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Extractables and leachables: Regulatory perceptive

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Regulatory requirements for extractables and leachables are utmost important step in submission of the products to the regulatory agencies in the category of opthamalics and orally inhaled nasal drug products. There were several criticalities associated in the container closure system assessment in identifying the probable leachables that could impact the quality of the product. Control extractions studies provide an insight based on the technical characteristics and logical conclusions made. PQRI guidance document provided major insights in understanding the analytical evaluation limits, specifications and procedural things conducting control extraction studies and leachable studies. This presentation provides a summary and overview of regulatory requirements for extractables and leachables majorly in Controlled extraction studies, leachable studies for the identification of probable leachables by different instrumental techniques in orally inhaled nasal drug products and opthamalics.

Biography

Kishore Kumar Hotha has more than 12 year's expertise in analytical/Bioanalytical Research. His focus is on method development using Liquid Chromatography (HPLC)/Liquid Chromatography with Mass Spectrometry (LC/MS/MS) for the analysis of drugs in impurity identifications, bioanalysis and for extractables and leachables. He is having broad experience in the area of small and large molecules method development. He completed his PhD from Jawaharlal Technological University. He has published more than 30 papers in reputed journals. He is the editorial board member/scientific reviewer of several international and reputed journals. He is Analytical Expert in Novel Laboratories Inc. which is a is a full-service pharmaceutical company that develops, manufactures, markets and distributes difficult to develop, technology-driven specialty generics for the US and European markets.

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