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Optimization of the lyophilization cycle by using process analytical technology

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Process Analytical Technology (PAT) is use of sophisticated instruments and scientific techniques at line and on line for continuous monitoring of critical parameters in manufacturing of Lyophilized formulations. Process Analytical Technology (PAT) is a new concept initiated by US FDA for implementing in the manufacturing sector with the help of modern tools so as to assure quality of the lyophilized product and decrease Lyo process cycle times. It is designated to modernize quality control by shifting companies toward continuous product analysis using sophisticated instruments at every stage of the manufacturing process. It will enable the drug companies to improve efficiency and make safer products. It will allow them to gain a better understanding of their own process. It will help to minimize the drug shortages, stability issues and product recalls. The objective of the present paper was to analyze the PAT concept and in relation to the lyophilization process optimization. The other objective was to investigate and propose the reasons why PAT initiatives are useful for companies intended to manufacture parenteral lyophilized formulations at this point of time and the benefits they receive in the recent future on implementation of PAT. PAT itself involves increasing the amount of in-process testing during lyophilization process at various stages (freezing ,primary drying and secondary drying) in order to gain a more fundamental understanding of product and lyophilization process performance. In PAT every unit of a batch are subjected to online testing like drug uniformity of lyophilized product, moisture content in packs just after lyophilization operation. Usually, a discussion on PAT is limited to an increase in the number of results generated within a product lot; however, PAT also includes inter- and intra-batch batch understanding. By using appropriately designed sensors and probes located in - line, on - line, or at - line for monitoring or controlling an individual unit operation, or all operations (Continuous or batch mode). Use of NIR/LIF (on-line or at -line) can provide information on identification and characterization: on/at –line control of adequacy of mixing, assurance of acceptable cake, moisture content and reconstitution. Acoustic and electro acoustic spectroscopy, X-Ray Spectrometry, Electrochemistry, pH, conductivity, potentiometry, dielectric measurements, chronoamperometry, On-line Chromatography GC, LC, positive-displacement-driven, open tubular liquid chromatograph (OTLC), Use of chemometrics. Near Infra Red (NIR) AND Light Induced Fluorescence (LIF) methods for monitoring drug content homogeneity. These techniques were implemented after establishing a correlation between LIF assessment of homogeneity (PAT) and thief-sampling with off-line analysis Modernization of cGMP regulations will provide medicines of highest quality .It is this that facilitated introduction of PAT tools and concepts by companies to improve product quality. It can be concluded that the importance of PAT and growth rate of PAT implementing companies predicts the domination in global pharmaceutical sector by 2020.

Biography

Sreedhar Bandari has completed her M. Pharm from University College of pharmaceutical sciences, Kakatiya University, Warangal. He is doing Ph D in the area of "Pharmaceutical development of parenteral lyophilized dosage form" in centre for pharmaceutical sciences, JNTUH, Hyderabad. He has published 4 papers in reputed journals and also presented 3 papers in various national and international conferences. He is Member of IPA.

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Isolation of heptadecanoic acid and phytol from the plant of *Dregea volubilis* [Linn.] leaves

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The present study was undertaken to isolate phytoconstituents of *Dregea volubilis [Linn.]* Benth. Two compounds were isolated from leaves of alcoholic extract of *Dregea volubilis [Linn.] Benth by* continous hot soxhlet extraction and purification has been done by column chromatography method. The spectral analysis revealed that the isolated compounds are Heptadecanoic acid which is fatty acid and Phytol is diterpenoid moity. Both compounds showed significance anti hyperlipidemic and anti diabetic activities.