Acta Scientific Pharmaceutical Sciences (ISSN: 2581-5423)

Volume 3 Issue 7 July 2019

Short Communication

Role of Mass Spectrometry in Packaging Innovation and Solution

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Received: May 17, 2019; **Published:** June 07, 2019

DOI: 10.31080/ASPS.2019.03.0303

Abstract

Mass Spectrometry is playing a significant role to carryout testing of wide range of packaging materials, product compatibility, extractable and leachable etc. Impact of glass vial and syringe manufacturing impact a lot. Inductively coupled plasma/mass spectrometry, scanning electron microscopy, atomic force microscopy, and dynamic secondary ion mass spectroscopy showed significant differences in glass performance. Pre-filled syringes has better performance than vials for most tests and conditions. During manufacturing of vial flaming application is more in bottom surface and neck is more and these two areas become weaker. While come contact with high Ph product silica flex comes out from the glass surface as delamination of glass.

Keywords: Mass Spectrometry; Packaging

Following analysis are possible to carry out by Mass spectrometry

Glass vial, syringe, cartridge

- Delamination
- Extractable and Leachable
- Analysis of polyglycol coating, silicon oil

Rubber stopper, plunger

- Teflon and Flurocoated coating
- Extractable and leachable

Metal needles

- Extractable and Leachable

In order to avoid glass delamination and adsorption of protein siliconization application inside the glass vial and syringe is the best solution, excess silicone can form suspended oil-like droplets. Proteins can form around those droplets and change their natural state. Lubricant coatings, fluoropolymers are few excellent options to avoid contamination and protein adsorption Extractable and leachable are most critical for, injector pens, patches, and transdermal and wearable devices for self-infusion. Extractable and leachable are most important for inhalers and catheters as well.

For an extractables from a device component the AET (µg/g) can be determined as follows:

$$AET = \frac{SCT \cdot D_t}{D_d\, m}$$

D_d - Doses per day

D_t - Total Labelled doses

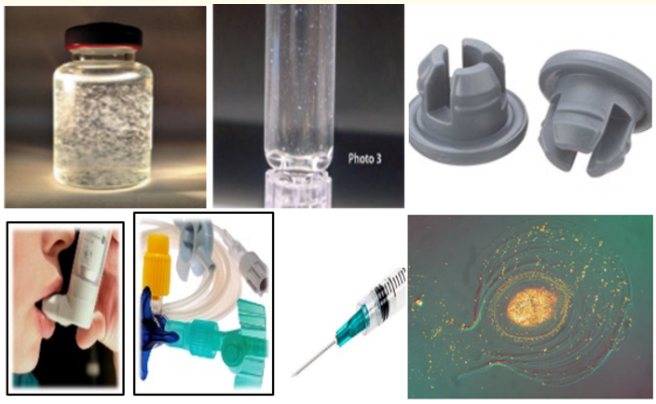
m - mass of component

The AET (µg/device) for a drug delivery device (e.g. an MDI) can be determined from Equation 2:

$$AET = \frac{SCT \cdot D_t}{D_d}$$

D_d - Doses per day

D_t - Total Labelled doses



Figure

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