METHOD VERIFICATION REPORT FOR (ASSAY) AZITHROMYCIN CAPSULE USP 500 mg BY HIGH PREFORMANCE LIQIUD CHROMATOGRAPHY

AMV AR. No.	
Protocol No.	
Report No.	
Batch No.	
Effective Date	

ANALYTICAL METHOD VALIDATION REPORT FOR AZITHROMYCIN USP 500 CAPSULE (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 2
	% 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 2
	% 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 2
	% 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 2
	% Standard RSD			RSD NMT 2.0 %.

ANALYTICAL METHOD VALIDATION REPORT FOR AZITHROMYCIN USP 500 CAPSULE (ASSAY)

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 2
	% 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**		

ANALYTICAL METHOD VALIDATION REPORT FOR AZITHROMYCIN USP 500 CAPSULE (ASSAY)

S.No.	Analytical parameter		Result			Acceptance criteria
	S. No	**Sample**	**Recovery in mg**	**Spike in mg**	**Average 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 Suitability					
	Tailing factor					Not more than 2
	% Standard RSD					RSD NMT 2.0 %.
6.0	**Robustness:**					
6.1	**Test**		**Parameters**	**Result**		
	For Wavelength of UV-Visible Detector:		At 208 nm			
			At 212 nm			
			System Suitability			
			Tailing factor			Not more than 2
			% Standard RSD			RSD NMT 2.0 %.
6.2	**For Flow rate:**		At 1.8 ml / min			
			At 2.2 ml / min			
			System Suitability			
			Tailing factor			Not more than 2
			% Standard RSD			RSD NMT 2.0 %.
6.3	**For Column temperature:**		At 50.5°C			
			At 49.5°C			
			System Suitability			
			Tailing factor			Not more than 2
			% Standard RSD			RSD NMT 2.0 %.
7.0	**Solution stability:**					

ANALYTICAL METHOD VALIDATION REPORT FOR AZITHROMYCIN USP 500 CAPSULE (ASSAY)

S.No.	Analytical parameter		Result			Acceptance criteria
	Parameters	Results (%)	Tailing factor (NMT-2)	% 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: