

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

44120004

Director Técnico

16/214

Atul
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PP site

Pharmaceuticals & Intermediates Division

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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	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 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 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 : cepi
Date : 21-03-14

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



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