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SILICONE TUBING EXTRACTABLES AND THEIR CONNECTION TO PARTICULATES

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Extractables and particulates information of single-use components including tubing is one of the primary considerations for their selection for pharmaceutical applications. The information is used to assess risk to patient safety, product compatibility, process performance and demonstrate due diligence to regulatory agencies. Many factors need to be considered in the extractables study design such as solvent choice, testing conditions including time, temperature and agitation, surface area to volume ratio, wall thickness, selection of analytical techniques, detection/quantitation limits, and expression of results. Studies must be performed under similar conditions that reflect those that can be encountered during use.

We have been also evaluating particulates originating from tubing, and have found that sample preparation and testing methods must be closely controlled to obtain reproducible and relevant data. Parameters such as the nature of flow, the storage of effluent and the tubing treatments can dramatically impact results. The situation is complicated by the fact that most of the particles released from polymers are immiscible liquid droplets in the testing solution and therefore they are unstable in terms of shape, size, and availability. Light obscuration and microscopic experiments will be discussed which have helped us evaluate particle size distributions and the proportions of liquid and solid particulates, as well as understand the effects of the conditions used to prepare the effluent before it is analyzed.

We will suggest study designs for silicone tubing and discuss how particulates and extractables are related.

