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xi The establishment of data-based safety thresholds for leachables and extractables in orally inhaled and nasal drug products (OINDPs) is an important scientific advancement that helps OINDP manufacturers make knowledge-based safety and risk assessments for extractables and leachables and ensure the safety of their products for patient use.

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assessment established through a joint effort of scientists from the FDA, academia, and ...

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A safety assessment for extractables or leachables is the process by which the effect of extractables or leachables on user health is established. As the issues associated with a direct assessment the leachables' effect on patient safety are significant, safety effects are typically assessed indirectly.

## ~~Identification, analysis and safety assessment of ...~~

- SCT: Safety Concern Threshold is defined as the threshold below which a leachable would have a dose so low as to present negligible safety concerns from carcinogenic and non-carcinogenic toxic effects. The safety concern threshold (SCT) for extractables and leachables has been defined as 0.15  $\mu\text{g/day}$ .

## ~~Extractables and leachables: An Introduction~~

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