Cleaning Validation – Comparative Analysis

(Ref.VAL-020)

		injections. **3.4.2. TOC:** • The lowest concentration of %active+ residue that can be readily detected by the instrument in four consecutive injections. • The determined LOD must be equal to or greater than that carbon concentration obtained by multiplying the standard deviation of six injections of Type I water (18 megohms-cm water = baseline) by a factor of 3.

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^2) =

Show calculations.

3.1.2. TOC Analysis

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