ANALYTICAL METHOD VALIDATION REPROT FOR LIVOFLOXACIN TABLETS (FOR ASSAY)

S. No	Analytical parameter	Result	Acceptance criteria
1.0	**Specificity** a) Blank interference: b) Placebo interference:		There shall be no interference in Sample response due to blank and placebo.
2.0	**Precision:** **2.1 System precision: For**		
	Area Replicate	**Area Response**	RSD NMT 2.0 %.
	1		
	2		
	3		
	4		
	5		
	6		
	Average		
	% RSD		
	System Suitability		
	Tailing factor		Not more than 1.8
	% Standard RSD		RSD NMT 2.0 %.
	2.2 Method precision:		
	Results Replicate	**Results (%)**	Six results RSD NMT 2.0 %.
	1		
	2		
	3		
	4		
	5		
	6		
	Average		
	% RSD		
	System Suitability		
	Tailing factor		Not more than 1.8
	% Standard RSD		RSD NMT 2.0 %.
	2.3 Intermediate precision: For		

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S. No	Analytical parameter		Result	Acceptance criteria
	Results Replicate		**Results (%)**	Six results RSD NMT 2.0 %.
	1			
	2			
	3			
	4			
	5			
	6			
	Average			
	% RSD			
	System Suitability			
	Tailing factor			Not more than 1.8
	% Standard RSD			RSD NMT 2.0 %.
	Analyst 1-			
	Batch No.	**Components**	**Assay %**	Result RSD NMT 2.0 %.
	Analyst 2-			
	Batch No.	**Components**	**Assay %**	
	Result % RSD			
3.0	**Linearity**			
	Level		**Area Response**	RSD NMT 2.0 %.
	80 %			
	90 %			
	100 %			
	110 %			
	120%			
	Average			
	% RSD			
	System Suitability			
	Tailing factor			Not more than 1.8
	% Standard RSD			RSD NMT 2.0 %.

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S. No	Analytical parameter	Result	Acceptance criteria
	Coefficient of determination (r2) .		(r2) NMT- 0.999
4.0	**Range**		
	Lower Level - For 80 % level		
	Area Replicate	**Area Response**	
	1		
	2		
	3		
	4		
	5		
	6		
	Average		
	Tailing factor		Not more than 1.8
	% Standard RSD		RSD NMT 2.0 %.
	Lower Level - For 120 % level		
	Area Replicate	**Area Response**	
	1		
	2		
	3		
	4		
	5		
	6		
	Average		
	Tailing factor		
	% Standard RSD		
	Acceptance Criteria		
	% RSD of upper concentration		RSD NMT 2.0 %.
	% RSD of lower concentration		RSD NMT 2.0 %.
	Correlation Coefficient		(r2) should be greater than 0.99
5.0	**Accuracy and Recovery**		

S. No	Sample	Recovery	Spike	Average	

ANALYTICAL METHOD VALIDATION REPROT FOR LIVOFLOXACIN TABLETS (FOR ASSAY)

S. No	Analytical parameter		Result			Acceptance criteria
			in mg	**in mg**	**results in %**	Each individual sample recovery should lie within the range of 98% to 102%.
	1.	80 % sample				
	2.	100 % sample				
	3.	120 % sample				
	System Stability					
	Tailing factor					Not more than 1.8
	% Standard RSD					RSD NMT 2.0 %.
6.0	**Robustness:**					
6.1	**Test**		**Parameters**	**Result**		
	For Wavelength of UV-Visible Detector:		At 358 nm			
			At 362 nm			
			System Stability			
			Tailing factor			Not more than 1.8
			% Standard RSD			RSD NMT 2.0 %.
6.2	**For Flow rate:**		At 0.72 ml / min			
			At 0.88 ml / min			
			System Stability			
			Tailing factor			Not more than 1.8
			% Standard RSD			RSD NMT 2.0 %.
6.3	**For Column temperature:**		At 44.5°C			
			At 45.5°C			
			System Stability			
			Tailing factor			Not more than 1.8
			% Standard RSD			RSD NMT 2.0 %.
7.0	**Solution stability:**					

ANALYTICAL METHOD VALIDATION REPROT FOR LIVOFLOXACIN TABLETS (FOR ASSAY)

S. No	Analytical parameter		Result			Acceptance criteria
	Parameters	Results (%)	Tailing factor (NMT-1.8)	% Standard RSD (NMT-2.0 %)	Fresh and verification standard difference (NMT-2.0 %)	Recovery value (NMT-2.0 %) from the initial result
	Initial					
	4 hours.					
	8 hours.					
	12 hours.					
	24 hours.					

Conclusion:

Prepared by

Date:

Checked by

Date: