

## Cleaning Validation – Comparative Analysis

(Ref.VAL-020)

		water = baseline) by a factor of 3.
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**4. Method**

Prepare and analyse a series of standards of the active residue to be examined in the range 10%, 50%, 100%, 200% and 400% of calculated Maximum Allowable Carryover(MAC) concentration. Prepare 3 individual samples at each concentration. Analyse on HPLC and TOC. Tabulate results as detailed in results section and plot linear regression and show results of linear regression analysis for both HPLC and TOC analysis.

**5. Results**

**3.1 Linearity of Active Residue**

**3.1.1. HPLC Analysis**

Active Concentration (ug/mL)	Peak Area of Active
(10%)	
(50%)	
(100%)	
(200%)	
(400%)	

Plot Concentration vs. Peak Area (calculate linear regression)

Insert graph.

Correlation coefficient (R<sup>2</sup>) =

Show calculations.

**3.1.2. TOC Analysis**

Actual Carbon (ppm)	Total Organic Concentration	Measured Total Organic Carbon Response (ppm)
(10%)		
(50%)		
(100%)		
(200%)		
(400%)		

Plot Actual TOC Concentration (ppm) vs Measured TOC Response

Insert graph.

Correlation Coefficient (R<sup>2</sup>) =

Show calculations.

**3.2. Accuracy**

For each measured response over the concentration range examined in the Linearity test calculate % **recovery** and % **RSD** for each of the triplicate samples.

where % recovery = 
$$\frac{\text{result found}}{\text{result expected}} \times 100$$

**3.2.1. HPLC Analysis**

Actual Concentration	Active	Measured response 1	Measured response 2	Measured response 3	Average result	Mean % recovery	% RSD
(10%)							