



Duke Chem

Lote: 0110616

Product: Diacerein EP Batch N°: 442504110
Manufacturing date: February 2016 Control N°: 8706
Re-test date: February 2018 Specification: EPA504400

Test	Limits	Results
Appearance	Yellow crystalline powder	Yellow crystalline powder
Identification		
Infrared	Analog to standard	Analog to standard
Impurity B and H (aloe-emodin and triacetyl aloe-emodin) (HPLC)	$\leq 15\text{ppm}$	$< 15\text{ppm}$
Related Substances (HPLC)		
	Imp C (rhein) $\leq 0.2\%$	$< 0,05\%$
	Imp D (monoacetyl rhein Isomer A) $\leq 0.5\%$	0,09%
	Imp E (monoacetyl rhein Isomer B) $\leq 0.5\%$	0,27%
	Imp F (heptaacetyl aloin) $\leq 0.15\%$	Not detected
	Individual impurity $\leq 0.10\%$	$< 0,05\%$
	Total Impurities $\leq 2.0\%$	0,42%
Chromium (AAS)	$\leq 10\text{ppm}$	$< 10\text{ ppm}$
Loss on Drying (105°C)	$\leq 0.5\%$	0,09%
Sulphated Ash	$\leq 0.1\%$	0,04%
Assay (HPLC)	98.0 – 102.0% (dried subs.)	99,8%
Residual Solvents (HS-GC)		
	N-methylpyrrolidone $\leq 500\text{ppm}$	Not detected
	Methanol $\leq 3000\text{ppm}$	Not detected
	Ethanol $\leq 5000\text{ppm}$	$< 5000\text{ppm}$
	Acetone $\leq 5000\text{ppm}$	$< 5000\text{ppm}$
	Toluene $\leq 890\text{ppm}$	$< 890\text{ppm}$

Date: 14 March 2016

E. Casanovas
Quality Control

Pol. Industrial Sant Pere Molanta
Avgda. Mare de Déu de Montserrat, 93 - 99
Tel.: 34-938 180 186 - Fax: 34-938 180 311
Olèrdola - 08799 (Barcelona) Spain
e-mail: dukechem@dukechem.com



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