

LOT AGFARMA 151373

PHARMACEUTICAL AND INTERMEDIATES



touching lives

ATUL LTD

Atul 396020, Gujarat, India
Telephone: (+91 2632) 230000 | 230101 Telefax: (+91 2632) 233639
Email: atul_pi@atul.co.in Website: www.atul.co.in
Corporate Identity Number: L99999GJ1975PLC002859

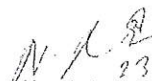
CERTIFICATE OF ANALYSIS

Product : DAPSONE EP/BP P.O.No. :
Batch No : 15/015 MFG. DATE : Jun.-2015
Batch Quantity : 5.00 kg EXP. DATE : May.-2020

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	179
1.3.2	Light absorption			
	- at 260 nm	A	700 - 760	731
	- at 295 nm	A	1150 - 1250	1190
1.3.3	TLC	--	Similar to reference standard	Passes
1.4	Related substances byTLC	--	To comply with the test mentioned in EP/BP	Passes
1.5	Loss on Drying	%	Max. 0.30	0.10
1.6	Sulphated ash	%	Max. 0.10	0.05
1.7	Assay (by titration on dried basis)	%	99.0 - 101.0	99.6
2.0	<u>Additional Tests</u>			
2.1	Residual Solvent			
2.1.1	Methanol	ppm	NMT 2000	BDL
2.1.2	Mono Chloro Benzene	ppm	NMT 360	BDL
2.1.3	Benzene	ppm	NMT 2	BDL

Remarks The above product **PASSES** as per specification of EUROPEAN PHARMACOPOEIA 8.0

Analyst: 
Date : 23-07-15


Head, QA



Lalbhai Group

Registered office: Atul House, G I Patel Marg, Ahmedabad 380014, Gujarat, India
Telephone: (+91 79) 26461294 | 26463706 Telefax: (+91 79) 26404111