

1.1.1.2 Specification

Appearance:	White colour, odourless, plastic container
Dimensions:	
- height:	79.0 ± 1.0 mm
- outside diameter:	35.0 ± 0.5 mm
- inside diameter	25.5± 0.5 mm
- neck diameter:	30.4 ± 0.2 mm
Identification (IR):	Identical
Checking of closures:	Comply

1.1.1.3 Tests

Appearance

Test:	Checked by visual examination
Requirement:	White colour, odourless, plastic container

Dimensions

Test:	Measured by a suitable calliper.
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Dimensions:	
- height:	79.0 ± 1.0 mm
- outside diameter:	35.0 ± 0.5 mm
- inside diameter	25.5± 0.5 mm
- neck diameter:	30.4 ± 0.2 mm

Identification

Method:	IR
Instrument:	BRUKER ALPHA FTIR spectrophotometer system
Test:	Record the infrared spectrum of the sample.
Requirement:	The infrared spectrum of the sample has to comply with that of the reference standard's.

Checking of closures

Test: Pressing the lid to the container and the closure is controlled.

Requirement: Comply

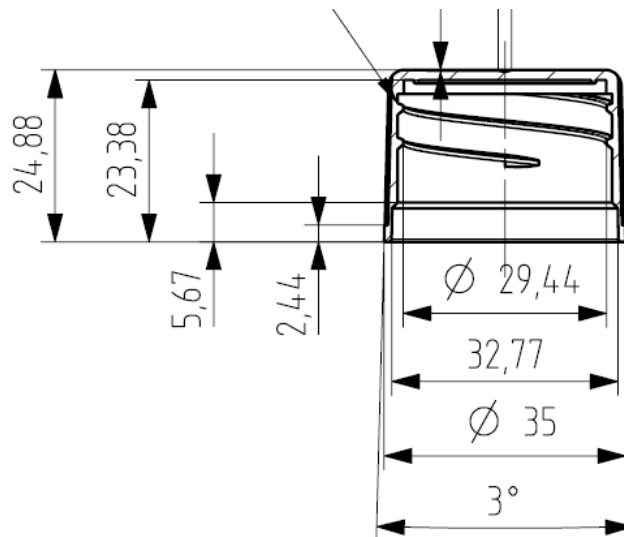
1.2 Polypropylene lid

1.2.1 Polypropylene lid D-161

(CoA, Analytical Report and Declaration are attached.)

Description: Red colour, plastic Polypropylene lid

Type: Tatren HM 5046



1.2.1.1 Specifications

Appearance: Red colour, odourless, plastic lid with induction insert

Dimensions:

- outside diameter: 35.0 ± 1 mm

- inside diameter: 29.44 ± 0.5 mm

Checking of closures: Comply

1.2.1.2 Tests

Appearance

Test: Checked by visual examination

Requirement: Red colour, odourless, plastic lid with induction insert

Dimensions

Test: Measured by a suitable calliper.

Requirement:

- outside diameter: 35.0 ± 1 mm

- inside diameter: 29.44 ± 0.5 mm

Checking of closures

Test: Pressing the lid to the container and the closure is controlled.

Requirement: Comply

1.3 Polyethylene bag for bulk product (CoA, Analytical Report, Declaration and IR are attached)

1.3.1 Description

Clear, colourless, low density polyethylene bag.

Type:

Tipolen FC 243-55

1.3.2 Specification

Appearance: The bags should be clean and free of dirt.

Dimension: 60x70 cm

Identification IR: identical

Microbiological purity: NMT 10^3 TAMC / 25 cm^2
NMT 10^2 TYMC / 25 cm^2
Absence of *Escherichia coli* / 25 cm^2

1.3.3 Analytical Procedures

Appearance

Test: Checked by visual examination

Requirement: The bags should be clean and free of dirt

Identification

Method: IR

Instrument: BRUKER alpha FTIR spectrophotometer system

Test:

Diamond cell sample preparation: approximately 1x1 mm pieces are cut from the bag, and placed onto one part of the high pressure diamond cell of the ATR unit. The infrared spectrum is recorded.

Requirement:

The infrared spectrum of the sample has to comply with that of the reference standards.

Microbiological purity

Test:

According to Ph. Eur by our contract laboratory.

Requirement: NMT 10^3 TAMC / 25 cm²
NMT 10^2 TYMC / 25 cm²
Absence of *Escherichia coli* / 25 cm²

A-8.2-03-13/2007-V:1

MŰBIZONYLAT

Előállító neve:	KARSAI ALBA KFT. 8000 SZÉKESFEHÉRVÁR Zsurló u. 12- Alba Ipari Zóna
Megrendelő neve:	Meditop Gyógyszeripari KFT. raktára
Termék megnevezés:	Meditop flakon fehér M-445
Azonosító szám:	2046662/01-03, 2046665/01
Alapanyag / színező:	PE BS 501-17 /HP 17101
Mennyisége:	28 400 db
Gyártási idő:	2020.05.
A termék előállítása a gyártó és a megrendelő által kölcsönösen elfogadott jellemmintának megfelelő előállítással történik. A termék toxikus anyagokat nem tartalmaz és nem ad le.	
Kelt: 2020.12.14.	
Kiállító:	Jóváhagyó:
Nagy Ibolya	Sáfrány Balázs

KARSAI ALBA KFT.
Székesfehérvár, Zsurló u. 12.
Alba Ipari Zóna
MINŐSÉGELLENŐRZÉS



meditop

Pharmaceutical Ltd.

ANALYTICAL REPORT

6014/2020

Name: Polyethylene container M-445, 40 ml

Batch number: 2046662

Manufacturing date: 05/2020

Manufacturer: Karsai Alba Kft.

TESTS	ACCEPTANCE CRITERIA	<u>RESULTS</u>
Appearance	White colour, odourless, plastic container	complies
- height	79.0 ± 1.0 mm	79.45 mm
- outside diameter	35.0 ± 0.5 mm	35.24 mm
- inside diameter	25.5 ± 0.5 mm	25.37 mm
- neck diameter	30.4 ± 0.2 mm	30.38 mm
Identification (IR)	Identical	Identical
Checking of closure	Comply	complies

Remarks: -

Conclusion: Complies

Date: 16-12-2020

Signature:

Zsolt Öszi
Quality Control Manager

Declaration of Conformity

*The goods produced by the Karsai Alba Kft.
Address: 8000 Székesfehérvár, Zsurló u. 12., Hungary*

Product names:

D-161, Closures

Raw material: PP Tatren HM 50 46

Manufacturer of raw material: SLOVNAFT a.s

Colors: PE 4744 L red

Manufacturer of colors: Plasticolor Hungary Kft.

M-445, Containers

Raw material: PE BA 550-13

Manufacturer of raw material: MOL Petrolkémia Zrt.

Colors: HP17101

Manufacturer of colors: Gabriel Chemie

We declare that the above mentioned products' materials and articles meet the following requirements

- "Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food"
 - The requirements of „Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004”.
 - The requirements of “Regulation (EC) 2023/2006 GMP and ISO 9001”.
- The overall migration limit of the product complies with Commission Regulation (EU) No 10/2011*

*Karsai Alba Kft. uses ISO 9001:2015, HACCP and BRC quality control systems.
The production of our products complies with the Regulation No 2023/2006/EK.
From the acquisition of the raw materials through the production until our final products we deliver we apply these rules in order to maintain the quality of our products.
The specified moulding technology and the production environment ensure that the chemical characteristics of the product material will not be changed during the production procedure.*

Storage conditions:

Original and closed packaging. Storage dry and dark place.

Temperature: 0-30 °C, Humidity: max 60% Rh

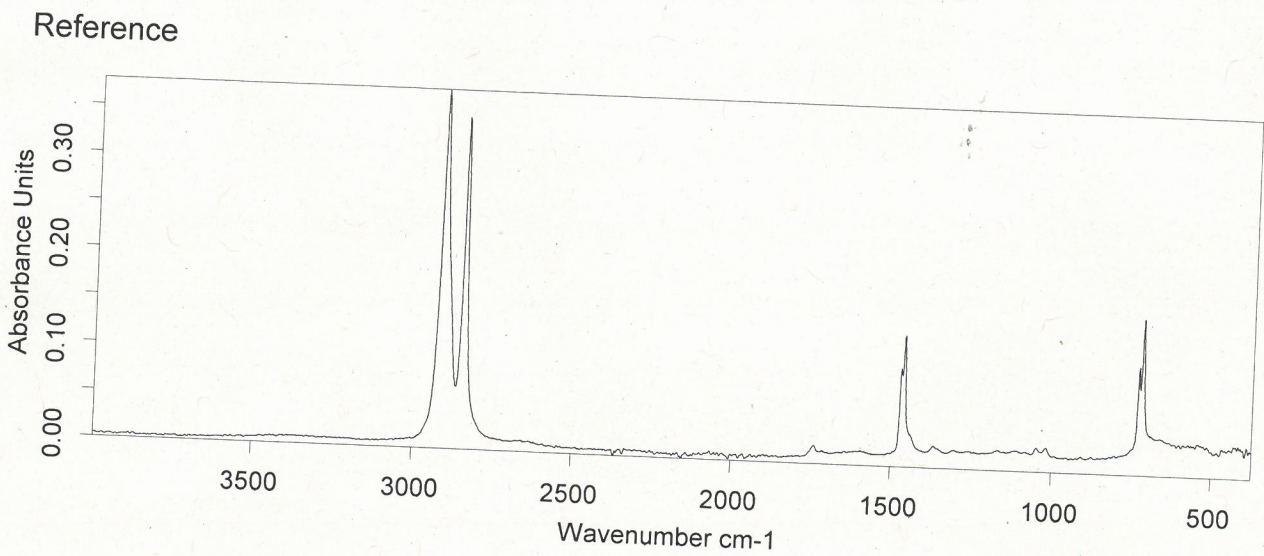
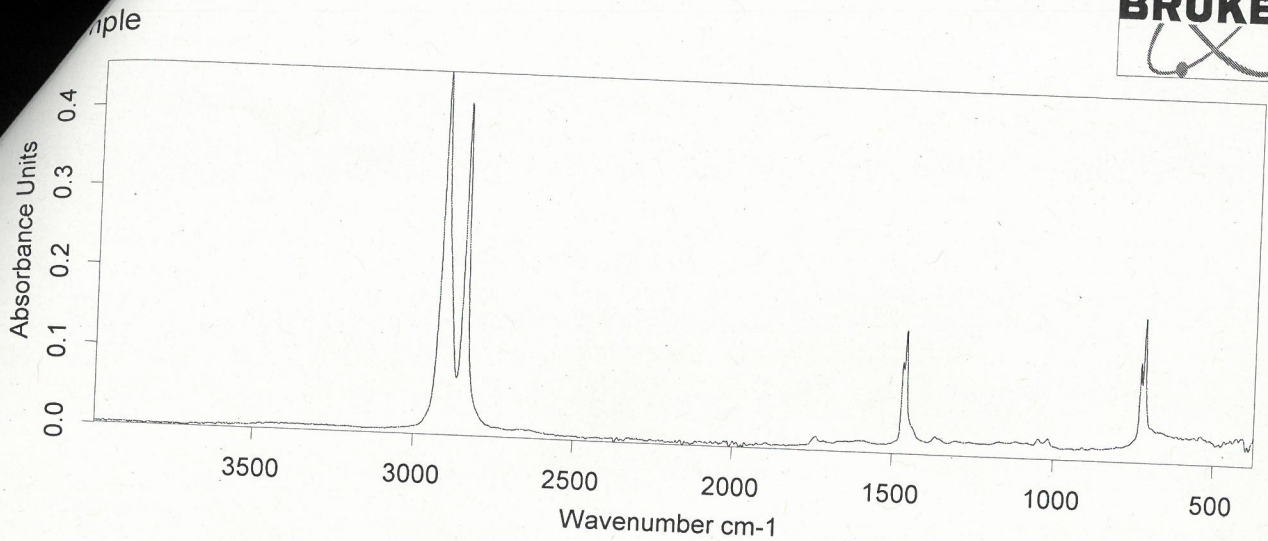
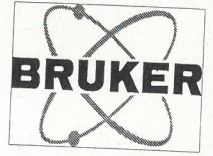
Storage time: Closure: max 3 years

Issued on 14.12.2020

KARSAI ALBA KFT.
Székesfehérvár, Zsurló u. 12.
Alba Ipari Zóna
Működési Igazgató
Szűcs Balázs
Q/A Manager



Spectra Comparison



Result: OK

Correlation: 99.90 %

Threshold: 95.00 %

Sample: Mûanyag flakon 40 ml Karsai Covit 20C14114601.3

Compared with Reference: Mûanyag flakon 40 ml Karsai Covit 20C14114601.2

Method file: Mûanyag flakon 40ml Karsai Covit Favipiravir.QCM (2020/12/15 18:45:06 (GMT+1))

Operator: Bajcsi Bettina

Date and time (measurement): 15/12/2020 19:45:19.270 (GMT+1)

Comment:



Bajcsi Bettina
Signature (Operator)

[Signature]
Signature (Release)

2020 DEC 16.

KARSAI ALBA KFT.

MŰBIZONYLAT

Előállító neve:	KARSAI ALBA KFT. 8000 SZÉKESFEHÉRVÁR Zsurló u. 12- Alba Ipari Zóna
Megrendelő neve:	Meditop Gyógyszeripari KFT. raktára
Termék megnevezés:	Kerek kupak Meditop flakonhoz D-161
Azonosító szám:	2046664/01; 2046685/01
Alapanyag / színező:	Tatren HM 5046
Mennyisége:	43 200 db
Gyártási idő:	2020.12.
A termék előállítása a gyártó és a megrendelő által kölcsönösen elfogadott jellemintának megfelelő előállítással történik. A termék toxikus anyagokat nem tartalmaz és nem ad le.	
Kelt: 2020.12.14.	
Kiállító:	Jóváhagyó:
Nagy Ibolya 	Sáfrány Balázs 

KARSAI ALBA KFT.
Székesfehérvár, Zsurló u. 12.
Alba Ipari Zóna
MINŐSÉGELLENŐRZÉS



meditop

Pharmaceutical Ltd.

ANALYTICAL REPORT

6016/2020

Name: Polypropylene lid D-161

Batch number: 2046685

Manufacturing date: 12/2020

Manufacturer: Karsai Alba Kft.

TESTS	ACCEPTANCE CRITERIA	<u>RESULTS</u>
Appearance	Red colour, odourless, plastic lid with induction insert	complies
- outside diameter - inside diameter	35.0 ± 1.0 mm 29.44 ± 0.5 mm	35.00 mm 29.54 mm
Checking of closure	Comply	complies

Remarks: -

Conclusion: Complies

Date: 17-12-2020

Signature:


Zsolt Öszi
Quality Control Manager

Declaration of Conformity

*The goods produced by the Karsai Alba Kft.
Address: 8000 Székesfehérvár, Zsurló u. 12., Hungary*

Product names:

D-161, Closures

Raw material: PP Tatren HM 50 46

Manufacturer of raw material: SLOVNAFT a.s

Colors: PE 4744 L red

Manufacturer of colors: Plasticolor Hungary Kft.

M-445, Containers

Raw material: PE BA 550-13

Manufacturer of raw material: MOL Petrolkémia Zrt.

Colors: HP17101

Manufacturer of colors: Gabriel Chemie

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 - The requirements of “Regulation (EC) 2023/2006 GMP and ISO 9001”.
- The overall migration limit of the product complies with Commission Regulation (EU) No 10/2011*

*Karsai Alba Kft. uses ISO 9001:2015, HACCP and BRC quality control systems.
The production of our products complies with the Regulation No 2023/2006/EK.
From the acquisition of the raw materials through the production until our final products we deliver we apply these rules in order to maintain the quality of our products.
The specified moulding technology and the production environment ensure that the chemical characteristics of the product material will not be changed during the production procedure.*

Storage conditions:

Original and closed packaging. Storage dry and dark place.

Temperature: 0-30 °C, Humidity: max 60% Rh

Storage time: Closure: max 3 years

Issued on 14.12.2020

KARSAI ALBA KFT.
Székesfehérvár, Zsurló u. 12.
Alba Ipari Zóna
Műhely utca 12/A
Sajrány Balázs
Q/A Manager

