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Certificate of analysis

Name: PENTOXIFYLLINE
BATCH: A12343L
D. OF ANALYSIS: 26-06-2012

CODE: 6178039
MANUFACTURING DATE: 03-2012
RETEST DATE: 03-2017

Quality control results:

Test	Specifications	Unit	Results
DESCRIPTION:			
Characters	Practically white crystalline powder with slight charac odor.		Complies
IDENTIFICATION:			
Melting point	104 - 106	°C	104 - 106
IR spectrum	Conforms to standard		Complies
OTHER TESTS:			
Clarity of solution	Clear		Complies
Color of solution	<= Y7		Complies
Acidity (0.4 g)	<= 0.2 mL NaOH 0.01 N		Complies
Loss on drying	<= 0.2	%	0.1
IMPURITIES:			
Chloride	<= 50	ppm	Complies
Sulphate	<= 100	ppm	Complies
Heavy metals	<= 10	ppm	Complies
Residue on ignition	<= 0.1	%	<0.1
RELATED SUBSTANCES (HPLC):			
Teobromina	<= 0.10	%	<0.10
Theophylline	<= 0.10	%	<0.10
Caffeine	<= 0.10	%	<0.10
Impurity J	<= 0.10	%	<0.10
Any other impurity (HPLC)	<= 0.10	%	<0.10
Sum of impurities (HPLC)	<= 0.50	%	<0.50
RESIDUAL SOLVENTS:			
Isopropyl alcohol	<= 500	ppm	< 500
Methylene Chloride	<= 500	ppm	< 500
Dimethylacetamide	<= 500	ppm	< 500
ASSAY:			
Potentiometric assay	99.0 - 101.0	% (dried subst)	100
PHYSICAL TESTS:			
Tapped density	0.400 - 0.550	g/mL	0.522

THIS PRODUCT MEETS SPECIFICATIONS Ph. Eur.

Status: APPROVED
Release date: 26/06/2012 09:52
Released by: Marc Roure

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