



Atul

Atul Ltd ✓

Pharmaceuticals and Intermediates Business

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CERTIFICATE OF ANALYSIS

PRODUCT : DAPSONE EP ✓

BATCH NO : 12/015 ✓

DESPATCH QTY. : 25.00 kg ✓

MFG. DATE : Aug. 2022 ✓

EXP. DATE : Jul. 2027 ✓

Sr. No.	Test	Result	Requirement	Result
1.0	PHARMACOPOEIAL TESTS			
1.1	Appearance	--	White or slightly yellowish-white, crystalline powder.	White crystalline powder
1.2	Solubility	--	Practically insoluble in water; freely soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in dilute mineral acids.	Complies
1.3	Identification			
1.3.1	Melting point	°C	Between 175 and 181	179
1.3.2	Ultraviolet and visible absorption spectrophotometry		Absorption maxima: 260 nm and 295 nm Specific absorbance at the absorption maxima:	
		A	260nm : 700 to 760	738
		A	295nm : 1150 to 1250	1201
1.3.3	Thin-layer chromatography	--	The principle spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principle spot in the chromatogram obtained with the reference solution.	complies
1.4	Loss on Drying	%	Maximum 0.30	0.03
1.5	Sulfated ash	%	Maximum 0.1	0.03
1.6	Assay on dried basis (by Titration)	%	99.0 to 101.0	99.9
1.7	Related substances (by HPLC)			
1.7.1	4-(4-aminobenzene-1-sulfonyl)phenol or Impurity-A	%	Maximum 0.30	0.17
1.7.2	4-(benzenesulfonyl)aniline or Impurity-B	%	Maximum 0.40	0.28
1.7.3	4,4'-[oxybis(4,1-phenylene)sulfonyl]dianiline or Impurity-C	%	Maximum 0.30	0.13
1.7.4	2,4-Diamino DPS	%	Maximum 0.10	BDL
1.7.5	4-Amino, 4-Chloro DPS	%	Maximum 0.10	BDL
1.7.6	4-Chloro DPS	%	Maximum 0.10	BDL
1.7.7	Unspecified Impurities	%	Maximum 0.10	BDL
1.7.8	Total Impurities	%	Maximum 1.0	0.58
2.0	INHOUSE TESTS			
2.1	Assay by HPLC on dried basis	%	98.0 to 102.0	99.8
2.2	Residual solvent			
2.2.1	Methanol	ppm	Maximum 2000	BDL
2.2.2	Monochlorobenzene	ppm	Maximum 360	BDL
2.2.3	Benzene	ppm	Maximum 2	BDL

Remarks : The above product **COMPLIES** as per Specification No. SP/FP/DAP-EP(GEN)/01, Revision No. 17
CAS No. 80-08-0

Prepared by :

02-02-23

Checked by :

02-02-23

Approved by :

02-02-23

Registered office: Atul House, G I Patel Marg, Ahmedabad 380 014, Gujarat, India

CIN: L99999G1975PLC002659



Atul Group.

05 JUL. 2023

METAPHARMACEUTICAL

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