

Cleaning Validation – Swab Test

(Ref. VAL-020)

MAC per cm ² level	Average Recovery (Budesonide) ppm HPLC	Average recovery (Pulmicort carbon) ppm TOC
(50%)		
(100%)		
(400%)		

- Plot Average Recovery Active 1 ppm HPLC vs Average recovery Active 2 ppm TOC

Linear regression line =

Correlation coefficient (R) =

Coefficient of determination (R²) =

5.2. Visually Clean Limit

The Visually clean Limit must be determined while performing the swab recovery studies. This is done by visually inspecting the surface and determining the highest concentration of active residue that is not easily detectable by visual inspection. This concentration is then recorded as the Visually clean limit.

Visually Clean Limit = _____

5.3. Determining Final HPLC and TOC Swabbing Limits Based on Recovery Studies

HPLC Swabbing Limits

Determine the lowest and most conservative active recovery value obtained during the method validation study for HPLC analysis.

Lowest HPLC swab recovery value = _____

Calculate the final HPLC swabbing limit for the surface tested:

$\frac{\text{Active MAC per cm}^2 \text{ of total surface area} \times \text{swabbing area} \times \text{lowest swab recovery}}{\text{average recovery from swabbing material}}$

average recovery from swabbing material

= "X" mg per swab

divide by extraction volume and multiply by 1000 to give ppm limit per swab

HPLC Swabbing Limit = _____ = _____

mg per swab

HPLC Swabbing Limit (ppm) = _____ = _____

ppm per swab

Example Calculation:

$$\frac{0.000417 \text{ mg/cm}^2 \times 100 \text{ cm}^2 \times 0.6864}{0.9877} = 0.02898 \text{ mg per swab}$$

If each swab is extracted using 25.0 mL of water, the limit becomes:

$$\rightarrow 0.02898 \text{ mg}/25 \text{ mL} \times 1000 \text{ } \mu\text{g/mL} = 1.16 \text{ } \mu\text{g/mL} \text{ or } 1.16 \text{ ppm per swab.}$$

5.4. TOC Swabbing Limits

Determine the lowest and most conservative active recovery value obtained during the method validation study for TOC analysis.

Lowest TOC swab recovery value = _____