

Checklist for Analytical Method Validation (Chemical)

TEST	ASSAY/RELATED SUBSTANCES		
PARAMETER	No.	DOCUMENTS REQUIRED	AVAILABILITY
Specificity	1	Testing Method	
	2	Acceptance criteria	
	3	Chromatograms/spectrum for following solutions:-	
		a) Standard	
		b) Sample	
		c) Blank/Placebo	
		d) Spike solution	
		e) System suitability tests	
	4	Impurities available	
		a) Peak purity for PDA detector or spike solution for non-PDA detector	
		b) Relative Retention Time (RRT)	
		c) Resolution (R) where applicable	
	5	Impurities not available	
	a) Stress data (minimum data for humidity, heat and light)		
	b) Peak purity		
	c) Relative Retention Time (RRT)		
	d) Resolution (R) where applicable		
Linearity	1	Testing Method	
	2	Acceptance criteria	
	3	Minimum five (5) levels of standard solutions	
	4	Data for linear regression equation, Y-intercept, slope, r^2 and linearity graph	
Range	1	For the assay of drug substances: 80% - 120% of working concentration (WC)	
	2	For the determination of an impurity: from the reporting level of an impurity to 120% of the specification	
Accuracy	1	Testing Method	
	2	Acceptance criteria	
	3	Minimum three (3) levels of concentration in triplicates covering the specified range	
	4	Result : reported as percent recovery by the assay of known added amount of analyte in the sample, OR as the difference between the mean and the accepted true value together with the confidence intervals	
Precision (Repeatability)	1	Testing Method (using sample/product as the test solution)	
	2	Acceptance criteria	
	3	Minimum three (3) levels of concentration in triplicates covering the specified range . OR	

Analytical Checklist For Storyboard Readiness

Liying Dong



Analytical Checklist For Storyboard Readiness:

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