



Disclaimer for non-GMP Testing

Life Sciences Services

- Customer Declines Compendial Method Verification

Statement

The results contained in this document are for informational purposes only. They have been generated using non-verified compendial method(s) as per customer's documented request. These results are not intended to support any GMP activities or decisions.

- Customer Declines Method Validation

Statement

The results contained in this document are for informational purposes only. They have been generated using non-validated method(s) as per customer's documented request. These results are not intended to support any GMP activities or decisions.

- Customer Declines Method Transfer

Statement

The results contained in this document are for informational purposes only. They have been generated using non-transferred method(s) as per customer's documented request. These results are not intended to support any GMP activities or decisions.

- Customer Requests R&D Services

Statement

The results contained in this document are for informational purposes only. They have been generated using R&D process(es) as per customer's documented request. These results are not intended to support any GMP activities or decisions.

- Customer Requests E&L Services

Statement

The results from this R&D Extractable Study were specifically designed to detect unknowns and therefore obtained using a non-validated method. These results are intended to support a detailed Leachable Analysis and cannot be used for the purposes of long-term stability studies or for methods associated with the batch release of marketed drug products.

- Customer Requests application of customer specifications for compendial method

Statement

This result obtained with the compendial method is outside the compendial specification, but within the specification provided by the customer. Because the method has not been validated beyond the compendial specification range, the reported value is not a valid result. Such results are for information only and not to be used for cGMP decision making.

- Customer Requests to test a compendial item to a monograph test while not applying specification

Statement

The customer requested to perform this compendial article to the monograph method, but without the application of any specifications or status. SGS is providing the result as found. The customer assumes full responsibility for the use of the result for any purposes other than internal information only use.