

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

14024-303

Director Técnico

Atul

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PP site

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CERTIFICATE OF ANALYSIS

Product : **DAPSONE EP/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 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	178
1.3.2 Light absorption			
- at 260 nm	A	700 - 760	747
- at 295 nm	A	1150 - 1250	1217
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	0.08
1.6 Sulphated ash	%	Max. 0.10	0.03
1.7 Assay (by titration)	%	99.0 - 101.0	99.8
2.0 Additional Tests			
2.1 Assay by HPLC	%W/W	NLT 98.0 - NMT 102.0	99.5
2.2 Related substances by HPLC			
2.2.1 4 Amino 4' Hydroxy DPS	% W/W	NMT 0.4	0.2
2.2.2 2,4' Diamino DPS	% W/W	NMT 0.1	ND
2.2.3 4 Amino DPS	% W/W	NMT 0.4	0.3
2.2.4 4 Amino 4 Chloro DPS	% W/W	NMT 0.1	ND
2.2.5 O-Dimer of Dapsone	% W/W	NMT 0.3	0.2
2.2.6 4 Chloro DPS	% W/W	NMT 0.1	ND
2.2.7 Individual Unidentified Impurities	% W/W	NMT 0.10	0.04
2.2.8 Total Impurities	% W/W	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	59
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 : CEH

Date : 21-03-14

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



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