Compound Data Sheet

FM457/2 Red

PRELIMINARY!

General description

Bromobutyl compound, unconventionally cured. Latex free and free from MBT.
Extremely low extractables level.
Application range: universal; especially suitable for WFI applications.

Physical properties

	Unit	Method	Target	Range
Hardness	°Shore A	ISO 7619-1 (1 sec. Indentation) Avg of 3 measurements	47	± 5
Density	g/cm³	ISO 2781	1.262	± 0.025
Ash	%	Internal Method(s): Calc. 4h @ 700° C	40.7	± 2.0
Compression Set	%	ISO 815	30	max.
Tensile Strength	N/mm²	ISO 37	4	min.

Chemical properties

FM457(**) 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 FM457(**) are presented in the table on page 2.
A typical UV spectrum of the USP <381> / EP 3.2.9. extract of FM457(**) is presented in the figure on page 3.

Biological properties

FM457(**) 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 FM457(**) is enclosed on page 5.

Compound statement

A statement about compound FM457(**) in respect to natural rubber latex, nitrosamines, MCBT, Heavy metals, TSE/BSE and GMO is enclosed on page 6.

(**) Note: FM457 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: 11 Oct 2010

Reviewed by: _____ Material Development Date: 12 Oct 2010

Approved by: _____ Quality Assurance Date: 14 Oct 2010

Typical USP <381> / EP 3.2.9. chemical properties of FM457(**)

Characteristic		Amount tested	Units	Limit	Typical Values	
Appearance of solution	*Turbidity*	Sol. S	NTU	Type I: ≤ 6.0 *(*)*		0.1
	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	0.06	0.06
					EP	0.06
					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		0.2
Extractable heavy metals		Sol. S	ppm Pb	≤ 2	EP	<2
					USP	<2
Extractable zinc		Sol. S	ppm Zn	≤ 5.0		<0.01
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.

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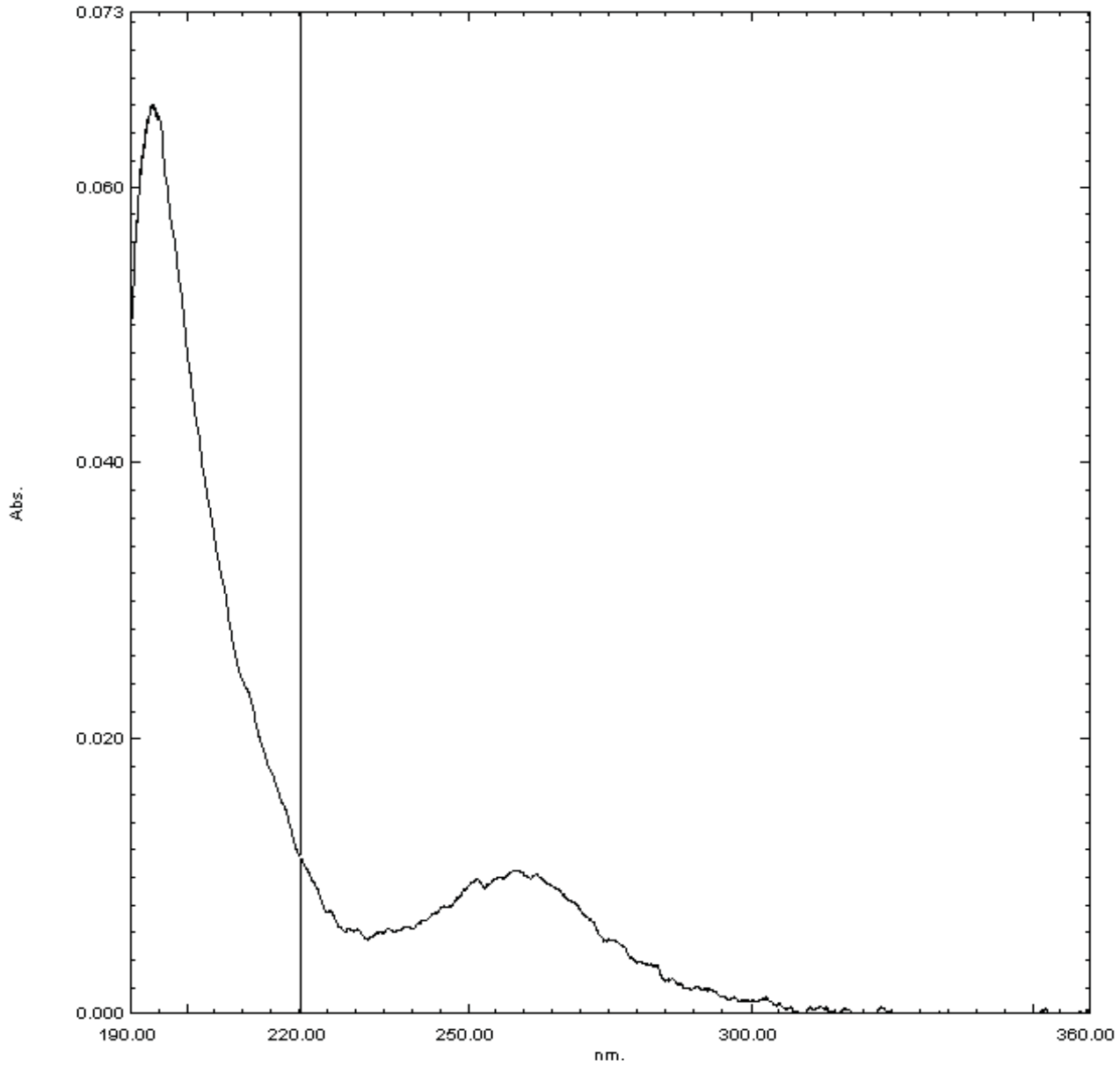
Typical UV-spectrum of USP <381> / EP 3.2.9. extract of FM457(**)



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Typical USP <87> Elution Test Certificate of FM457(**)

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TEST RESULT REPORT N°10-B1030-N1

Project Number:	**TE 10445**	**Study Number:**	**10-B1030-N1**
Sponsor:	**Helvoet Pharma Belgium NV**	**Report Date:**	**20/05/2010**
Contact:	*Mrs. Nadia Nouri*		
Address:	Industrieterrein Kolmen 1519 3570 Alken, Belgium	Date Sample Arrival: Technical Initiation:	12/05/2010 17/05/2010
PO.Number:	PB1001706	Technical Completion:	20/05/2010

Study	**Elution Test - ISO**	Temp/Time	37°C/24 hours
Test Item	V9341 FM457/0 0 kGy Gamma t=24m	Ratio	25cm²/20mL
Lot	Ch808934	Vehicle	MEM-Complete

REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." and "USP 32-NF 27, 2009: <87> Biological reactivity test, in vitro." Toxikon Reference: SOP 3.1.2.3, rev. 08

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The samples and control articles were autoclaved prior to the preparation of the extracts. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% carbon dioxide (static). 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 item or control article in triplicate 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 the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity). The test item is considered non-cytotoxic if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

RESULTS: No reactivity (Grade 0) was exhibited by the cell cultures exposed to the test item at the 48 hours observation. Severe reactivity (Grade 4) was observed for the positive control article. The negative control article showed no signs of reactivity (Grade 0).

OPINION AND INTERPRETATION: Based on the evaluation criteria mentioned above, the test item is considered non-cytotoxic.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

ir. Peter Cornelis
Study Director

Vanessa Ruymen
Quality Assurance

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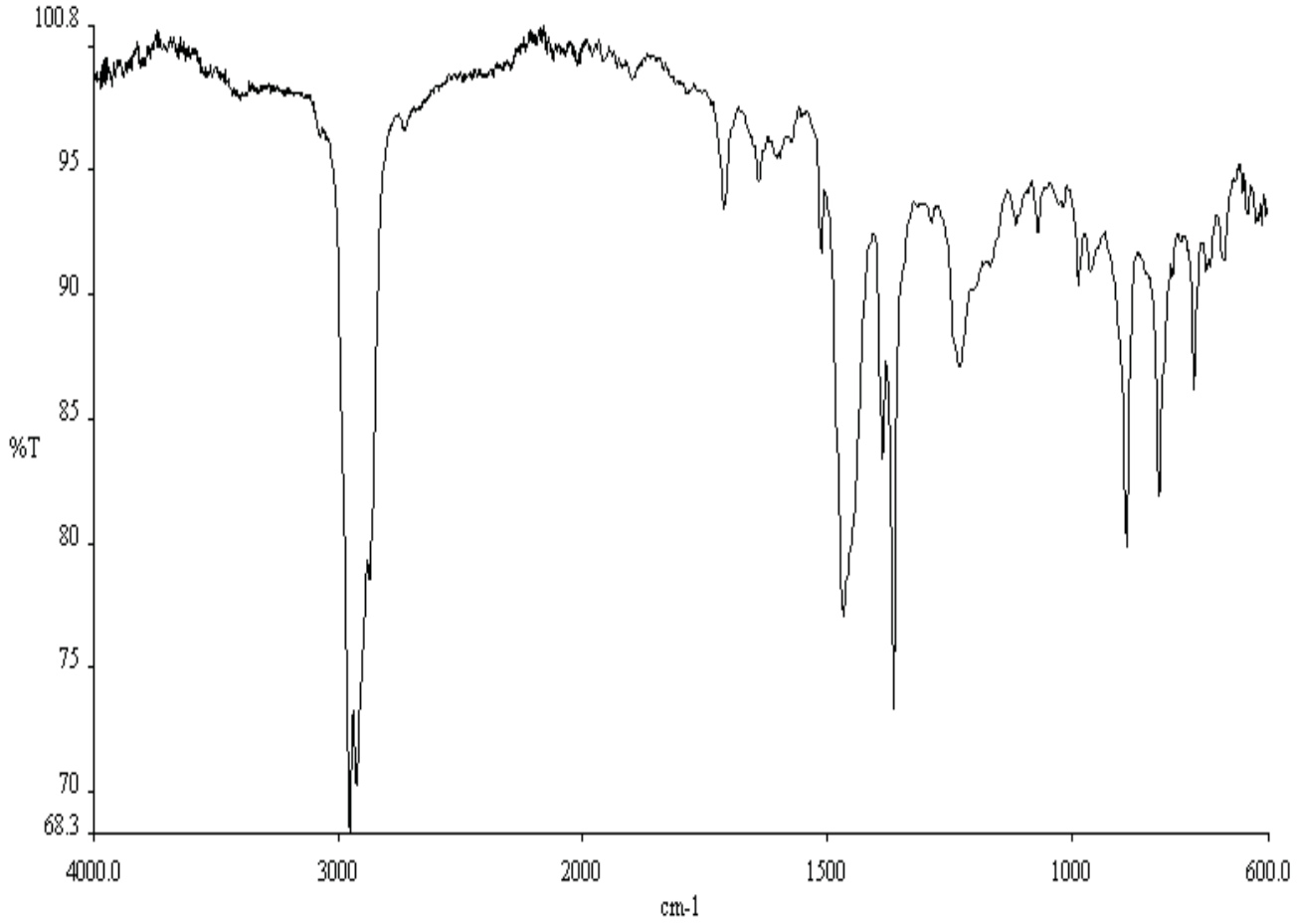
Typical infrared spectrum of a pyrolysate (4000-600 cm-1) of FM457(**)



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Compound statement for FM457(**)

Natural rubber latex

Compound FM457(**) is free from natural rubber and natural rubber latex.

Nitrosamines

Compound FM457(**) does not use rubber chemicals that are associated with hazardous nitrosamines formation.

MCBT

Compound FM457(**) does not contain 2-mercaptobenzothiazole (MCBT, also named MBT), or any of its derivatives.

Heavy Metals

- Compound FM457(**) fulfils the European Community Guideline 94/62/EC for heavy metals in packaging materials.

- Compound FM457(**) 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 FM457(**) 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 FM457(**) does not contain ingredients made from GMO's (Genetically Modified Organisms).

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