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. | | | | | | Page 1 of 3 |
| Item Code | : | BD0270P0DB | | | | | | |
| Mfg. Date | : | Sep/2018 | Batch No. | : | MSNNJ18017 | AR. No. | : | DFR0320 |
| Exp. Date | : | Aug/2023 | Batch Size | : | 559.1 KGS | Release Date | : | 26.09.18 |

| 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 232.0 nm and specific absorbance at the maximum is 444.52 | 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 | 0.075 Au | Not more than 0.15 Au. |
| 3.3 | Absorbance at 650 nm | 0.021 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** | | |

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|---|---|---|---|
| | Impurity E + Impurity D | 0.005 % | Not more than 0.05% |
| | Impurity F | BQL (<0.03%) | Not more than 0.1% |
| | Impurity G | 0.007 % | Not more than 0.05% |
| | Impurity H | BQL (<0.03%) | Not more than 0.1% |
| | 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 | 0.009 % | 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 | 0.19 % 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 | 101 % w/w | Between 98.5 w/w % and 101.5 % w/w. (On dried basis) |
| 14 | Residual Solvents (By GC) | | |
| | Methanol | BQL (<10.138ppm) | Not more than 500ppm |
| | Methyl acetate | Not Detected | Not more than 500ppm |
| 15 | Assay by HPLC | On dried basis : 100.4 %<br>On as is basis : 100.2 % | Between 98.5 % and 101.0 % (On dried basis) |
| | Additional Test | | |
| 16 | pH | 4.01 | Between 3.5 and 4.5 |

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|---|---|---|---|
| 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. |
| 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 | 0.43 gm/ml | Between 0.35 gm/ml and 0.60 gm/ml |
| 26 | Particle Size | 10% Particle : 4.29 µ | Between 2 to 6 micron. |
| | | 50% Particle : 11.6 µ | Between 8 to 20 micron. |
| | | 90% Particle : 31.8 µ | Between 25 to 50 micron. |
| | | 100%Praticle : 66.8 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 |
|---|---|---|
| 26.09.18 | 26.09.18 | 26.09.18 |
| **(Jignesh Desai)** | **(Rakesh Bhatt)** | **(Nilesh Prajapati)** |
| **Sr. Officer-QA** | **Sr.Executive-QA** | **Managar-QA** |