

Atul
ATUL LTD

PP site
Pharmaceuticals & Intermediates Division

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CERTIFICATE OF ANALYSIS

Product : DAPSONE BP/BP
Batch No. : 14/001
Despatch Qty : 50.00 kg

MFG. DATE : 25-01-14
EXP. DATE : Dec.-2018

Sr. Test No.	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 280 nm	A	700 - 780	747
- at 295 nm	A	1150 - 1250	1217
1.3.3 TLC	-	Similar to reference standard	Passes
1.4 Related substances by TLC	-	To comply with the test mentioned in EP/BP	Passes
1.5 Loss on Drying	%	Max. 0.30	0.08
1.6 Sulphated ash	%	Max. 0.10	0.03
1.7 Assay (by Hraction)	%	99.0 - 101.0	99.8
2.0 <u>Additional Tests</u>			
2.1 Assay by HPLC	%WW	NLT 98.0 - NMT 102.0	99.5
2.2 Related substances by HPLC			
2.2.1 4 Amino 4' Hydroxy DPS	%WW	NMT 0.4	0.2
2.2.2 2,4' Diamino DPS	%WW	NMT 0.1	ND
2.2.3 4 Amino DPS	%WW	NMT 0.4	0.3
2.2.4 4 Amino 4 Chloro DPS	%WW	NMT 0.1	ND
2.2.5 O-Dimer of Dapsone	%WW	NMT 0.3	0.2
2.2.6 4 Chloro DPS	%WW	NMT 0.1	ND
2.2.7 Individual Unidentified Impurities	%WW	NMT 0.10	0.04
2.2.8 Total Impurities	%WW	NMT 1.5	0.6
2.3 Residual Solvent (Methanol)	ppm	Max. 2000	ND
2.4 Particle size			
2.4.1 Less than 50µ	%	For Information only	14
2.4.2 Less than 150µ	%	For Information only	89
2.4.3 Less than 250µ	%	For Information only	96
2.5 Heavy Metals	ppm	Maximum 10	< 10

Remarks : The above product **PASSES** as per specification : SP/FP/DAP-EP (GEN)/01

Analyst : Ref
Date : 21-03-14

N.A.
Head, QA 24-03-14



LALBHAI GROUP

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