

**Atul****Atul Ltd**

Pharmaceuticals and Intermediates Business

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CERTIFICATE OF ANALYSIS

PRODUCT : DAPSONE EP/BP

BATCH NO. : 20/007

DISPATCH QTY. : 25.00 Kg

MFG. DATE : Sept.2020

EXP. DATE : Aug.2025

Sr. No.	Test	Result unit	Requirement	Result
1.0	<u>Pharmacopoeial Tests</u>			
1.1	Description	--	A white or slightly yellowish-white crystalline powder	White crystalline powder
1.2	Solubility	--	Insoluble in water, freely soluble in acetone, sparingly soluble in alcohol and freely dissolves in dilute mineral acids.	Passes
1.3	Identification test			
1.3.1	Melting point	°C	175 - 181	178
1.3.2	Light absorption			
	- at 260 nm	A	700 - 760	735
	- at 295 nm	A	1150 - 1250	1200
1.3.3	TLC	--	Similar to reference standard	Passes
1.4	Related substances by TLC	--	Any spot obtained with test solution(a), apart from the principal spot, is not more intense than the reference solution(b) (1.0%) and not more than two such spots are more intense than reference solution (C) (0.2%)	No spot is more intense than reference solution(b) and No spot is more intense than reference solution(c)
1.5	Loss on Drying	%	Max. 0.30	0.09
1.6	Sulphated ash	%	Max. 0.10	0.03
1.7	Assay (by titration on dried basis)	%	99.0 - 101.0	99.7
2.0	<u>Additional Tests</u>			
2.1	Assay (HPLC) on dry basis	%	98.0 - 102.0	99.8
2.2	Related substances by HPLC			
2.2.1	4 Amino 4' Hydroxy DPS	% W/W	NMT 0.40	0.19
2.2.2	2,4' Diamino DPS	% W/W	NMT 0.10	BDL
2.2.3	4 Amino DPS	% W/W	NMT 0.40	0.26
2.2.4	4 Amino 4 Chloro DPS	% W/W	NMT 0.10	BDL
2.2.5	O-Dimer of Dapsone	% W/W	NMT 0.30	0.23
2.2.6	4 Chloro DPS	% W/W	NMT 0.10	BDL
2.2.7	Individual Unidentified Impurities	% W/W	NMT 0.10	0.03
2.2.8	Total Impurities	% W/W	NMT 1.5	0.74
2.3	Residual Solvent			
2.3.1	Methanol	ppm	NMT 2000	BDL
2.3.2	Mono Chloro Benzene	ppm	NMT 360	BDL
2.3.3	Benzene	ppm	NMT 2	BDL
2.4	Heavy Metals	ppm	Maximum 10	< 10

Remarks : The above product **PASSES** as per specification : SP/FP/DAP-EP (GEN)/01Prepared by : OWW
16.12.20Checked by : OR
16.12.20Approved by : NK
16.12.20

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

CIN: L99999GJ1975PLC002859



Lalbhai Group