ANALYTICAL METHOD VALIDATION SUMMARY REPORT FOR DISSOLUTION OF RAMITHIAZIDE (RAMIPRIL AND HYDROCHLOROTHOAZIDE 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	1.0000	NLT 0.999
		Correlation coefficient of Hydrochlorothiazide	1.0000	
3	System precision	**For Ramipril 5 mg & Hydrochlorothiazide 12.5 mg**		
		%RSD of Ramipril	0.23%	NMT 2.0%
		%RSD of Hydrochlorothiazide	0.20%	
		For Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		%RSD of Ramipril	0.11%	NMT 2.0%
		%RSD of Hydrochlorothiazide	0.05%	
		For Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		%RSD of Ramipril	0.19%	NMT 2.0%
		%RSD of Hydrochlorothiazide	0.10%	
4	Precision	**Method precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg**		
		% RSD of Release of Ramipril	2.8%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.3%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Release of Ramipril	0.8%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	0.4%	
		Method precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Release of Ramipril	2.8%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.4%	
		Intermediate precision for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Release of Ramipril	2.9%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.5%	

QbD Quality by Design	**ANALYTICAL METHOD VALIDATION SUMMARY REPORT FOR DISSOLUTION OF RAMITHIAZIDE (RAMIPRIL AND HYDROCHLOROTHOAZIDE TABLETS BY HPLC METHOD**

ANALYTICAL METHOD VALIDATION SUMMARY CONT.....

Sr. No.	Parameter	Specification	Results	Acceptance Criteria
4	Precision	**Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 12.5 mg**		
		% RSD of Release of Ramipril	2.0%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.3%	
		Intermediate precision for Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Release of Ramipril	0.9%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.5%	
		% Cumulative RSD for Ramipril 5 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Release of Ramipril	3.5%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	2.4%	
		% Cumulative RSD Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		% RSD of Release of Ramipril	1.8%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	2.4%	
		% Cumulative RSD Ramipril 10 mg & Hydrochlorothiazide 25 mg		
		% RSD of Release of Ramipril	2.0%	NMT 5.0%
		% RSD of Release of Hydrochlorothiazide	1.5%	
		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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ANALYTICAL METHOD VALIDATION SUMMARY CONT…..

Sr. No.	Parameter	Specification	Results	Acceptance Criteria
5	Accuracy	**Ramipril 5 mg & Hydrochlorothiazide 12.5 mg and Ramipril 10 mg & Hydrochlorothiazide 25 mg**		
		Accuracy at each Level for Ramipril	97.8% to 101.0%	95.0% to 105.0%
		Accuracy at each Level for Hydrochlorothiazide	99.9% to 103.7%	
		Mean Accuracy for Ramipril	99.4%	
		Mean Accuracy for Hydrochlorothiazide	101.8%	
		Ramipril 10 mg & Hydrochlorothiazide 12.5 mg		
		Accuracy at each Level for Ramipril	97.3% to 99.0%	98.0% to 102.0%
		Accuracy at each Level for Hydrochlorothiazide	100.0% to 100.8%	
		Mean Accuracy for Ramipril	98.1%	
		Mean Accuracy for Hydrochlorothiazide	100.4%	
6	Robustness	**For Ramipril**		
		% Difference for Flow rate 0.9 mL/min	1.2%	NMT 5.0%
		% Difference for Flow rate 1.1 mL/min	1.4%	
		% Difference for Column temperature at 23°C	0.1%	
		% Difference for Column temperature at 27°C	0.4%	
		% Difference for Buffer pH 2.3	1.0%	
		% Difference for Buffer pH 2.7	0.6%	
		% Difference for Low RPM	0.6%	
		% Difference for High RPM	1.1%	
		% Difference for Low medium volume	1.8%	
		% Difference for High medium volume	2.3%	

QbD Quality by Design	**ANALYTICAL METHOD VALIDATION SUMMARY REPORT FOR DISSOLUTION OF RAMITHIAZIDE (RAMIPRIL AND HYDROCHLOROTHOAZIDE TABLETS BY HPLC METHOD**

ANALYTICAL METHOD VALIDATION SUMMARY CONT…..

Sr. No.	Parameter	Specification	Results	Acceptance Criteria
6	Robustness	**For Hydrochlorothiazide**		
		% Difference for Flow rate 0.9 mL/min	1.0%	NMT 5.0%
		% Difference for Flow rate 1.1 mL/min	1.1%	
		% Difference for Column temperature at 23°C	1.2%	
		% Difference for Column temperature at 27°C	1.0%	
		% Difference for Buffer pH 2.3	0.5%	
		% Difference for Buffer pH 2.7	0.3%	
		% Difference for Low RPM	0.6%	
		% Difference for High RPM	0.7%	
		% Difference for Low medium volume	0.1%	
		% Difference for High medium volume	2.4%	
7	Solution stability	**For Ramipril**		NMT 2.0%
		Standard solution stability upto 25 hrs	0.53%	
		Sample solution stability upto 24 hrs	0.51%	
		For Hydrochlorothiazide		
		Standard solution stability upto 25 hrs	0.36%	
		Sample solution stability upto 24 hrs	0.27%	