

LAB-085: Laboratory Analytical Determinations

Table 1:

Table 1

Solution	Injections
Blank (Diluent/Media)	1
Quantitation Limit (if applicable)	1
Resolution Solution (if applicable)	1
Working standard	6
Check standard	1
Working standard	2
Samples (up to 12)	1
Working standard	2
Samples (up to 12)	1
Working standard	2

% RSD for response and retention time see table 2, Additional SST requirements according to test method.

% Ratio see to table 3

% RSD see table 2

% RSD see table 2

Table 2:

Table 2

Test	Acceptance Criteria (%RSD)
Assay / CU / Dissolution response	≤ 2.0%
Degradation Analysis response	≤ 10.0%
Assay / CU / Dissolution/ Degradation Analysis retention time	≤ 1.0 %

Table 3:

Table 3

Test	% Difference	Acceptance Criteria (% Ratio)
Assay / CU / Dissolution	≤ 2.0%	98.0 – 102.0
Degradation Analysis	≤ 10.0%	90.0 – 110.0

Table 4:

Table 4:

Solution	Readings	
Working standard	6	%
Check standard	1	
Working standard	2	%
Samples (up to 12)	1	
Working standard	2	%
Samples (up to 12)	1	
Working standard	2	%
Samples (up to 12)	1	

Annotations:

- Line 1: % RSD for absorption see table 5
- Line 2: % Ratio see to table 6
- Line 3: % RSD see table 5
- Line 4: % RSD see table 5

Table 5:

Table 5

Test	Acceptance Criteria (%RSD)
Assay / CU / Dissolution	≤ 2.0%

Table 6:

Table 6

Test	% Difference	Acceptance Criteria (% Ratio)
Assay / CU / Dissolution	≤ 2.0%	98.0 – 102.0