FUSION QBD® - GRADIENT STEPS

Variation Flexibilities in Classical DOE
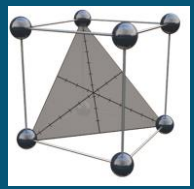
Beyond others, you can now include a **second gradient step** as a <u>pump program variable</u> in a <u>single DOE experiment</u>.

The following two options are available in Fusion QbD 9.9.2:

(1) Varying Slope for both Gradients in a single study by keeping initial and final %Strong Solvent constant.
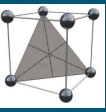
(2) Varying either initial or final % Strong Solvent of a Gradient and varying Slope for both Gradients.

- ! Note, usually we ask our customers not to include any segments in the gradient ramp, as quality of the method might be compromised from that and in a multivariate experiment other optimization parameters than slope can often be used and should then be preferred.*

- But no rule without exceptions. Therefore in the case where it doesn't go without gradient steps, Fusion now provides more flexibility in including study factors from the pump program in your DOE experiment.

*Compare our technical note on segmented gradient.
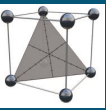
Varying Slope for both Gradients in a single study by keeping initial and final %Strong Solvent constant

(1) The example shows a gradient program, where **Initial Hold**, **Gradient 1** and **Gradient 2** are included as a study factor.

(2) In addition the **Blending of two Strong Solvents** is included in the study.

(3) The light green region stands for the study space. Prediction inside this region will be provided by such an experiment in all study factor combinations of the selected range.

(4) Note: **Intermediate Hold Time** can be included as a study factor.

Varying **initial or final % Strong Solvent for** a Gradient by varying **Gradient Slope**

(1) The example shows a gradient program, where **Initial Hold**, **Gradient 1** and **Gradient 2** are included as a study factor.

(2) In addition the **Variation of the Initial % Strong Solvent** and **Blending of two Strong Solvents** is included in the study.

(3) The light green region stands for the study space. Prediction inside this region will be provided by such an experiment.

(4) Note: You can decide to which Gradient the variation of the %Strong Solvent should be applied.
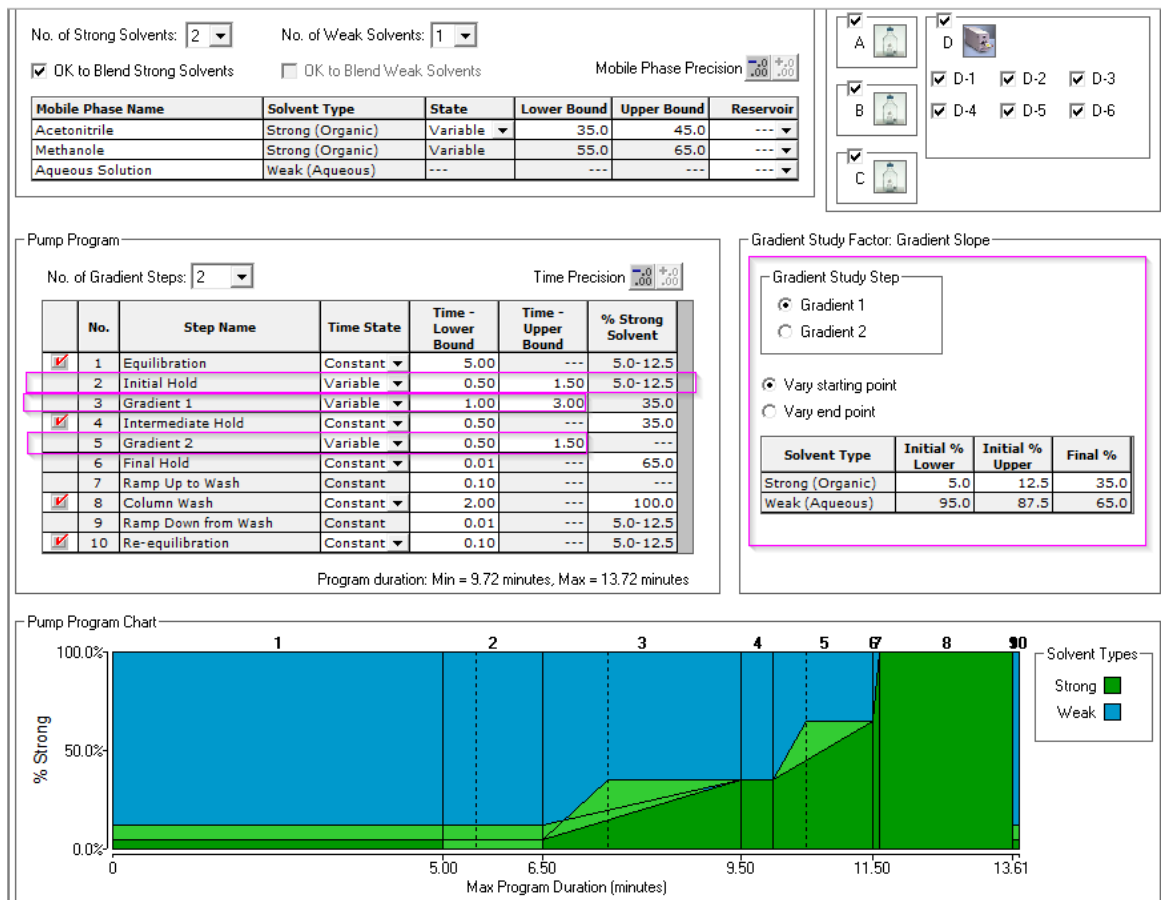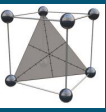
Robustness Simulation with multiple pump program related study factors

(1) As the expected variation for all pump program related study factors finally results from the variation of the **Mobile Phase Composition** a new MPC Variable has been implemented that can serve as a single parameter for Robustness Simulation.

Contact us for more Information

Fusion QbD® software is used worldwide in the pharmaceutical industry for LC method development, validation, and transfer.

To get a full understanding of AQbD/APLM Best Practices with Fusion QbD, please contact us for our **training or consultancy services**.

Cromingo e.K. – All Fusion QbD products and services from a single source in close collaboration with S-Matrix Corporation.

Reach out to us directly for further information **info@cromingo.com**

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