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

14 H05 A B07

Director Técnico S

CERTIFICATE OF ANALYSIS

Batch-number	: 444785 (S1562)	Container	: PE-bags in fiber drum
Product	: SULFACETAMIDE SODIUM CRYSTALS	CAS Nr.	: 6209-17-2
Manuf.date	: September 25, 2013	Re-test date	: September 24, 2018

Description	Specification	Analysis result
Identification	White, crystalline powder, odorless	complies
Solubility	Infrared spectrum: pos., identity tests: pos.	complies
Solution in water	Pass tests	complies
Melting point sulfacetamide	Clear and colorless, NMT st.GY4	complies
Water by KF	181 - 184 °C	183 °C
Sulfanilamide	6.0 - 7.8 %	7.2 %
Bi-Acetylsulfanilamide	max. 0.2 %	0.12 %
Dapsone	max. 0.10 %	0.02 %
N4-Acetylsulfanilamide	max. 0.10 %	<0.02 %
Each other impurity (highest value)	max. 0.10 %	<0.03 %
Total organic impurities	max. 0.5 %	0.02 %
pH 5 % in water	max. 0.5 %	0.17 %
Chloride	8.0 - 9.5	9.0
Sulphate	max. 100 ppm	< 100 ppm
Heavy metals	max. 200 ppm	< 200 ppm
Selenium	max. 10 ppm	< 10 ppm
Assay, titration dry substance	max. 10 ppm	< 10 ppm
Foreign particles	99.0 - 100.5 %	99.8 %
	max. 10 ppm	complies

Residual solvents: In the production process no solvents are used as mentioned in the USP and EP class 1

We have tested the material and confirm that the product we shipped meets the requirements of the current valid edition USP/Ph.Eur

Release date : October 03, 2013

Katwijk Chemie bv
 M.J. Oudshoorn
 Quality Unit

