


**ANALYTICAL METHOD VALIDATION SUMMARY REPORT FOR ASSAY
AND CONTENT UNIFORMITY OF RAMITHIAZIDE (RAMIPRIL AND
HYDROCHLOROTHIAZIDE TABLETS BY HPLC METHOD**
ANALYTICAL METHOD VALIDATION SUMMARY

Sr. No.	Parameter	Specification	Results	Acceptance Criteria
1	Specificity	Blank	No interference	No Interference
		Placebo	No interference	No interference
2	Linearity	Correlation coefficient of Ramipril	0.9999	NLT 0.999
		Correlation coefficient of Hydrochlorothiazide	0.9999	
3	System precision	%RSD of Ramipril	0.13%	NMT 2.0%
		%RSD of Hydrochlorothiazide	0.07%	
		Tailing Factor of Ramipril	1.00	NMT 2.0
		Tailing Factor of Hydrochlorothiazide	1.04	
		Theoretical plates of Ramipril	10410	NLT 2000
		Theoretical plates of Hydrochlorothiazide	10705	
4	Precision for Assay	Method precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	0.71%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.52%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	0.13%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.24%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Assay of Ramipril	0.71%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.79%	
		Intermediate precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	0.20%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.29%	
		Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	0.20%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.41%	
		Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Assay of Ramipril	0.10%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.08%	


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4	Precision for Assay	% Cumulative RSD for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	0.71%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.71%	
		% Cumulative RSD Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Assay of Ramipril	1.52%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	1.10%	
		% Cumulative RSD Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Assay of Ramipril	0.98%	NMT 2.0%
		% RSD of Assay of Hydrochlorothiazide	0.77%	
5	Precision for Content uniformity	Method precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		AV Value of Ramipril	1.8%	NMT 15
		AV Value of Hydrochlorothiazide	3.9%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		AV Value of Ramipril	1.6%	NMT 15
		AV Value of Hydrochlorothiazide	3.7%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		AV Value of Ramipril	7.5%	NMT 15
		AV Value of Hydrochlorothiazide	1.6%	
		Intermediate precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		AV Value of Ramipril	4.6%	NMT 15
		AV Value of Hydrochlorothiazide	1.4%	
		Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		AV Value of Ramipril	1.9%	NMT 15
		AV Value of Hydrochlorothiazide	6.0%	
		Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		AV Value of Ramipril	7.9%	NMT 15
		AV Value of Hydrochlorothiazide	7.5%	


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Sr. No.	Parameter	Specification	Results	Acceptance Criteria
5	Precision for Content uniformity	% Difference for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% Difference for Ramipril	0.8%	NMT 3.0%
		% Difference for Hydrochlorothiazide	2.1%	
		% Difference for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% Difference for Ramipril	0.4%	NMT 3.0%
		% Difference for Hydrochlorothiazide	2.9%	
		% Difference for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% Difference for Ramipril	1.1%	NMT 3.0%
		% Difference for Hydrochlorothiazide	1.4%	
6	Accuracy	Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		Accuracy at each Level for Ramipril	98.5% to 101.1%	98.0% to 102.0%
		Accuracy at each Level for Hydrochlorothiazide	101.2% to 101.6%	
		Mean Accuracy for Ramipril	100.1%	
		Mean Accuracy for Hydrochlorothiazide	101.4%	
		Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		Accuracy at each Level for Ramipril	98.5 %to 101.5%	98.0% to 102.0%
		Accuracy at each Level for Hydrochlorothiazide	99.3% to 99.7%	
		Mean Accuracy for Ramipril	100.1%	
		Mean Accuracy for Hydrochlorothiazide	99.5%	
7	Robustness	For Ramipril		
		% Difference for Flow rate 0.9 mL/min	0.0%	NMT 2.0%
		% Difference for Flow rate 1.1 mL/min	0.1%	
		% Difference for Organic content decrease	0.8%	
		% Difference for Organic content increase	0.2%	
		% Difference for Buffer pH 2.3	0.9%	
		% Difference for Buffer pH 2.7	0.8%	


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7	Robustness	For Hydrochlorothiazide		
		% Difference for Flow rate 0.9 mL/min	0.5%	NMT 2.0%
		% Difference for Flow rate 1.1 mL/min	0.3%	
		% Difference for Organic content decrease	0.7%	
		% Difference for Organic content increase	1.2%	
		% Difference for Buffer pH 2.3	1.2%	
		% Difference for Buffer pH 2.7	1.3%	
8	Filter study	For Ramipril		NMT 2.0%
		% Difference for sample filtered through 0.22 μ filter	0.08%	
		% Difference for sample filtered through 0.45 μ filter	0.03%	
		For Hydrochlorothiazide		
		% Difference for sample filtered through 0.22 μ filter	0.02%	
		% Difference for sample filtered through 0.45 μ filter	0.15%	
9	Solution stability	For Ramipril		NMT 2.0%
		Standard solution stability upto 28 hrs	1.79%	
		Sample solution stability upto 22 hrs	1.90%	
		For Hydrochlorothiazide		
		Standard solution stability upto 28 hrs	1.76%	
		Sample solution stability upto 22 hrs	1.75%	