

## Guidance Number: 003

### Appendix 1: In-Process Control Test Types – System Suitability Testing Examples

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IN-PROCESS CONTROL TEST	System Suitability Test Description
Reaction Completion (HPLC/GC)	<b>Area percent methods</b> - Authentic markers for rt and id ref. Duplicate sample injection.
Reaction Completion (TLC)	<b>Quantitative</b> - range of standards of impurity/material of interest. <b>Limit test</b> – single application of standard material at limit.
Solvent Content (HPLC/GC)	<b>Quantitative</b> – blank injection, sensitivity std, agreement of standards (2 or 3 injections, 3 injections for RSD check), do S/N check if appropriate.
Assay (HPLC/GC)	<b>Wt % result</b> – blank injection, agreement of standards (2 or 3 inj., 3 inj. for RSD check), do resolution check, if appropriate <b>Area %</b> - Authentic markers for rt and id ref. (single sample injections)
Impurity Test (HPLC/GC)	<b>% Impurity (<math>\text{imp} \times 100 / (\text{main} + \text{imp})</math>)</b> – blank injection, sensitivity std. <b>Area %</b> - mixed imp marker on end.
Impurity Test (TLC)	Identity standard, Rf check <b>Limit</b> – Std at limit, Rf check, sensitivity std. <b>Quantitative</b> – Range of stds, Rf check, sensitivity std.
Loss on Drying (Quantitative)	<b>Oven</b> – single determination <b>Denver/Computrac</b> – in duplicate, pre- set method, calibrated heating chamber and balance.
Loss on Drying (Limit)	<b>Oven</b> – single determination <b>Denver/Computrac</b> – in duplicate, pre-set method, calibrated heating chamber and balance.
UV Absorbance (Quantitative)	Background correct instrument with blank.
Titration (Quantitative)	<b>Instrumental</b> – Sensor calibration <b>Manual</b> – Duplicate sample only
Refractive Index	Check Standard (e.g. solvent)
Clarity (Nephelometric)	Calibration Standards
KF Titration	Calibrate prior to use (3 x water injections, instrument calculates RSD)
Particle Size Distribution	Control sample (if applicable)
Melting Range	USP standard (if applicable)
TLC Filter Wash	Range of standards only
Vessel Preparation	<b>Moisture content</b> – use calibrated instrument, duplicate sample. <b>GC</b> – blank injection, Agreement of standards, and resolution check