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

SUN PHARMA

Certificate of Analysis

Product	:	Mesalazine Ph. Eur.						
Item Code	:	BD0270P0DB						
Mfg. Date	:	Sep/2018	Batch No.	:	MSNNJ18013	AR. No.	:	DFR0315
Exp. Date	:	Aug/2023	Batch Size	:	502.27 KGS	Release Date	:	18.09.18

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 231.9 nm and specific absorbance at the maximum is 447.40	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	0.032 Au	Not more than 0.15 Au.
3.3	Absorbance at 650 nm	0.003 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	0.005 %	Not more than 0.05%
	Impurity F	BQL (<0.03%)	Not more than 0.1%
	Impurity G	0.003 %	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	0.019 %	Not more than 0.05 %
	Total impurities (known + Unknown	0.055 %	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	0.02 % 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	0.26 % w/w	Not more than 0.5 % w/w.
12	Sulphated Ash	0.09 % w/w	Not more than 0.2 % w/w.
13	Assay by titrimetric	100.4 % w/w	Between 98.5 w/w % and 101.5 % w/w. (On dried basis)
14	Residual Solvents (By GC)		
	Methanol	16 ppm	Not more than 500ppm
	Methyl acetate	BQL (<10.195ppm)	Not more than 500ppm
15	Assay by HPLC	On dried basis : 100.4 % On as is basis : 100.1 %	Between 98.5 % and 101.0 % (On dried basis)
	Additional Test		
16	pH	4.05	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	40 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	0.21 gm/ml	Between 0.2 gm/ml and 0.35 gm/ml
25.2	Tapped Density	0.45 gm/ml	Between 0.35 gm/ml and 0.60 gm/ml
26	Particle Size	10% Particle : 4.62 µ	Between 2 to 6 micron.
		50% Particle : 13.0 µ	Between 8 to 20 micron.
		90% Particle : 29.4 µ	Between 25 to 50 micron.
		100%Praticle : 51.7 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
JDD 19.09.18	RBh 19.09.18	19.09.18
(Jignesh Desai) **Sr. Officer-QA**	**(Rakesh Bhatt)** **Sr.Executive-QA**	**(Nilesh Prajapati)** **Manager-QA**