunities in the context of Quality by Design. The ultimate goal is to highlight the QbD concepts and terminology can be applied to analytical methods and to suggest how adoption of a QbD approach might be used to develop more robust analytical methods and effective control systems.

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## Evaluation of skeletal muscle relaxant activity of aqueous of abutilon indicum leaves extract in albino mice in comparison with diazepam

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Evaluation of skeletal muscle relaxant activity of aqueous of abutilon indicum leaves extract in albino mice in comparison with diazepam. Abutilon indicum (Indian Abutilon, Indian mallow) is a small shrub in the Malvaceae family. Pharmacological activities of this plant are analgesic, larvicidal, hepatoprotective, hypoglycemic, antioxidant, antineoplastic, antimalarial, antiulcer and anti-inflammatory properties. Leaves are used as demulcent, aphrodisiac, laxative, diuretic, and sedative. The present study is to evaluate muscle relaxant activity of aqueous extract of Abutilon indicum leaves. Material & Methods: Leaves of Abutilon indicum, Albino mice, SOXHELTS apparatus for bark extraction, Rota rod, Diazepam. Study Design: Five groups of albino mice, each consisting five animals. Control /Group -I - 2ml/kg Normal Saline, Standard/ Group-II -- 10mg/kg Diazepam, Test -I / Group III - 100mg/kg of ALEAI\*, Test-II / Group IV - 200mg/kg of ALEAI\*, Test-III / Group V - 400mg/kg of ALEAI\* (\*A LEAI -Aqueous leaf extracts Abutilon indicum). Muscle relaxant activity will be studied using Rota rod apparatus by standard procedure. Results:-will be discussed at time of presentation. Discussion & conclusion: will be discussed at time of presentation.

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