

**Atul****Atul Ltd**

Pharmaceuticals and Intermediates Business

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CERTIFICATE OF ANALYSISPRODUCT : **DAPSONE EP/BP**BATCH NO. : **21/013**BATCH QTY : **533.50kg**MFG. DATE : **Oct.2021**EXP. DATE : **Sep.2026**

Sr. No.	Test	Result unit	Requirement	Result
1.0	<u>PHARMACOPOEIAL TESTS</u>			
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°C	177
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	758
		A	295nm : 1150 to 1250	1240
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%	0.09
1.5	Sulfated ash	%	Maximum 0.1%	0.03
1.6	Assay on dried basis (by Titration)	%	99.0 to 101.0 %	99.7
1.7	Related substances (by HPLC)			
1.7.1	4-(4-aminobenzene-1-sulfonyl)phenol or Impurity-A	% W/W	Maximum 0.30%	0.15
1.7.2	4-(benzenesulfonyl)aniline or Impurity-B	% W/W	Maximum 0.40%	0.26
1.7.3	4,4-[oxybis(4,1-phenylene)sulfonyl]dianiline or Impurity-C	% W/W	Maximum 0.30%	0.17
1.7.4	2,4 Diamino DPS	% W/W	Maximum 0.10%	BDL
1.7.5	4 Amino 4 Chloro DPS	% W/W	Maximum 0.10%	BDL
1.7.6	4 Chloro DPS	% W/W	Maximum 0.10%	BDL
1.7.7	Unspecified Impurities	% W/W	Maximum 0.10%	BDL
1.7.8	Total Impurities	% W/W	Maximum 1.0%	0.58
2.0	<u>INHOUSE TESTS</u>			
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 2000ppm	BDL
2.2.2	Monochlorobenzene	ppm	Maximum 360ppm	BDL
2.2.3	Benzene	ppm	Maximum 2ppm	BDL

Remarks : The above product **COMPLIES** as per specification : SP/FP/DAP-EP (GEN)/01Prepared by : 000001
04.12.21Checked by : Reh
04.12.21

Approved by :

04.12.21

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

CIN: L99999GJ1975PLC002859



Lalbhai Group