

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

18A 03/003

Director Técnico



Atul Ltd

Pharmaceuticals and Intermediates Business

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Atul

CERTIFICATE OF ANALYSIS

Product : **DAPSONE EP/BP**

Batch No. : **17/015**

Dispatch Qty : **25.00 kg**

MFG. DATE : **Jul-2017**

EXP. DATE : **Jun.-2022**

Sr. Test No.	Result unit	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	750
- at 295 nm	A	1150 - 1250	1226
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	0.03
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	0.19
2.2.2 2,4' Diamino DPS	% W/W	NMT 0.10	BDL
2.2.3 4 Amino DPS	% W/W	NMT 0.40	0.27
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	0.19
2.2.6 4 Chloro DPS	% W/W	NMT 0.10	BDL
2.2.7 Individual Unidentified Impurities	% W/W	NMT 0.10	0.04
2.2.8 Total Impurities	% W/W	NMT 1.5	0.69
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)/01

Analyst : FM

Date : 22-11-17

Head, QA

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