



## CERTIFICATE OF ANALYSIS

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<b>Name of the Material:</b> Pyrimethamine Ph. Eur. (Micronized)			
<b>Mfg. License No.</b>	G/1315	<b>CAS No.</b>	58-14-0
<b>Batch No.</b>	PMD-2C-202006	<b>Batch Size</b>	171.00 Kg
<b>Mfg. Date</b>	October-2020	<b>Retest Date</b>	September-2024
<b>Received Date</b>	22/10/2020	<b>Release Date</b>	28/10/2020
<b>A. R. No.</b>	PMD-20/14		
<b>Storage Conditions</b>	Do not store above 30°C. Protect from light.		

## RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
01	Description	White crystalline powder	White or almost white, crystalline powder or colourless crystals
02	Solubility	Complies	Practically insoluble in water, slightly soluble in ethanol (96 per cent)
03	Identification:		
	Test A: Melting Point	241.1°C	239°C to 243°C
	Test B: Ultra-violet absorbance	Complies	The solution shows an absorption maximum at 272 nm and an absorption minimum at 261 nm. The specific absorbance at the maximum is 310 to 330.
	Test C: Infrared absorption spectrophotometry	Complies	The infrared absorption spectrum of sample is concordant with the reference spectrum of Pyrimethamine RS/WS.
	Test D: Thin Layer Chromatography	Complies	The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution.
04	Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution BY <sub>6</sub> .

<b>Prepared by</b>  (Jr. Executive - Q.C.) Ms. Krishna Patel	<b>Checked by</b>  (Sr. Executive - Q.C.) Mr. Mrugesh Naik	<b>Approved by</b>  (Sr. Manager - Q.C.) Mr. Machindra Mungase
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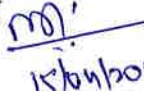

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## RESULTS OF ANALYSIS

Sr. No.	Test	Observation	Specification
05	Acidity or alkalinity	Complies	It requires not more than 0.2 ml of 0.01 M sodium hydroxide to change the colour of indicator to pink.
		Complies	It requires not more than 0.4 ml of 0.01 M hydrochloric acid to change the colour of solution to red or orange.
06	Related Substance (By HPLC):		
	Unspecified Impurities	0.05%	For each impurity, Not more than 0.10 %
	Total Impurities	0.05%	Not more than 0.3%
07	Sulfates	Less than 80 ppm	Not more than 80 ppm
08	Loss on drying	0.24% w/w	Not more than 0.5%
09	Sulfated Ash	0.03% w/w	Not more than 0.1%
10	Assay (By Potentiometrically)	100.1%	Not less than 99.0% and not more than 101.0%, Calculated with reference to the dried substance.

**Remark:** The material **Complies** as per Ph. Eur. specification.

Prepared by  (Jr.Executive - Q.C.) Ms.Krishna Patel	Checked by  (Sr.Executive - Q.C.) Mr.Mrugesh Naik	Approved by  (Sr.Manager - Q.C.) Mr.Machindra Mungase
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