

# VALIDATION OF ANALYTICAL METHOD IN QUALITY CONTROL OF DRUG PRODUCTS ON THE BASIS OF KUSUM PHARM LLC

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Introduction. Analytical method validation – one of the basic requirements of the pharmaceutical industry, because there is still no established conventional system for validation work. The objective of any analytical measurement is to obtain consistent, reliable and accurate data. Validated analytical methods play a major role in achieving this goal. The results from method validation can be used to judge the quality, reliability and consistency of analytical results, which is an integral part of any good analytical practice.

**Aim.** To develop a method validation procedure as per Pharmacopoeia requirement for pharmaceutical laboratory like Quality control laboratory ‘Kusum Pharm’.

Materials and methods. Precaution during the planning of the validation studies: the standard’s method validation data are adequate and sufficient to meet the laboratory’s method requirements; the laboratory must be able to match the performance data as described in the standard method; the validation of a specific method must be demonstrated through laboratory experiments by routinely analyzing samples; ensure that user’s equipment, the people, the reagents and the environment are qualified to perform the analysis; make proper plan or flow chart for evaluation and validation of standard methods.

**Results and discussion.** Analytical method validation parameter as per ICH guideline

Sr. No.	Validation Characteristics	Identification	Testing for Impurities		Assay
			Quantitative Tests	Limit Tes	- Dissolution - Content
1	Accuracy (Recovery)	-	+	-	+
2	Precision (2 parts)				
	Method precision	-	+	-	+
	Intermediate precision	-	+(1)	-	+(1)
3	Specificity (2)	+	+	+	+
4	Detection of Limit	-	-(3)	+	-
5	Quantitation Limit	-	+	-	-
6	Linearity	-	+	-	+
7	Range	-	+	-	+

«-» signifies that this characteristic is not normally evaluated;

«+» signifies that this characteristic is normally evaluated.

System suitability (for assay Montelukast Sodium)

Sr. No	Parameter	Results	Acceptance criteria
1	RSD	0.11	NMT 2.0
2	Resolution between Cis - isomer and Montelukast	1.3	NLT 1.0
3	Signal – to – Noise	51.63	NLT 10

Based on the validation parameters, it is established that method is able to identify the subjected substance within acceptable parameters for RSD, resolution & S/N.

Mostly results depends on the following basis: chemists, chemicals, instruments, laboratory environment.

Chemist – they are most common cause for results' variation. To eliminate their involvement we can perform Ruggedness with different chemist. ICH says it Intermediate precision. Use of two trained chemists and perform same analysis to get comparative results within 2.0 % of actual results.

Chemicals – they are silent culprit of results' variations. To identify their role in the method, we can perform Robustness. We deliberately use different changes chemical grade and their specification, Solution preparation and their physicochemical properties.

Instruments – they are back bone of any analysis. To ensure their working suitability, we follow repeatability of same sample ICH says it Instrument precision approach. We use two instrument with same capacity, religiously calibrated and reliable for the given method. This gives us awareness of method's response on two instruments.

Laboratory environment: another unpredictable critical factor. To remove this error from our method, we use Ruggedness also part of Intermediate precision. We perform method in different laboratory, different days, different analysts and so on so we can confirm method ability in different labs.

**Conclusions.** We developed a required established validation documentation such as SOPs, validation protocols and reports, which are very easy to use and can be propose to QC for easy operation. Developed documents clearly show how validation will be conducted analytical methods, they said critical steps and acceptance criteria.

Proposed life cycle help to choose analytical method validation parameters.

Developed a successful SOP No: SOP/QC/031/00 for "Validation of analytical methods" Which can define common requirements, procedures, planning and execution of analytical methods validation as per requirement.

Developed a organized protocol and self explainery report for validation of analytical methods. A practical approach on validation of analytical methods for the laboratory quality control LLC "Kusum Pharm".