

Lot: 0110419



Atul

Atul Ltd

Pharmaceuticals and Intermediates Business

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CERTIFICATE OF ANALYSIS

Product : **DAPSONE EP/BP**
Batch No. : **17/019**
Dispatch Qty : **25.00 kg**

MFG. DATE : Nov.-2017
EXP. DATE : Oct.-2022

Sr. No.	Test	Result	Requirement	Result
1.0	Pharmacopoeial Tests			
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	177
1.3.2	Light absorption			
	- at 260 nm	A	700 - 760	758
	- at 295 nm	A	1150 - 1250	1245
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	0.10
1.6	Sulphated ash	%	Max. 0.10	0.04
1.7	Assay (by titration on dried basis)	%	99.0 - 101.0	99.5
2.0	Additional Tests			
2.1	Assay (HPLC) on dry basis	%	98.0 - 102.0	99.4
2.2	Related substances by HPLC			
2.2.1	4 Amino 4' Hydroxy DPS	% W/W	NMT 0.40	0.18
2.2.2	2,4' Diamino DPS	% W/W	NMT 0.10	BDL
2.2.3	4 Amino DPS	% W/W	NMT 0.40	0.27
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	0.21
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	0.73
2.3	Residual Solvent			
2.3.1	Methanol	ppm	NMT 2000	17
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)/01

Analyst : FM
Date : 31-01-18

NA
Head, QA 31.01.18

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