

Certificate of analysis

Name: PENTOXIFYLLINE

CODE: 6178039

BATCH: A11236L

MANUFACTURING DATE: 04-2011

D. OF ANALYSIS: 03-05-2011

RETEST DATE: 03-2015

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 - 105
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	<50
Sulphate	<= 100	ppm	<100
Heavy metals	<= 10	ppm	<10
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.)	100.5
PHYSICAL TESTS:			
Tapped density	0.400 - 0.550	g/mL	0.448

THIS PRODUCT MEETS SPECIFICATIONS Ph. Eur.

Status: APPROVED
Release date: 03/05/2011 16:21
Released by: Gemma Codina

Generated and signed electronically