



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**ANALYTICAL METHOD VALIDATION/VERIFICATION REPORT FOR OMEPRAZOLE CAPSULES  
BP 20 BP (ASSAY)**

**METHOD VERIFICATION  
REPORT FOR (ASSAY)  
OMEPRAZOLE CAPSULES BP 20 mg  
BY  
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY**

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



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



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S.No.	Analytical parameter	Result	Acceptance criteria	
	2		Six results RSD NMT 2.0 %.	
	3			
	4			
	5			
	6			
	Average			
	% RSD			
	<b>System Suitability</b>			
	Tailing factor			Not more than 1.8
	% Standard RSD			RSD NMT 2.0 %.
	<b>Analyst 1-</b>			
	<b>Batch No.</b>	<b>Components</b>	<b>Assay %</b>	
	<b>Analyst 2-</b>			
	<b>Batch No.</b>	<b>Components</b>	<b>Assay %</b>	
	Result % RSD			
<b>3.0</b>	<b>Linearity</b>			
	<b>Level</b>	<b>Area Response</b>	RSD NMT 2.0 %.	
	80 %			
	90 %			
	100 %			
	110 %			
	120%			
	Average			
	% RSD			
	<b>System Suitability</b>			
	Tailing factor		Not more than 1.8	
	% Standard RSD		RSD NMT 2.0 %.	
	Coefficient of determination (r <sup>2</sup> )		(r <sup>2</sup> ) NMT- 0.999	
<b>4.0</b>	<b>Range</b>			
	<b>Lower Level - For 80 % level</b>			
	<b>Area Replicate</b>	<b>Area Response</b>		



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S.No.	Analytical parameter	Result	Acceptance criteria			
	1					
	2					
	3					
	4					
	5					
	6					
	Average					
	Tailing factor		Not more than 1.8			
	% Standard RSD		RSD NMT 2.0 %.			
<b>Lower Level - For 120 % level</b>						
	<b>Area Replicate</b>	<b>Area Response</b>				
	1					
	2					
	3					
	4					
	5					
	6					
	Average					
	Tailing factor					
	% Standard RSD					
<b>Acceptance Criteria</b>						
	% RSD of upper concentration		RSD NMT 2.0 %.			
	% RSD of lower concentration		RSD NMT 2.0 %.			
	Correlation Coefficient		(r <sup>2</sup> ) should be greater than 0.99			
<b>5.0</b>	<b>Accuracy and Recovery</b>					
	<b>S.No.</b>	<b>Sample</b>	<b>Recovery in mg</b>	<b>Spike in mg</b>	<b>Average results in %</b>	
	1.	50 % sample				Each individual sample recovery should lie within the range of 98% to 102%.
	2.	100 % sample				



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S.No.	Analytical parameter	Result			Acceptance criteria	
	3.	150 % sample				
	<b>System Stability</b>					
	Tailing factor				Not more than 1.8	
	% Standard RSD				RSD NMT 2.0 %.	
<b>6.0</b>	<b>Robustness:</b>					
6.1	<b>Test</b>		<b>Parameters</b>	<b>Result</b>		
	<b>For Wavelength of UV-Visible Detector:</b>		At 358 nm			
			At 362 nm			
			<b>System Stability</b>			
			Tailing factor			Not more than 1.8
	% Standard RSD			RSD NMT 2.0 %.		
6.2	<b>For Flow rate:</b>		At 0.78 ml / min			
			At 0.82 ml / min			
			<b>System Stability</b>			
		Tailing factor			Not more than 1.8	
		% Standard RSD			RSD NMT 2.0 %.	
6.3	<b>For Column temperature:</b>		At 44.5°C			
			At 45.5°C			
			<b>System Stability</b>			
		Tailing factor			Not more than 1.8	
		% Standard RSD			RSD NMT 2.0 %.	
<b>7.0</b>	<b>Solution stability:</b>					
	<b>Parameters</b>	<b>Results (%)</b>	<b>Tailing factor (NLT-1.8)</b>	<b>% Standard RSD (NMT-2.0 %)</b>	<b>Fresh and verification standard difference (NMT-2.0 %)</b>	<b>Recovery value (NMT-2.0 %) from the initial result</b>
	Initial					
	4 hours.					
	8 hours.					
	12 hours.					
	24 hours.					



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**Conclusion:**

**Prepared by**

**Date:**

**Checked by**

**Date:**