
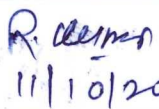



CERTIFICATE OF ANALYSIS

Product Name	Mesalamine - IP
Mfg By	Paragon Organics
Batch No.	PRG/MS/2308003
Date of Mfg.	Aug - 2023
Date of Expiry	Jul - 2028
Batch Qty.	226.10 Kg

Sr. No.	TEST	SPECIFICATIONS	RESULT
1.	Description	Almost white or light grey of light pink powder or crystals.	Light gray powder
2.	Identification test by Infrared absorption Spectrophotometry	Compare the spectrum with that obtained with Mesalamine reference standard or with the reference spectrum of Mesalamine.	Concordant
3.	Light absorption	The absorbance is not more than 0.15 at 440 nm and 0.10 at 650 nm	Complies
4.	Reducing substance	The solution should blue or violet-brown.	Complies
5.	Heavy metals	Not more than 20 ppm	Less than 20 ppm
6.	Chlorides	Not more than 0.1 %	0.009 % w/w
7.	Sulphates	Not more than 200 ppm.	Less than 200 ppm
8.	Sulphated Ash	Not more than 0.2 %	0.008 % w/w
9.	Loss on drying	Not more than 0.5 %	0.27 % w/w
10.	Impurities A And C by HPLC		
	a) Impurity - A	Not more than 0.02 %	ND
	b) Impurity - C	Not more than 0.02 %	ND

Remark :- In the opinion of undersigned the material of the standard Quality as per IP


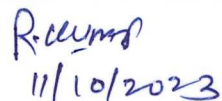

Prepared By	Checked By	Approved By
 11/10/2023	 11/10/2023	 11/10/2023

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Batch No.	PRG/MS/2308003
Date of Mfg.	Aug - 2023
Date of Expiry	Jul - 2028
Batch Qty.	226.10 Kg

	Related substance by HPLC		
11.	a) Impurity - B	Not more than 0.2 %	0.08 %
	b) Impurity - D	Not more than 0.1 %	0.03 %
	c) Impurity - H	Not more than 0.1 %	ND
	d) Impurity - G	Not more than 0.3 %	0.09 %
	e) Any other impurity	Not more than 0.1 %	0.06 %
	f) Total impurities	Not more than 1.0 %	0.58 %
12.	Impurity K by HPLC	Not more than 0.001 %	ND
13.	Assay by potentiometric titration (on dried basis)	Not less than 98.5 % and not more than 101.5 % w/w	100.8 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per IP

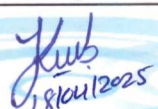
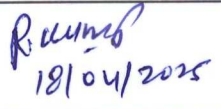

Prepared By	Checked By	Approved By
 11/10/2023	 11/10/2023	 11/10/2023

CERTIFICATE OF ANALYSIS

Product Name	Mesalamine - USP
Mfg By	Paragon Organics
Batch No.	PRG/MS/2503025
Date of Mfg.	Mar-2025
Date of Expiry	Feb-2030
Batch Qty.	252.70 Kg

Sr. No.	TEST	SPECIFICATIONS	RESULT
1.	Description	Almost white or light grey or light pink powder or crystals.	Light gray powder
2.	Identification test by a) Infrared spectroscopy b) Assay by HPLC	IR spectrum of the test sample should be concordant with that of reference standard spectrum. The retention time of the peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	Concordant Complies
3.	pH	Between 3.5 to 4.5	4.11
4.	Clarity of solution	The sample solution is clear.	Complies
5.	Chloride	No more chloride than corresponds to 0.7 mL of 0.02 N hydrochloric acid (0.1%)	Complies
6.	Sulfate	No more sulfate than corresponds to 1.0 mL of 0.02 N sulfuric acid (0.2%).	Complies
7.	Residue on Ignition	Not more than 0.20 % w/w	0.008 % w/w
8.	Hydrogen Sulfide and Sulfur Dioxide	The test paper so obtained does not become discoloured.	Complies
9.	Loss on Drying	Not more than 0.50 % w/w	0.23 % w/w
10.	Related substance by HPLC a) 3-Aminosalicylic Acid b) Any other impurity c) Total impurities	Not more than 0.20 % Not more than 0.20 % Not more than 1.0 %	0.002 % 0.128 % 0.221 %
11.	Assay by HPLC (Dried Basis)	Between 98.5 % to 101.5 % w/w	99.67 % w/w
12.	Content of Aniline, 2-Aminophenol and 4-Aminophenol by GC a) Aniline b) 2-Aminophenol c) 4-Aminophenol	Not more than 0.0005 % Not more than 0.02 % Not more than 0.02 %	ND ND ND

Remark :- In the opinion of undersigned the material of the standard Quality as per USP


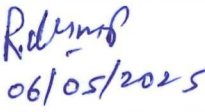
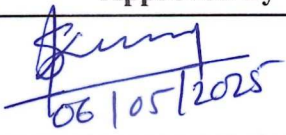
Prepared By	Checked By	Approved By
		

CERTIFICATE OF ANALYSIS

Product Name	Mesalamine - BP/EP
Mfg By	Paragon Organics
Batch No.	PRG/MS/2504031
Date of Mfg.	Apr-2025
Date of Expiry	Mar-2030
Batch Qty.	252.60 Kg

Sr. No.	TEST	SPECIFICATIONS	RESULT
1.	Description	Almost white or light grey of light pink powder or crystals.	Light gray powder
2.	Solubility	Very slightly soluble in water, practically insoluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides and in dilute hydrochloric acid.	Complies
3.	Identification test by		
	a) UV-VIS Spectrophotometry	When examined in the range 210 nm to 250 nm, the solution shows an absorption maximum at about 230 nm. the specific absorbance at maximum is 430 to 450.	Complies
	b) Infrared absorption Spectrophotometry	Compare the spectrum with that obtained with Mesalazine reference standard or with the reference spectrum of Mesalazine.	Concordant
	c) Thin layer chromatography	The Principle spot in the chromatogram obtained with the test solution is similar in position, colour and size to the chromatogram obtained with the reference solution.	Complies
4.	Appearance of solution	The absorbance is not more than 0.15 at 440 nm and 0.10 at 650 nm.	Complies
5.	Reducing substance	The solution should be blue or violet-brown.	Complies
6.	Chloride	Not more than 0.10 % w/w	0.013 % w/w
7.	Sulfates	Not more than 200 ppm	Complies

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

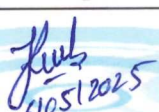
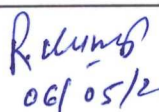
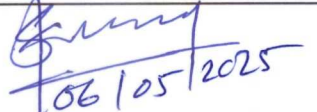
Prepared By	Checked By	Approved By
 06/05/2025	 06/05/2025	 06/05/2025

CERTIFICATE OF ANALYSIS

Product Name	Mesalamine - BP/EP
Mfg By	Paragon Organics
Batch No.	PRG/MS/2504031
Date of Mfg.	Apr-2025
Date of Expiry	Mar-2030
Batch Qty.	252.60 Kg

Sr. No.	TEST	SPECIFICATIONS	RESULT
8.	Sulphated Ash	Not more than 0.20 % w/w	0.010 % w/w
9.	Loss on drying	Not more than 0.50 % w/w	0.24 % w/w
10.	Impurities A and C by HPLC		
	a) Impurity-A	Not more than 0.02 % (200 ppm)	ND
	b) Impurity-C	Not more than 0.02 % (200 ppm)	ND
11.	Impurity-K by HPLC	Not more than 0.001 % (10 ppm)	ND
12.	Related substance by HPLC		
	a) Impurity-E	Not more than 0.05 %	0.019 %
	b) Impurity-F	Not more than 0.10 %	ND
	c) Impurity-G	Not more than 0.05 %	ND
	d) Impurity-H	Not more than 0.30 %	0.002 %
	e) Impurity-J	Not more than 0.10 %	ND
	f) Impurity-L	Not more than 0.05 %	ND
	g) Impurity-M	Not more than 0.05 %	0.014 %
	h) Impurity-O	Not more than 0.10 %	0.032 %
	i) Impurity-P	Not more than 0.10 %	ND
	j) Impurity-R	Not more than 0.05 %	ND
	k) Any other impurity	Not more than 0.05 %	0.014 %
	l) Total impurities	Not more than 0.50 %	0.127 %
13.	Assay by potentiometric titration (dried basis)	Between 98.5 % to 101.5 % w/w	99.6 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

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 06/05/2025	 06/05/2025	 06/05/2025