1. **ADE substitution**
2. **Rinse Limit ADE Calculation:**

Where:

LR = Rinse Limit of API, in micrograms per milliliter (μg/mL) or ppm

ADE Value = Acceptable daily exposure value of API for current product, mg

1000 = Convert mg to µg

MBS = Minimum batch size of the next product, g

MDD = Maximum daily dose of next product, g

Area Sampled = Total surface area of the equipment train, in2

Surface Area = Total surface area of the equipment train, in2

Rinse Volume = Final grab sample volume, mL

1. **Swab Limit ADE Calculation:**

Where:

Ls = Swab Limit of API, in micrograms per milliliter (μg/mL) or ppm

ADE Value = Acceptable daily exposure value of API for current product, mg

1000 = Convert mg to µg

MBS = Minimum batch size of the next product

MDD = Maximum daily dose of next product

Area Sampled = Total surface area of the equipment train, in2

Swab Area = Swab area of the API for current product

Extraction Volume = Solvent volume for the API swab, mL