FAGRON

Certificate of Analysis

Productname: Ranitidini hydrochloridum

Number of analysis/Inspection Code: 1 / KEUR-97013B

Batchnumber: 13D10-B89-283010

Reference code / No.: 2804 / RH(1) 007 10 11

Analysed according to: PH.EUR 7.7

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Chloride
Appearance of solution	Clear / <=BY5	Conform		1%m/V
pH	4,5 - 6,0	5,8		1%m/V
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,05	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	<0,05	%	
Impurity F	<=0,2	<0,05	%	
Impurity G	<=0,2	<0,05	%	
Impurity H	<=0,2	<0,05	%	
Impurity I	<=0,2	<0,05	%	
Impurity J	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than A	<=0,5	<0,05	%	
Heavy metals	<=20	Conform	ppm	
Loss on drying	<=0,75	0,0	%	60 °C; vacuum
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Ranitidine hydrochloride	98,5 - 101,0	99,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Synergy Health.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

24-06-13

Expiration: 04-2014

Conclusion: APPROVED

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