Sun Pharmaceutical Industries Ltd.
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Ahmednagar - 414 111, Maharashtra, INDIA.
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CIN : L24230GJ1993PLC019050

SUN PHARMA

CERTIFICATE OF ANALYSIS

Order No. : 0730025468			
Product	**MESALAZINE Ph. Eur.**	**A.R.No.**	QFP/17/1790
Batch No.	ASANF17041	**Mfg date**	November 2017
Release date	23.11.17	**Exp. Date**	October 2022

Specification No. : BD0270P0DA **Rev. No. : 7.0**

Sr.	Test	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		
2.2	B) Infrared absorption :	Infrared absorption spectrum in KBr dispersion of sample is concordant with the spectrum of Mesalamine working standard.	Infrared absorption spectrum in KBr dispersion of sample should be concordant with the spectrum of Mesalamine working standard.
3	Appearance of solution		
3.1	Appearance of solution	Solution is clear	Solution should be clear
3.2	Absorbance at 440 nm	0.03 Au	Not more than 0.15 Au.
3.3	Absorbance at 650 nm	0.01 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	Not more than 0.1%
	Impurity G	BDL	Not more than 0.05%
	Impurity H	BQL	Not more than 0.1%
	Impurity J	BQL	Not more than 0.1%
	Impurity L	BDL	Not more than 0.05%
	Impurity M	BDL	Not more than 0.05%
	Impurity O	BQL	Not more than 0.1%
	Impurity P	BQL	Not more than 0.1%
	Impurity R	BDL	Not more than 0.05%
	UnKnown Impurities		
	Unspecified impurities	BDL	Not more than 0.05 %
	Total impurities (known + Unknown	0.007 %	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

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Sr.	Test	Results	Specification
7	Aniline (Impurity K) (By HPLC) *	No potential	Not more than 10 ppm
8	Chloride	0.0 % w/w	Not more than 0.1 % w/w.
9	Sulphates	Less than 200 ppm.	Not more than 200 ppm.
10	Heavy metals	Less than 10 ppm.	Not more than 10 ppm.
11	Loss on drying	0.23 % w/w	Not more than 0.5 % w/w.
12	Sulphated Ash	0.07 % w/w	Not more than 0.2 % w/w.
13	Assay by titrimetric	99.1 % w/w	Between 98.5 w/w % and 101.5 % w/w. (On dried basis)
14	Residual Solvents (By GC)		
	Methanol	BQL	Not more than 100 ppm
15	Bulk Density		
15.1	Bulk Density	0.28 gm/ml	Between 0.2 gm/ml and 0.35 gm/ml
15.2	Tapped Density	0.58 gm/ml	Between 0.35 gm/ml and 0.60 gm/ml
16	Sulphanilic acid * (By HPLC)	No potential	Not more than 0.10 %
17	Hydrogen sulfide and sulfur dioxide	Complies	Lead acetate test paper should not become discoloured.
18.	pH	3.77	Between 3.50 and 4.50
19.	Particle size (By Malvern)	10 % = 5 micron 50 % = 14 micron 90 % = 31 micron	10 % between 2 to 6 micron 50 % between 8 to 20 micron 90 % between 25 to 50 micron
20	Total aerobic microbial count	Less than 10 CFU/gm	Not more than 1000 CFU/gm
21	Total combined yeast & Mould count	Less than 10 CFU/gm	Not more than 100 CFU/gm
22	Escherichia coli	Not detected	Should be absent
23	Salmonella species	Not detected	Should be absent
24	Pseudomonas aeruginosa	Not detected	Should be absent
25	Staphylococcus aureus	Not detected	Should be absent

*** = No potential for this impurity as it is not being used in the manufacturing process.**

Conclusion: Product complies with the quality standards as per **Ph. Eur., In-house & Customer's** specification.

Date of issue: 25.11.17

Prepared by 25-11-17 Checked by 25.11.17 Approved by 25.11.17

S.B. Musmade – Officer QA S. J. Kawade – Executive QA K.D. Gaikwad – Manager QA

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