2.1.P.7 Container Closure System

Package size for clinical study:
10 tablets in Alu//Alu blisters

1 Primary packaging materials

Alu//Alu blister

- Soft tempered Aluminium foil for cold forming
- Aluminium foil hard tempered Primer for printing on the mat side and thermosealable lacquer to PVC/PVdC on the bright side, 20 µm

Specifications of Soft tempered Aluminium foil
(*Ar, CoA and declaration are attached*)

• Total thickness	0.13 mm ± 10%
• Weight	213.8 -261.4 g/m2
• Identification (IR)	Identical

Specifications of Aluminium foil for closing
(*Ar, CoA and declaration are attached*)

• ALU-Thickness	18.4 – 21.6 µm
• Heat-seal lacquer	7.00 ± 1.0 g/m^2
• Print lacquer	1.0 ± 0.4 g/m^2
• Identification (IR)	Identical

2 Secondary packaging materials

None.

VIZSGÁLATI JEGY

Vizsgálati jegy száma: 4847/2018

Minta neve: OPA25/ALU/PVC60

Azonosító szám: 201801494

Gyártási szám: 266592/1

Csomagolási egység: 42 tekercs

Mintavétel dátuma: 2018.11.14.

Mintavevő: Mészárosné

Megmintázott csom.egys.szám: 7

Minta mennyisége: 7x1 m

A minta további adatai:

A vizsgálati jegyet kiadta	**Őszi Zsolt**	**Dátum**	**2019.12.16.**
Hivatkozás	**A gyártó minőségi bizonylata**		
Vizsgálat	**Minőségi követelmény**	**Eredmény**	**Vizsgálta, Mf száma**
Szélesség	126 ± 0,5 mm	126,30 mm	Bajcsi B. 775/146.-147.
Vastagság	0,13 mm ± 10,0 %	0,127 mm	Bajcsi B. 775/146.-147.
Tömeg	213,8 -261,4 g/m^2	230,58 g/m^2	Bajcsi B. 775/146.-147.
Azonosság (IR)	Azonos (matt, fényes oldal) (matt, fényes oldal)	azonos	Bajcsi B. 775/146.-147.

Megjegyzés: –

Minősítés: Megfelel

Dátum: 2020.02.07

Aláírás:

Constantia Flexibles

FINAL INSPECTION - CERTIFICATE OF ANALYSIS

266592/01

CUSTOMER:	MEDITOP KFT	NUMBER OF REELS:	42
BATCH NUMBER:	266592	QUANTITY in kg:	700,1
CUSTOMER ORDER NO.:	201800623	QUANTITY in m:	23.100
CUSTOMER ART. NO.:	---	OUTSIDE DIAMETER:	400
CUSTOMER CHARGE NO.:	---	CORE DIAMETER:	76
DESIGN:	3-SV OPA 25/ALU 45/PVC 60 UN	MANUFACT. DATE:	25.10.2018
WIDTH:	126 mm		

MATERIAL: **PATZ 497/25-45-60 coldform**

TESTING PARAMETER	TOLERANCE	DIMENSION	TESTING RESULTS				
			n	min	max	Ø	s
OPA weight	25,9 - 31,7	g/m²	109	26,0	31,6	29,5	0,8
OPA thickness	22,5 - 27,5	µm	109	22,6	27,5	25,6	0,7
Adhesive + Primer (K1)	3,7 - 5,7	g/m²	10	4,8	5,6	5,0	0,2
ALU weight (WE)	111,8 - 131,2	g/m²	16	118,1	131,0	124,9	3,5
ALU thickness (WE)	41,4 - 48,6	µm	16	43,7	48,5	46,2	1,3
Adhesive (K2)	3,2 - 4,8	g/m²	17	3,9	4,2	4,1	0,1
PVC weight (K2)	70,7 - 86,5	g/m²	106	77,2	86,0	80,2	1,6
PVC thickness (K2)	54,0 - 66,0	µm	106	59,0	65,7	61,3	1,2
Total weight unprinted (K2)	213,8 - 261,4	g/m²	17	235,5	246,0	240,2	3,3
Sealing strength	≥ 8,5	N/15mm	1	9,1	9,1	9,1	0,0

Reel width: All measured reels are within the tolerance of ± 0,5 mm.
Rollenbreite: Alle gemessenen Rollen liegen innerhalb der Toleranz von ± 0,5 mm.

QUALITY CONTROL: Hochegger, Achim **QUALITY MANAGEMENT:** i.A. DI K. Bleier **DATE:** 29.10.2018

NOT ORIGINALLY SIGNED DUE TO ELECTRONICAL DATA TRANSFER.

Manufacturer:
Constantia Patz Ges.m.b.H.
Guntramserstraße 7, A-2620 Loipersbach
T +43 2635 600-0, F +43 2635 600 1970
office.patz@cflex.com
www.cflex.com

ANMERKUNG: Wir bestätigen, dass der oben genannte Order in Übereinstimmung mit der Kunden-Lieferspezifikation produziert wurde.

REMARKS: We confirm that the above order was manufactured in conformance with the customer specification.

2020 FE

1 General Product Information

Date:	28.06.2021	
Producer:	Constantia Patz Ges.m.b.H Guntramserstraße 7 A-2620 Loipersbach	office.patz@cflex.com www.cflex.com
Customer:	MEDITOP PHARMACEUTICAL LTD., Hungary	
Constantia Spec. No.:	PATZ 497/25-45-60 coldform – unprinted	
Material description:	Cold-formable aluminium bottom foil for “Alu-Alu” Blister	

Material description (from the outer to the inner layer):

Layer	based on
oPA	Polyamide
Adhesive	Polyurethane
Primer	Epoxy resin
Aluminium soft	Alloy 8079 CP
Adhesive	Polyurethane
PVC	Polyvinyl chloride

Product contact layer: PVC

Type of package/application: Packaging material for solid pharmaceutical products

2 Food Contact Legislation

2.1 General

The product named on this document complies with the applicable requirements of

- EU “Framework” Regulation (EC) No. 1935/2004
- Regulation (EC) No. 2023/2006 on good manufacturing practice
- Directive 94/62/EC and the Model Toxics in Packaging Legislation (as drafted by the Toxics in Packaging Clearinghouse/ Source Reduction Council of CONEG) regarding the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium < 100 ppm.

2.2 Conditions of Use

The product is suitable for the direct contact with pharmaceutical products

Product: solid pharmaceutical products

Time/temperature conditions: long term storage > 30 days at room temperature

The product has been tested and evaluated taking into account applicable food contact legislation.

2.3 Overall Migration Limit (OML) of the Product Contact Layers

EU Regulation No. 10/2011 sets out the test conditions for **plastic** materials and articles. Other test conditions for the determination of the overall migration may be considered for products which do not fall under the scope of 10/2011/EC or for which specific measures exist on national level.

The product is in compliance with the OML of 10 mg/dm² following evaluation of relevant samples under following test conditions:

Food simulant	Testing conditions (time/temperature)	Global Migration in [mg/dm²]
Tenax	10 days 60°C	<1

The compliance refers only to migration compliance and not to technical fit-for-use.

2.4 Information about Non-Product Contact Side

Layer	Country	Legal Provisions (recommendations, code of practice, decrees) for plastics, paper, adhesives, coatings and other components
oPA	EU	EU regulation Nr. 10/2011 as amended. The used starting monomers and additives are listed in the union list of EU Regulation Nr. 10/2011
	USA	21 CFR § 177.1500
Adhesive	USA	21 CFR § 175.105
	EU	All starting monomers and additives are listed in the union list of EU Regulation Nr. 10/2011 as amended
Primer	EU	Article 3 of the EU-Framework Regulation 1935/2004/EC if applied on the non-food contact surface of food packaging. The lacquer is formulated and manufactured in accordance with the “EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles”.

2.5 Aluminum

The composition of the aluminum alloy 8079 CP is according to EN 573-3 and can be used in contact with foodstuff according to EN 602.
The used rolling oil complies with FDA 21 CFR § 178.3910 (a) Surface lubricants used in manufacture of metallic articles.

Aluminum foils > 6 µm are regarded as a functional barrier.

The product complies with the applicable requirements of the Council of Europe Resolution CM/Res(2013)9 on metals and alloys used as food contact materials.

2.6 Functional Barrier

The material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of EU Regulation No. 10/2011.

2.7 Information about Product Contact Layers

Layer	Country	Legal Provisions (recommendations, code of practice, decrees) for plastics, paper, adhesives, coatings and other components
Adhesive	USA	21 CFR § 175.105
	EU	All starting monomers and additives are listed in the union list of EU Regulation Nr. 10/2011 as amended
PVC film	EU	EU regulation Nr. 10/2011 as amended. The used starting monomers and additives are listed in the union list of EU Regulation Nr. 10/2011
	PHR	European Pharmacopoeia 9 chapter 3.1.11. Listed in US DMF and compliant with USP 39 General Chapter <661.1> section “Physicochemical Tests
	D	Bedarfsgegenständeverordnung, BfR Recommendation II

2.8 Information about Specific Restrictions

The used raw materials contain substances that have a restriction according to EU Regulation No. 10/2011 as amended.

The restricted substances listed in the following table may be present in the finished product:

CAS No. PM Ref Nr. or FCM substance No	Substance	Restriction*
0000075-01-4	vinyl chloride	SML = ND
0000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
0000080-05-7	2,2-bis(4-hydroxyphenyl)propane (BPA)	SML = 0.05 mg/kg
0000080-62-6	methacrylic acid, methyl ester	SML (T) = 6 mg /kg
0000091-08-7	2,6-toluene diisocyanate (expressed as isocyanate moiety)	SML (T) = ND
0000101-68-8	diphenylmethane-4,4′-diisocyanate (expressed as isocyanate moiety)	SML (T) = ND
0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	SML (T) = 18 mg/kg
0000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg
0000105-60-2	caprolactam	SML (T) = 15 mg/kg
0000106-89-8	epichlorohydrin	SML = ND
0000106-99-0	butadiene	SML = ND
0000107-21-1	ethyleneglycol	SML = 30 mg/kg
0000108-05-4	acetic acid, vinyl ester	SML = 12 mg/kg
0000111-46-6	Diethyleneglycol (expressed as ethyleneglycol)	SML (T) = 30 mg/kg
0000141-32-2	acrylic acid, n-butyl ester (expressed as acrylic acid)	SML (T) = 6 mg /kg

0000502-44-3	caprolactone	SML (T) = 0.05 mg/kg
0000584-84-9	2,4-toluene diisocyanate (expressed as isocyanate moiety)	SML (T) = ND
0000822-06-0	hexamethylene diisocyanate (expressed as isocyanate moiety)	SML (T) = ND
0000919-30-2	3-aminopropyltriethoxysilane	SML = 0.05 mg/kg
0001321-74-0	divinylbenzene	SML = ND
0001675-54-3	2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE)	SML = 9 mg/kg (1895/2005)
0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
0003724-65-0	crotonic acid	SML = 0.05 mg/kg
0004098-71-9	1-isocyanato-3-isocyanatomethyl- 3,5,5-trimethylcyclohexane	QM 1 mg/kg SML (T) = ND
0005873-54-1	diphenylmethane-2,4′-diisocyanate	QM 1 mg/kg SML (T) = ND
0015571-58-1	di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML (T) = 0.006 mg/kg
0026401-86-5	mono-n-octyltin tris(isooctyl mercaptoacetate) (expressed as tin)	SML (T) = 1.2 mg/kg
0026401-97-8	di-n-octyltin bis(isooctyl mercaptoacetate) (expressed as tin)	SML (T) = 0.006 mg/kg
0027107-89-7	mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML (T) = 1.2 mg/kg
0036443-68-2	triethyleneglycol bis[3-(3-tert- butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg
0134701-20-5	2,4-dimethyl-6-(1-methylpentadecyl)phenol	SML = 1 mg/kg
Ref. No. 34230	alkyl(C 8-C 22)sulphonic acids	SML = 6 mg/kg

* restrictions can be a specific migration limit (SML), a maximum concentration (QM), a maximum quantity per surface area (QMA), or a 'no detectable migration' (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers.

The restrictions have been checked by an accredited 3rd party laboratory. For migration tests suitable food simulants have been used. The restrictions were proved not to be exceeded either by analytical testing or by worst case calculation when used under the conditions specified in section 2.2. For the evaluation an area / volume ratio of 6 dm^2 / 1 kg food/product was taken into account.

2.9 Dual Use Additives

As required by EU Regulation (EU) No 10/2011 the following table identifies substances used as additives in plastics and subject to a restriction in food through an authorization as food additive or flavouring (as listed in the Union Guideline on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, point 3.6.3 table 1 and 2).

CAS Nr.	Substance	Food Additive	Restriction in plastics
0000064-19-7	acetic acid	E 260	-
0000077-92-9	citric acid	E 330	-

0000128-37-0	2,6-di-tert-butyl-p-cresol	E 321	SML = 3 mg/kg
0000471-34-1	calcium carbonate	E 170	-
0000497-19-8	sodium carbonate	E 500	-
0007631-86-9	silicon dioxide*	E 551	-
0009004-65-3	methylhydroxypropylcellulose	E 464	-
0009005-64-5	polyethyleneglycol sorbitan monolaurate	E 432	
0009016-00-6	polydimethylsiloxane (Mw > 6 800 Da)	E 900	-
0013463-67-7	Titanium dioxide	E 171	-
0014807-96-6	talc	E 553b	-
0025013-16-5	tert-butyl-4-hydroxyanisole	E 320	SML = 30 mg/kg
0068441-17-8	polyethylene waxes, oxidised	E 914	-
-	Glycerolester	E 471	-

*silicon dioxide is fixed in the matrix in such a way that no migration into food is expected

The above list of dual use additives is complete to the extent that accurate information was received from our raw material suppliers.

2.10 Bisphenol A

A primer is used on the product averted side that contains BPA in minor traces. In all cases migration tests proved that the migration of BPA out of the lacquer - and therefore also out of the product delivered to your company – lies below the detection limit and is not traceable.

2.11 Vinyl Chloride Monomer (VCM)

The product contains PVC / Vinyl Chloride Monomer. We confirm that the product complies with the restriction on vinyl chloride monomer according to 10/2011/EC.

2.12 Recycled materials

The product contains recycled plastics ☐ Yes ☒ No

2.13 Elemental Impurities

ICH Guideline Q3D: „GUIDELINE FOR ELEMENTAL IMPURITIES”

Identifying the potential elemental impurities extracted from container closure systems should be based on a scientific understanding of likely interactions between a particular drug product type and its packaging. If the container closure system does not contain elemental impurities, no additional assessment needs to be performed. It is recognized that the probability of elemental leaching into solid dosage forms is minimal and does not require further consideration in an assessment.

The sum of concentration levels lead, mercury, cadmium and hexavalent chromium present in any package or package component does not exceed 100 parts per million by weight (requirements of directive 94/62/EC on packaging and packaging waste). Other elemental

impurities are not intentionally added due to information of our raw material suppliers. The only metals present in the foil are in the aluminum alloy.

2.14 Phthalates

We confirm that the product constitutionally does not contain phthalate plasticizers. This information is based on a theoretical evaluation of the formulation/specification and the confirmations from raw material suppliers.

Since we do not expect these substances to be present, we do not analyze for these substances in the delivered product.

3 Supporting Documents

Appropriate documentation including supplier DoCs, test results, calculations and other evidence on the safety or reasoning demonstrating compliance are retained on the production site and can be shown to the competent authority on their request.

4 Disclaimer

This statement is given in good faith and to the best of our current knowledge. It describes the status of the products specified under General Product Information. The user of the product (or downstream user, if applicable) is responsible for ensuring that the finished package complies with applicable limits under actual conditions of use. Furthermore, the packer is responsible for verifying possible interactions of the products or its components with the packed product (e.g. modification of odour, taste, consistency, migration, extractables & leachables etc.) which are to be checked prior to use and in function of the end-uses and to ensure the general appropriateness of the packaging material for the intended use.

This statement replaces all previous statements for the same specification. It remains valid until a relevant change in the legislation or new relevant scientific information changes the legal status of the delivered specification.

i.A. Stefan Stix
Regulatory Affairs Manager

i.A. Johannes Koch
Application Engineer

This document has been electronically issued and is valid without signature.

VIZSGÁLATI JEGY

Vizsgálati jegy száma: 1138/2020

Anyag neve, minősége: Nyomatlan alumínium fólia 0,02x124 mm

Gyártási szám: 50751R1 **Azonosító szám:** 20120164736

Beérkezés dátuma:2020-03-03 **Gyártó/Szállító:** Aluberg

Csomagolási egységszám: 30 **Beérkezett mennyiség:**30 tekercs

Mintavétel dátuma: 2020-03-03 **Mintavevő:** Balogh M.

Megmintázott csom.egys.szám:7 **Minta mennyisége:** 7x1m

Mintavétel célja: teljes vizsgálat, ismételt vizsgálat, egyéb: .....

Minőségi követelményrendszer: **ME-CSA-221 verzió:01**

VIZSGÁLATOK	KÖVETELMÉNY	EREDMÉNY	VIZSGÁLTA MF. száma
Külső csomagolás	A tekercsek sértetlenek és tiszták	megfelel	Kovács E.
Tekercselés	Berepedés és sorja mentes, szoros és gyűrődésmentes	megfelel	Kovács E.
Szélesség	124 ± 2 mm	124,2 mm	Kovács E.
Alréteg vastagság	18,4 – 21,6 µm	19,71 µm	Kovács E.
Termolakk réteg	7,0 ± 1,0 g/m^2	7,01 g/m2	Kovács E.
Védőlakk réteg	1,0 ± 0,4 g/m^2	0,96 g/m2	Kovács E.
Azonosság (IR)	azonos	azonos	Kovács E.

Megjegyzés: –

Minősítés: Megfelel

Dátum: 2020.06.12. Aláírás:

Aluberg

Aluberg S.p.a. - Via Rebecchi, 1/2/3 - 24060 Bagnatica (BG) - Tel. 0356665200 - info@aluberg.it

CERTIFICATE OF ANALYSIS

2020 JÚN 12.

N° Delivery	Delivery Date	BATCH	Yr Order
96	14/01/2020	50751R1	361900785 dtd 19/11/2019

Quantity kg 434,8 **N° reels** 30

Aluminum 20µm hard tempered Primer for printing CT 311 on the mat side (Ext) Thermosealable lacquer to PVC/PVDC on the bright side

Dear
Meditop Pharmaceutical Ltd.

Ady Endre utca, 1
H - 2097 Pilisborosjeno - Budapest - Hungary Ungheria

Technical Specification TDS 31U02 **Yr code CS- ALUFOLIA20-M-1**

Batch controls	Method	Specification value	Average actual value	Approval	Test	DevStd
Total weight	IO 20	61,8 g/m² (Min. 56,3 Max 67,3)	63,02	yes		
Total thickness	IO 51	27,8 µm (Min. 25 Max 30,6)	27,92	yes		
Weight of primer for printing	IO 01	0,8 g/m² (Min. 0,6 Max 1)	0,84	yes	176	0,06
Weight of aluminium	IO 20	54 g/m² (Min. 49,7 Max 58,3)	55,74	yes	47	0,53
Weight of the thermosealable varnish	IO 01	7 g/m² (Min. 6 Max 8)	6,44	yes	176	0,14
Residual solvent	IO 13	Max 10 mg/m²	0,0	yes	5	0,0
Varnishes adhesion to the substrate	IO 06	No detachment	No detachment	yes	88	
Bonding to PVC - 220°C - 267 N/cm² - 1 second - 180°	IO 05	Min. 6 N/15mm	13,91	yes	44	0,65
FT-IR Spectra heat-seal lacquer compare	IO 34	Min. 98,5 %	99,90	yes	1	
FT-IR Spectra primer compare	IO 34	Min. 98,5 %	99,70	yes	1	
Melting point of thermosealable varnish	IO 17	100 °C (Min. 95 Max 105)	102	yes	5	2
Width	IO 16	124 mm (Min. 123,5 Max 124,5)	124,0	yes	5	

Technical characteristics	Method	Specification value
Primer for printing resistance to temperature	IO 11	Max 290 °C
Ultimate tensile strength of aluminium	ASTM D882	Min. 150 MPa
Elongation to aluminium break	ASTM D882	Min. 1,5 %
Water vapor permeability - 24h - 38°C / 90% r.h. and 25°C / 100% r.h.	DIN ISO 15106-3	Max 0,01 g/m²
Oxygen permeability - 24h - 23°C / 50% r.h. and 25°C / 50% r.h.	DIN 53 380-3	Max 0,005 cc/m²
Aluminium finesses		(Min. 98,5 Max 99,5) %

ÉRKEZETT
2020 MÁRC 03.
Átvette: Bdogh Mátyás

Aluberg S.p.a. Controllo qualità
ELENA RICCARDI

Confirm in all respect to our procedures, technical specifications and your order above mentioned

PRODUCT

Pharmaceutical push through foil, unprinted

MATERIAL COMPOSITION

Primer for printing / Aluminium 20µm hard tempered / Thermosealable lacquer to PVC/PVDC

Stratigraphy composition	Code	Thickness (µm)		Weight (g/m²)		Chemical composition
		Value	Tol.	Value	Tol.	
Primer	CT311	-	-	0,8	± 0,2	Polyester
Aluminium hard tempered		20,0	± 1,6	54,0	± 4,3	DIN EN 573-3 EN AW 8079
Heat seal	CT15	-	-	7,0	± 1,0	Vinyl-acrylic
Overall		**27,8 (*)**	**± 2,8 (*)**	**61,8**	**± 5,5**	

(*) Obtained from grammage

MATERIAL PROPERTIES

Residual solvent (IO 13)	<= 10 mg/m²
Varnishes adhesion to the substrate (IO 06)	No detachment
Bonding to PVC (IO 05)	>= 6 N/15mm (220°C - 267 N/cm² - 1 second - 180°)
Bonding to PVDC (IO 05)	>= 6 N/15mm (220°C - 267 N/cm² - 1 second - 180°)
FT-IR Spectra heat-seal lacquer compare (IO 34)	>= 98,5 %
Melting point of thermosealable varnish (IO 17)	100 °C ± 5
Primer for printing resistance to temperature (IO 11)	<= 290 °C
Ultimate tensile strength of aluminium (ASTM D882)	>= 150 MPa
Elongation to aluminium break (ASTM D882)	>= 1,5 %
Water vapor permeability (DIN ISO 15106-3)	<= 0,01 g/m² (24h - 38°C / 90% r.h. and 25°C / 100% r.h.)
Oxygen permeability (DIN 53 380-3)	<= 0,005 cc/m² (24h - 23°C / 50% r.h. and 25°C / 50% r.h.)

CLEARANCE CERTIFICATE

Product	This laminate is registered at the Food and Drug Administration with the DMF number 11322. CE Regulation 1935/2004 - 1895/2005 - 2023/2006 (GMP). Directive 94/62/CE and CONEG. EMEA/410/01. It doesn't contain phthalates.
Thermosealable lacquer	FDA 21 CFR § 175.300 Directives 2002/72/CE - 2004/19/CE - 2005/79/CE - 2007/19/CE CE Regulation n. 10/2011 and subsequent directives Resolution of the Council of Europe AP(2004)1 Italian Ministerial Decree of 21/03/1973 and subsequent directives

WARRANTY, STORAGE AND SHELF-LIFE

This warranty is only valid if the following conditions of storage are observed:

Condition of storage	Recommended storage conditions: - no direct sunlight - room temperature between 18°C - 30°C (optimum 18°C - 20°C) - relative humidity between 40% and 60% (optimum 40% - 50%)
Workability	Maximum 2 years from delivery date for sealing. Maximum 1 year from delivery date for printability.
Function	Maximum 5 years after processing on the packaging line.

LIABILITY EXCLUSION

Data mentioned in the technical specification, obtained in our laboratory or in our raw material supplier's laboratories, are valid as a general indication for the use of the product.
So, even if valid, they don't bind our Company that can not check the conditions of their use.