INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
TESTING LABORATORY - TESTING DIVISION
Issues

ATTEST
No. 472113179-01

on sample:

LDPE transparent film Novplasta, type: PHARMA 01

client:

NOVPLASTA CZ, s.r.o., T. G. Masaryka 854, 538 21 Slatiňany, Czech Republic
Company ID. No.: CZ25946404

producer:

Novplasta, s.r.o., Cerovská 152, 900 82 Šenkvice, Slovak Republik

Assessment of the technical parameters:
The evaluated parameters mentioned on the pages 2 of this Attest **meet** the purity requirements of **European Pharmacopoeia**, 10th Edition, **chapter 3.1.3. Polyolefines.**

The evaluated parameters mentioned on the page 3 of this Attest **meet** the requirements of **FDA 21 CFR 177.1520 (c) Specifications: 2.1.** Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking **and Specifications: 2.2.** Polyethylene for use in articles used for packing or holding food during cooking.

This Attest was issued on the basis of following document:
The accredited test reports No. 472113179-01 from May 7, 2020, issued by Institut pro testování a certifikaci, a.s. Zlín.

Date of issue: May 07, 2020
Attest is valid to: May 31, 2023

ZKUŠEBNÍ LABORATOŘ Institut pro testování a certifikaci, a.s.

Dipl. Ing. Jiří Samsonek, Ph.D.
Head of the testing laboratory

Conditions for use of the Attest and associated information:
1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

ATTEST
No. 472112181-01

Sample:
LDPE transparent film Novplasta, type: PHARMA 01

Value obtained according to the requirements of European Pharmacopoeia, chapter 3.1.3. Polyolefines – selected parameters

Parameters	Unit	Value obtained [1]	Limit value [2]
Material identification	-	LDPE	LDPE (confirmation)
Purity tests			
Appearance of solution S1		clear, colourless	clear (max opalescence degree I), colourless
Acidity and alkalinity	ml	0,34 ± 0,03	max 1,5 ml of 0,01 M NaOH / 1 l
		0,37 ± 0,03	max 1,0 ml 0,01 M HCl / 1 l
Absorbance	-	0,016 ± 0,002	from 220 to 340 nm max 0,2
Reducing substances	ml	0,08 ± 0,05	max 3,0 ml
Extractable titanium	µg/g	< 0,05	max 1 µg/g
Extractable zinc	µg/g	< 0,05	max 1 µg/g
Extractable aluminium	µg/g	< 0,15	max 1 µg/g
Extractable heavy metals	µg/g	< 2,5	max 2,5 µg/g
Sulphated ash	% w/w.	0,02 ± 0,02	max 1,0 %

Notes to the table:

1) value obtained including expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%
2) the required values of European Pharmacopoeia, 10th edition, charter 3.1.3 Polyolefines

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ATTEST
No. 472112181-01

Sample:
LDPE transparent film Novplasta, type: PHARMA 01

Value obtained according to the requirements of FDA 21 CFR 177.1520 (c)

Parameter	Unit	Value obtained				Uncertainty [1]	Limit
		1.	2.	3.	Mean		
Density	$g.cm^{-3}$	0,913	0,913	0,913	**0,913**	0,002	0,85 – 1,00 [2),3)]
Extractable fraction in n-hexane at 50°C/2h	% w/w	1,39	1,35	1,22	**1,32**	0,13	max. 5,50 [2)] max. 2,60 [3)]
Soluble fraction in xylene at 25 °C	% w/w	0,83	0,81	0,78	**0,81**	0,06	max. 11,30 [2),3)]

Notes to the table:

1) the reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%
2) limit values for PE according to FDA 21 CFR 177.1520 (c) Specifications: 2.1. Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking
3) limit values for PE according to FDA 21 CFR 177.1520 (c) Specifications: 2.2. Polyethylene for use in articles used for packing or holding food during cooking

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