

Sun Pharmaceutical Industries Ltd.
 Plot No. Z-15, Dahej SEZ Industrial Area,
 Tal. Vagra, Dahej - 392 130, Dist. Bharuch, Gujarat, INDIA.
 Phone : (02641) 280000-5 Fax : (91-02641) 280125
 www.sunpharma.com
 CIN : L24230GJ1993PLC019050



Certificate of Analysis

Product	:	Mesalazine Ph. Eur.	Page 1 of 3		
Item Code	:	BD0270P0DB			
Mfg. Date	:	Sep/2018	Batch No.	:	MSNNJ18016
AR. No.	:	DFR0318			
Exp. Date	:	Aug/2023	Batch Size	:	530.0 kgs
Release Date	:	25.09.18			

Sr.	Test	Observation/Results	Specification
1	Characteristics		
1.1	Appearance	Almost white Powder	Almost white or light Grey or light pink powder or crystals.
1.2	Solubility	Very slightly soluble in water Practically insoluble in Ethanol (96%). It dissolves in dilute solutions of alkali hydroxides and in dilute hydrochloric acid.	Very slightly soluble in water Practically insoluble in Ethanol (96%). It dissolves in dilute solutions of alkali hydroxides and in dilute hydrochloric acid.
2	Identification		
2.1	Identification- A	The maximum absorption is at 231.8 nm and specific absorbance at the maximum is between 447.56	UV absorption : The maximum absorption should be at about 230 nm and specific absorbance at the maximum is between 430 and 450.
2.2	Identification- B	Infrared absorption spectrum in KBr dispersion of sample is concordant with the spectrum of Mesalamine working standard.	Infrared absorption : Infrared absorption spectrum in KBr dispersion of sample should be concordant with the spectrum of Mesalamine working standard.
2.3	Identification- C	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Thin Layer Chromatography : The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.
3	Appearance of solution		
3.1	Appearance of solution	Solution is clear	Solution should be clear
3.2	Absorbance at 440 nm	0.136 Au	Not more than 0.15 Au.
3.3	Absorbance at 650 nm	0.033 Au	Not more than 0.10 Au.
4	Reducing Substances	The colour of solution is blue.	The colour of solution should be blue or violet brown.
5	Related Substances (By HPLC)		
	Known Impurities		
	Impurity E + Impurity D	0.007 %	Not more than 0.05%
	Impurity F	BQL (<0.03%)	Not more than 0.1%
	Impurity G	0.01 %	Not more than 0.05%
	Impurity H	BQL (<0.03%)	Not more than 0.1%

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	Impurity J	BQL (<0.03%)	Not more than 0.1%
	Impurity L	BDL	Not more than 0.05%
	Impurity M	BDL	Not more than 0.05%
	Impurity O	BQL (<0.03%)	Not more than 0.1%
	Impurity P	BQL (<0.03%)	Not more than 0.1%
	Impurity R	BDL	Not more than 0.05%
	UnKnown Impurities		
	Unspecified impurities	0.018 %	Not more than 0.05 %
	Total impurities (known + Unknown)	0.058 %	Not more than 0.5%
6	Content - by HPLC		
	Impurity A	Not Detected	Not more than 200ppm
	Impurity C	Not Detected	Not more than 200ppm
7*	Aniline (Impurity K) (By HPLC)		
	Known Impurities		
	Impurity K(Aniline)	Test Not Performed	Impurity K(Aniline) : Not more than 10 ppm
8	Chloride	0.03 % w/w	Not more than 0.1 % w/w.
9	Sulphates	Less than 200 ppm.	Not more than 200 ppm.
10	Heavy metals - Sample weight :1.0g	Less than 10 ppm.	Not more than 10 ppm.
11	Loss on drying	0.25 % w/w	Not more than 0.5 % w/w.
12	Sulphated Ash	0.04 % w/w	Not more than 0.2 % w/w.
13	Assay by titrimetric	100.9 % w/w	Between 98.5 w/w % and 101.5 % w/w. (On dried basis)
14	Residual Solvents (By GC)		
	Methanol	Not Detected	Not more than 500ppm
	Methyl acetate	Not Detected	Not more than 500ppm
15	Assay by HPLC	On dried basis : 100.5 % On as is basis : 100.2 %	Between 98.5 % and 101.0 % (On dried basis)
	Additional Test		
16	pH	3.98	Between 3.5 and 4.5
17	Hydrogen sulfide and sulfur dioxide	Lead acetate test paper does not become discoloured.	Lead acetate test paper should not become discoloured.
18	Total microbial Count	Less than 10 CFU/gm.	Not more than 1000 CFU/gm.
19	Total Combined Molds and Yeasts Count	Less than 10 CFU/gm.	Not more than 100 CFU/gm.

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Sr.	Test	Observation/Results	Specification
20	Escherichia coli	Absent	Should be absent.
21	Salmonella	Absent	Should be absent.
22	Pseudomonas aeruginosa	Absent	Should be absent.
23	Staphylococcus aureus	Absent	Should be absent.
24	Bile tolerant gram negative bacteria	Absent	Should be absent.
25	Bulk Density		
25.1	Bulk Density	0.22 gm/ml	Between 0.2 gm/ml and 0.35 gm/ml
25.2	Tapped Density	0.47 gm/ml	Between 0.35 gm/ml and 0.60 gm/ml
26	Particle Size	10% Particle : 4.22 μ	Between 2 to 6 micron.
		50% Particle : 12.0 μ	Between 8 to 20 micron.
		90% Particle : 32.7 μ	Between 25 to 50 micron.
		100% Particle : 85.9 μ	Not more than 90 micron.

***Note:** No potential for impurity K as it is not being used in manufacturing process.

BQL = Below Quantification Limit

BDL = Below Detection Level

Remarks : The Product Complies as per Ph.Eur. Specification.

Prepared By	Checked By	Approved By
 25.09.18 (Jignesh Desai) Sr. Officer-QA	 25.09.18 (Rakesh Bhatt) Sr.Executive-QA	 25.09.18 (Nilesh Prajapati) Managar-QA

Measurement Details

Sample Name Average of 'Mesalamine Ph.Eur.'

Operator navnath.jejurkar
Name

Batch No. MSNNJ18016

A.R.No. DFR0318A

Measurement Details

Measurement Date Time 19/09/18 11:18:28

Analysis Date Time 19/09/18 11:18:28

Result Source Averaged

Accessory Name Hydro MV

Analysis

Particle Name Mesalamine Ph.Eur

Dispersant Name Liquid Paraffin Light

Particle Absorption Index 0.010

Weighted Residual 0.71 %

Analysis Model General Purpose

Analysis

Particle Refractive Index 1.580

Dispersant Refractive Index 1.400

Laser Obscuration 12.97 %

Stirrer Speed Achieved 2000 rpm

Analysis Sensitivity Normal

Results

Concentration 0.0141 %

Uniformity 0.730

Specific Surface Area 678.4 m²/kg

D [3,2] 8.84 µm

D [4,3] 15.8 µm

Dv (35) 8.84 µm

Results

Span 2.370

Result Units Volume

Dv (10) 4.22 µm

Dv (50) 12.0 µm

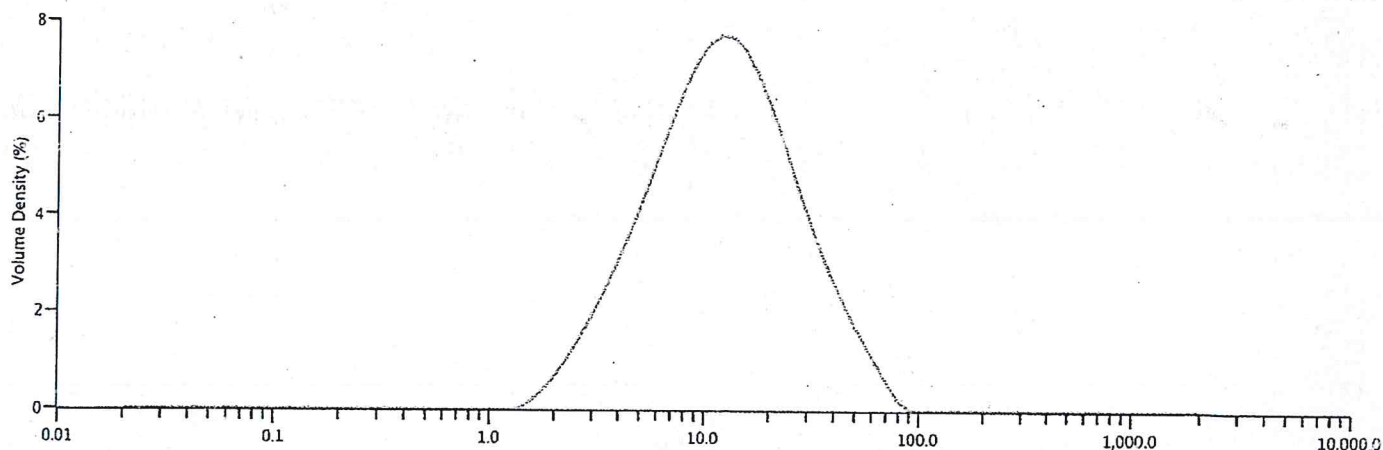
Dv (90) 32.7 µm

Dv (95) 42.6 µm

Dv (98) 54.6 µm

Dv (100) 85.9 µm

Frequency (compatible)



Size Classes (µm)
[105] Average of 'Mesalamine Ph.Eur.' - 19/09/18
11:18:28

Result

Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under	Size (µm)	% Volume Under
0.0100	0.00	0.0771	0.00	0.594	0.00	4.58	11.83	35.3	91.74	272	100.00	2100	100.00
0.0114	0.00	0.0876	0.00	0.675	0.00	5.21	15.18	40.1	94.11	310	100.00	2390	100.00
0.0129	0.00	0.0995	0.00	0.767	0.00	5.92	19.09	45.6	96.03	352	100.00	2710	100.00
0.0147	0.00	0.113	0.00	0.872	0.00	6.72	23.56	51.8	97.54	400	100.00	3080	100.00
0.0167	0.00	0.128	0.00	0.991	0.00	7.64	28.59	58.9	98.68	454	100.00	3500	100.00
0.0189	0.00	0.144	0.00	1.13	0.00	8.68	34.14	66.9	99.46	516	100.00		
0.0215	0.00	0.166	0.00	1.28	0.00	9.86	40.13	76.0	99.69	586	100.00		
0.0244	0.00	0.188	0.00	1.45	0.00	11.2	46.43	86.4	100.00	666	100.00		
0.0273	0.00	0.214	0.00	1.65	0.15	12.7	52.87	98.1	100.00	756	100.00		
0.0315	0.00	0.243	0.00	1.88	0.47	14.5	59.29	111	100.00	859	100.00		
0.0358	0.00	0.276	0.00	2.13	1.04	16.4	65.48	127	100.00	976	100.00		
0.0407	0.00	0.314	0.00	2.42	1.89	18.7	71.29	144	100.00	1110	100.00		
0.0463	0.00	0.357	0.00	2.75	3.09	21.2	76.60	163	100.00	1260	100.00		
0.0526	0.00	0.405	0.00	3.12	4.64	24.1	81.31	186	100.00	1430	100.00		
0.0597	0.00	0.460	0.00	3.55	6.60	27.4	85.39	211	100.00	1630	100.00		
0.0679	0.00	0.523	0.00	4.03	8.98	31.1	88.85	240	100.00	1850	100.00		

Malvern

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Mesalamine Ph.Eu

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