Compound Data Sheet

FM460/0 Dark Grey

General description

Bromobutyl compound, unconventionally cured. Latex free and free from MBT.
Extremely low extractables level.

Physical properties

	Unit	Method	Target	Range
Hardness	°Shore A	ISO 7619-1 (1 sec. Indentation) Avg of 3 measurements	46	± 5
Density	g/cm³	ISO 2781	1.348	± 0.025
Ash	%	Internal Method(s): Calc. 4h @ 700° C	48.0	± 2.0
Compression Set	%	ISO 815	22	max.
Tensile Strength	N/mm²	ISO 37	4	min.

Chemical properties

FM460(**) meets the chemical requirements for Type I Closures specified in General Chapter 3.2.9. of the European Pharmacopoeia and specified in General Chapter <381> of the United States Pharmacopoeia.
Typical USP <381> / EP 3.2.9. data for FM460(**) are presented in the table on page 2.
A typical UV spectrum of the USP <381> / EP 3.2.9. extract of FM460(**) is presented in the figure on page 3.

Biological properties

FM460(**) is non-cytotoxic and meets the requirements of the Elution Test as described in General Chapter <87> of the United States Pharmacopoeia.
A typical USP <87> Elution Test Certificate is enclosed on page 4.

Pyrolysate

An infrared spectrum of the pyrolysate of FM460(**) is enclosed on page 5.

Compound statement

A statement about compound FM460(**) in respect to natural rubber latex, nitrosamines, MCBT, Heavy metals, TSE/BSE and GMO is enclosed on page 6.

(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", ... refers to the colour of the said compound. Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.

Prepared by: _____ R&D Laboratory Date: 15 Oct 2010

Reviewed by: _____ Material Development Date: 02 Nov 2010

Approved by: _____ Quality Assurance Date: 08 Nov 2010

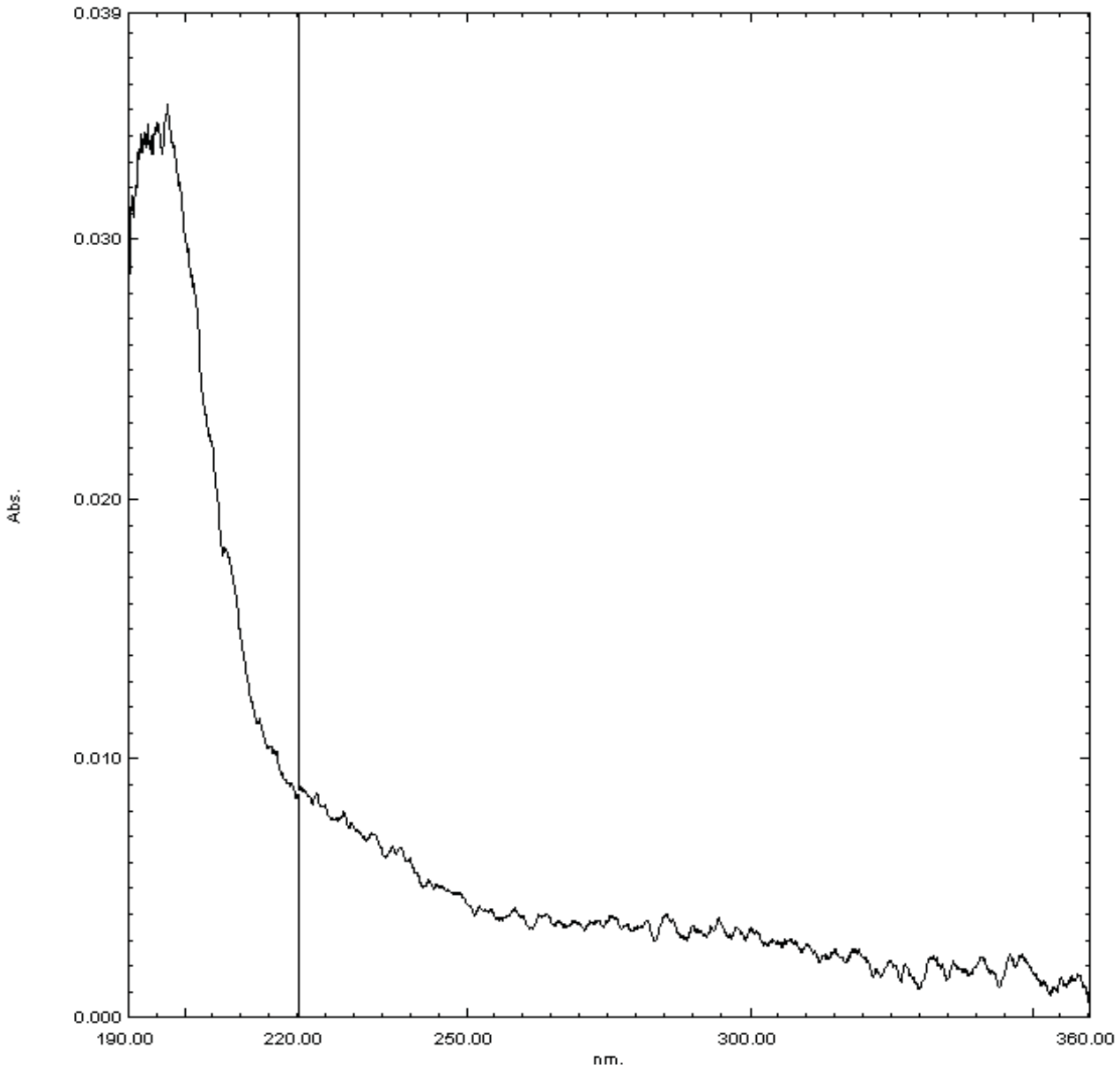
Typical USP <381> / EP 3.2.9. chemical properties of FM460(**)

Characteristic		Amount tested	Units	Limit	Typical Values	
Appearance of solution	*Turbidity*	Sol. S	NTU	Type I: ≤ 6.0 *(*)*		0.2
	Colour	Sol. S		See test procedure		pass
Acidity or alkalinity		Sol. S (20 ml)	ml 0.01M HCl	≤ 0.8	Blank	
			ml 0.01M NaOH	≤ 0.3	0.07	0.07
					EP	0.07
					USP	0.00
Absorbance		Sol. S	A_{max}220-360nm	Type I: ≤ 0.2		0.01
Reducing substances		Sol. S (20 ml)	ml 0.002M $KMnO_4$	Type I: ≤ 3.0		0.1
Extractable heavy metals		Sol. S	ppm Pb	≤ 2	EP	<2
					USP	<2
Extractable zinc		Sol. S	ppm Zn	≤ 5.0		0.02
Ammonium		Sol. S	ppm NH_4	≤ 2		<2
Residue on evaporation (only for EP)		Sol. S (50 ml)	mg	Type I: ≤ 2.0		0.2
Volatile sulphides		20 cm²	mg S	≤ 0.02		<0.02

(*) By definition corresponding with reference suspension II.

(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", … refers to the colour of the said compound.
Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.

Typical UV-spectrum of USP <381> / EP 3.2.9. extract of FM460(**)



(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", … refers to the colour of the said compound.
Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.

Typical USP <87> Elution Test Certificate of FM460(**)

TOXIKON EUROPE N.V.

TEST RESULT CERTIFICATE

Study Number:	**02-B0411-N1**	**Report Date:**	**05/03/2002**
Sponsor:	**Helvoet Pharma**		
Contact:	*Dhr. Luc Vanderheyden*		
Address:	Industriepark Kolmen 1519 B - 3570 Alken		
		Technical Initiation:	01/03/2002
PO.Number:	000185 OM	Technical Completion:	05/03/2002

Study	Elution Test – USP 24, NF 19	Temp/Time	37°C/24 Hr.
Test Article	FM 460/0 V9258	Ratio	60 cm²/ 20 ml
Lot	050201	Vehicle	MEM Complete

REFERENCE: This study was conducted based on the procedure described in the International Organization for Standardization, Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, USP 24,NF19, pp 1831-1832, 2000

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 (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The maintenance medium on the cell cultures is replaced by the extracts of the test article or control article in duplicate and the cultures are subsequently incubated for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on a scale from Grade 0 (No reactivity) to Grade 4 (Severe reactivity).
The test article meets the requirements of the test if none of the cultures exposed to the test article shows 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 or the negative control at the 48 hours observation. Severe reactivity (Grade 4) was observed for the positive control article.

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Elution Test, USP 24, NF19 , pp1831-1832,2000

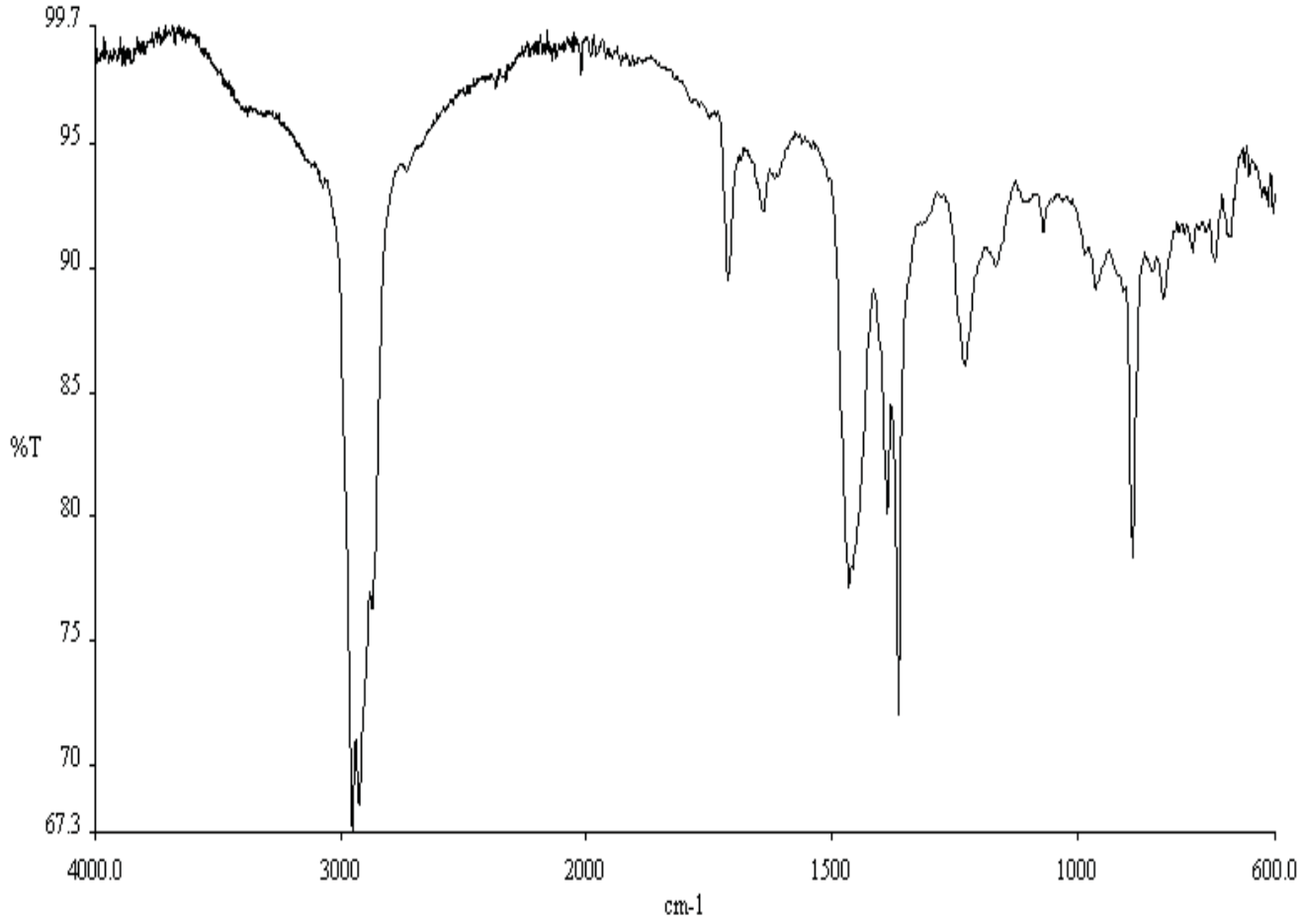
AUTHORIZED PERSONNEL

Dr. Ine Janssen
Study Director

Ing. Ingrid Lenotte
Quality Assurance

(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", … refers to the colour of the said compound. Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.

Typical infrared spectrum of a pyrolysate (4000-600 cm-1) of FM460(**)



(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", … refers to the colour of the said compound.
Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.

Compound statement for FM460(**)

Natural rubber latex

Compound FM460(**) is free from natural rubber and natural rubber latex.

Nitrosamines

Compound FM460(**) does not use rubber chemicals that are associated with hazardous nitrosamines formation.

MCBT

Compound FM460(**) does not contain 2-mercaptobenzothiazole (MCBT, also named MBT), or any of its derivatives.

Heavy Metals

- Compound FM460(**) fulfils the European Community Guideline 94/62/EC for heavy metals in packaging materials.

- Compound FM460(**) fulfils the CONEG regulation on reduction of toxics in Packaging Law.

Both directives state that packaging components should not contain more than 100 ppm of Lead (Pb), Cadmium (Cd), Mercury (Hg) and Hexavalent Chromium (VI) (Cr). Where the regulated metals are present at levels below the values stated above, they were not intentionally added during the manufacturing process.

TSE/BSE

Compound FM460(**) does not contain material of animal origin and hence is not associated with TSE/BSE risks.

(TSE = Transmissible Spongiform Encephalopathy; BSE = Bovine Spongiform Encephalopathy)

GMO

Compound FM460(**) does not contain ingredients made from GMO's (Genetically Modified Organisms).

(**) Note: FM460 refers to the type of compound, the extension "/0", "/1", … refers to the colour of the said compound.
Differently coloured compounds might be used for testing throughout this document. It is generally accepted that the colour is irrelevant for the properties discussed in this document.