Helvoet Pharma

Compound Data Sheet

FM5030 Grey

PRELIMINARY!

General description

Latex free and free from MBT.
Application range: bottle pack disks

Physical properties

Hardness	°Shore A	ISO 7619	40	± 5
Density	g/cm³	ISO 2781	1.128	± 0.025
Ash	%	Internal Method(s): Calc. 4h @ 700°C	27.0	± 2.0
Compression Set	%	ISO 815	35	max.
Tensile Strength	N/mm²	ISO 37	4	min.

Chemical properties

Tests performed according to European Pharmacopoeia, Section 3.2.9: 100 cm² rubber surface was autoclaved in 200ml distilled water for 30 min. at 121°C (Solution S).

Criterium	*Test Object*	*Units*	*Limits*	*Typical Results*
Appearance	Sol. S	NTU	***Type I***: 6.0*	3.5
			Type II: 18*	
Color	Sol. S		See test procedure	pass
Alkaline Matter	Sol. S (20 ml)	ml 0.01M HCl	0.8	0.01
		ml 0.01M NaOH	0.3	
Absorption (220-360nm)	Sol. S	absorbance	***Type I***: 0.2	0.10
			Type II: 4.0	
Reducing Substances	Sol. S (20 ml)	ml 0.002M $KMnO_4$	***Type I***: 3.0	0.30
			Type II: 7.0	
Heavy Metals	Sol. S	ppm Pb^{2+}	2	<2
Zinc	Sol. S	ppm Zn^{2+}	5.0	0.00
Ammonium	Sol. S	ppm NH_4^+	2	<2
Evaporation Residue	Sol. S (50 ml)	mg	***Type I***: 2.0	1.6
			Type II: 4.0	
Sulphide	20 cm²	mg S^{2-}	0.02	<0.02

*By definition corresponding with reference suspensions II and III resp.

Valid from: 02-jan-02
Replaces Data Sheet of: 23-Oct-01 (Preliminary)

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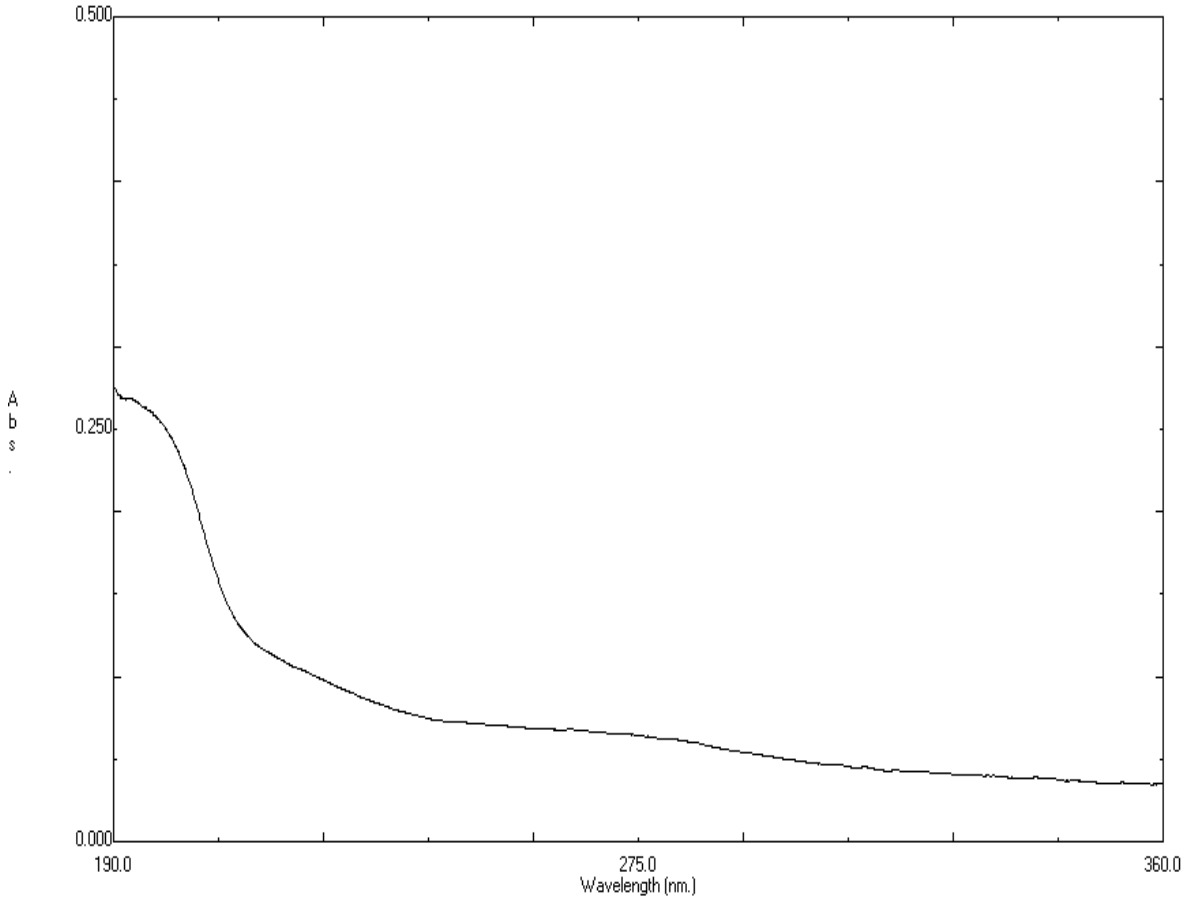
Compound Data Sheet

FM503

Typical UV-spectrum of aqueous extract according to the European Pharmacopoeia, Section 3.2.9.



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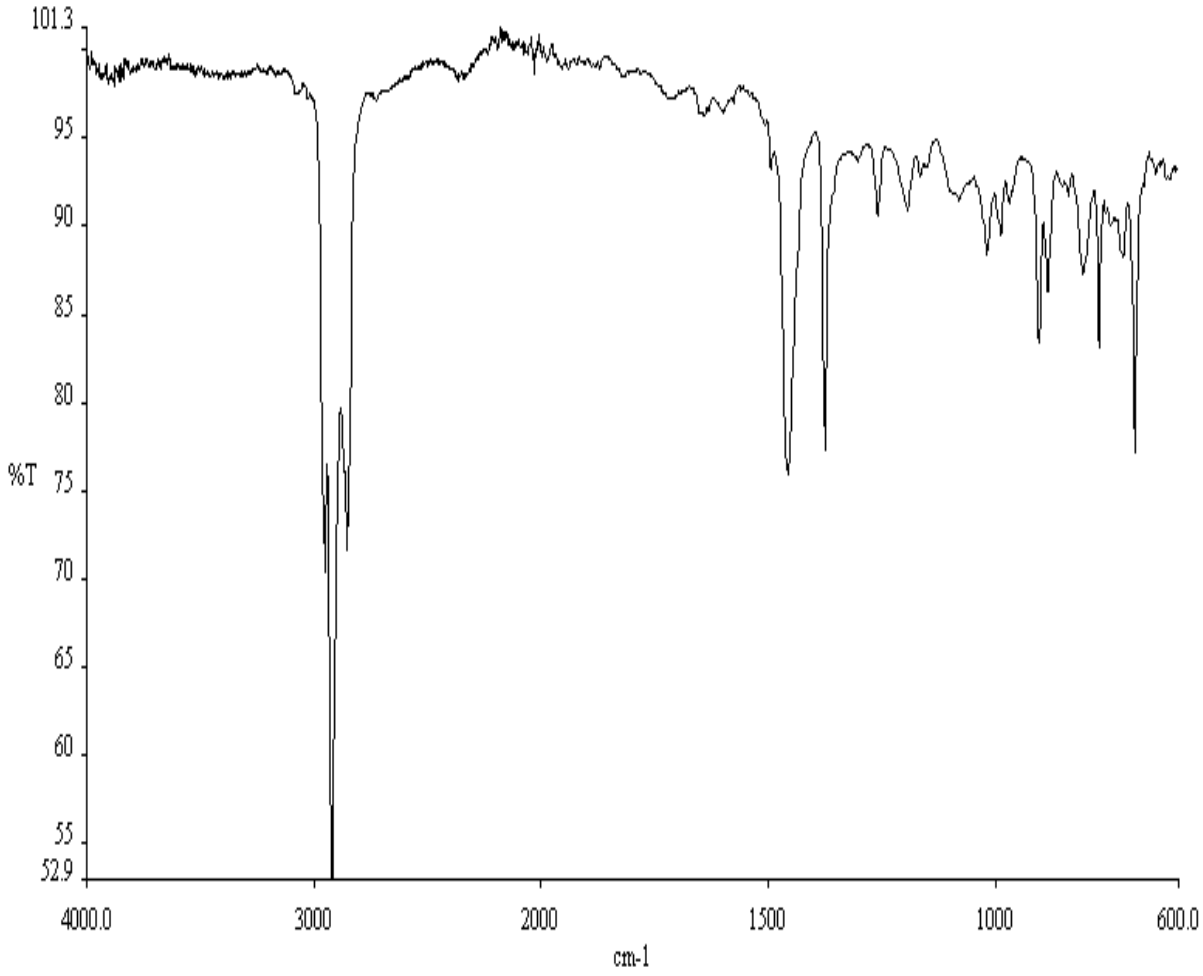
Compound Data Sheet

FM503

Typical infrared spectrum of a pyrolysate (4000-625 cm-1).



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TOXIKON

ISO-9001 Certified

TEST RESULT CERTIFICATE

Sponsor	Helvoet Pharma Belgium NV	**Technical Initiation**	01/31/01
Address	Industrieterrein Kolmen 1519 B-3750 Alken, Belgium	**Technical Completion**	02/02/01
Contact	Anita Thijs	**Report Date**	02/07/01
P.O. Number	Not Supplied by Sponsor	**Project Number**	01-0522-N1

Test Article	TP005-71/0 P7126 B	**Ratio**	60 cm² per 20 mL
Lot #	Ch. 049802	**Vehicle**	MEM complete
Study	USP MEM Elution Cytotoxicity	**Temp/Time**	37 ± 1 °C for 24 hours

REFERENCE: This study was based on the method described in USP 24, NF19, pp. 1831 - 1832, 2000.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% Carbon dioxide. Positive control (natural rubber) and negative control (negative control plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in duplicate for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% Carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observation. Severe reactivity (Grade 4) was observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Elution Test, USP 24.

AUTHORIZED PERSONNEL:

Inder J. Paika, Ph.D.
Study Director

Miriam Kummaiil, B.S.
Quality Assurance

15 Wiggins Avenue • Bedford, Massachusetts 01730
(781) 275-3330 • E-mail: www.toxikon.com