J Chromatogr Sep Tech 2016, 7:5(Suppl)
http://dx.doi.org/10.4172/2157-7064.C1.017

Setting acceptance criteria for validation of chromatographic methods of drug eluting stents: Minimum requirements for analytical variability

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Chromatographic methods are commonly used for the analysis of drug eluting stents (DESs). Accuracy and reliability of the analytical results are crucial for ensuring quality, safety and efficacy of DESs. Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results. Validation of analytical methods includes the identification of the performance parameters relevant for the given procedure, the definition of appropriate acceptance criteria and the appropriate design of the validation studies. Achieving an appropriate consideration of the analytical variability in assay procedures and setting acceptance criteria for analytical validations is however much more difficult than usually described. Criteria which are too wide may lead to unnecessary and incorrect out-of-specification (OOS) cases, resulting in bad reject decision for products. This study concentrates on analysis, through simulation, of the relation of method variability with specification limits for the total loaded dose of the active substance on the DES. The findings of this study point what levels of precision and accuracy are needed, in other words what is the magnitude of the allowable total error from all possible effects (both systematic and random) in an assay method in order to achieve the level of performance required for the methods applied routinely for the evaluation of the total loaded dose of DES as part of lot release/stability testing.

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Ciprofloxacin residue and their impact on biomolecules in eggs of laying hens following oral administration

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The present study was designed to evaluate ciprofloxacin residue and their impact on some biomolecules (albumin, total protein and cholesterol) in eggs of laying hens after oral administration. For that purpose, One group (A) of laying hens (n = 20) were orally administered 10 mg⁄kg ciprofloxacin for five consecutive days. The second group (n = 10) was untreated controls. Eggs were collected from day one of treatment and up to 25 days after withdrawal of treatment. Egg white and yolk from each egg were separated, and ciprofloxacin residues and biomolecules were analyzed by high-performance liquid chromatography method with fluorescence detection and humalyzer having commercial assay kits respectively. Ciprofloxacin was detectable in egg white on the first day of treatment in higher concentrations (1755 µg⁄kg) while at lower concentrations (362 µg⁄kg) in egg yolk. In both medium, concentrations increased during five days treatment period. After withdrawal of treatment, eight days and fourteen days were required to deplete the drug residue below the established LOD in albumen and yolk respectively. On the other hand, cholesterol level increased while albumin and total protein level decreased during treatment period. All these biomolecules returns to their normal level at about seventeenth or eighteenth day from the day of treatment. In all cases, the differences in drug residue concentrations and biomolecules concentrations during treatment and post treatment in egg were found significant. Based on the time needed for residue to deplete below the LOD, we can estimate that, within twenty days of treatment period, egg contents could contain harmful residue which can deplete the nutritional value of egg and thus could cause severe disease for consumer as well whereas it is safe after that period.

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