

Pharmacopoeia Compliance Declaration

ADVANCENETM (EM-4925-AAH & EE-1801-AAB)

This is a declaration of compliance from ETHYDCO that ADVANCENE PE products (**EM-4925-AAH & EE-1801-AAB**) comply with the applicable requirements of the pharmacopoeia 3.1.5 “Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations”

The end-user has to ascertain that the final item is suitable to come into contact with the intended pharmaceutical products, in the expected use conditions, performing the specific tests prescribed by the pharmacopoeia monographs and by the relevant approval procedures

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication, however, we do not assume any liability whatsoever for the accuracy and completeness of such information.

ETHYDCO makes no warranties, which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of ETHYDCO's products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

ADVANCENE is a trademark of ETHYDCO.

Last Updated: February 2023

Certificate of Analysis

Client: Ethydco
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Egypt, NJ 23641

Project Number: 9713431957

Revision: 0
CofA Issued Date: 27 JAN 2023
9713431957

Attachments: FTIR Scans
1.20.23

Contact: Mohamed Ossama Mahdy Mohamed
mossama@ethydco-eg.com

- Test Methods:**
- Current EP Chapter 3.1.5 Polyethylene with Additives for Containers Parenteral Preparations and for Ophthalmic Preparations
 - TM-33, Test Method for Determination of Extractable Metals in Polyethylene as per USP <661.1> Plastic Materials of Construction/ EP 3.1.5 Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations using ICP-MS

Sample ID: 9713431957.1, EE-1801-AAB				
Test	Date Started	Acceptance Criteria	Result	Comment
EP 3.1.5 ID A: IR Spectrum	20Jan2023	N/A	See attached FTIR Scan Labeled 9713431957.1	For informational purposes only.
EP 3.1.5 Appearance of Solution	18Jan2023	Solution S1 is clear and colourless.	Solution S1 is clear and colourless.	Conforms
EP 3.1.5 Acidity/Alkalinity	18Jan2023	NMT 1.5 mL of 0.01 M NaOH is required to change the colour of the indicator to blue. Not more than 1.0 mL of 0.01 M HCl is required to initiate the colour change of the indicator from yellow to orange.	0.2 mL of 0.01M NaOH was required to change the colour of the indicator to blue and 0.1 mL of 0.01 M HCl was required to initiate the colour change of the indicator from yellow to orange.	Conforms
EP 3.1.5 Absorbance	18Jan2023	Maximum 0.2, between wavelengths 220 nm to 340 nm on solution S1.	The maximum absorbance on solution S1 was 0.0, @220 nm.	Conforms
EP 3.1.5 Reducing Substances	18Jan2023	The difference between the titration volumes is not greater than 0.5 mL.	The difference between the titration volumes is 0.2 mL.	Conforms
EP 3.1.5 / TM-33 Extractable Aluminum	06Jan2023	Maximum 1 ppm	0 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Chromium	06Jan2023	Maximum 0.05 ppm	0.00 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Titanium	06Jan2023	Maximum 1 ppm	0 ppm	Conforms

Sample ID: 9713431957.1, EE-1801-AAB				
Test	Date Started	Acceptance Criteria	Result	Comment
EP 3.1.5 / TM-33 Extractable Vanadium	06Jan2023	Maximum 0.1 ppm	0.0 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Zinc	06Jan2023	Maximum 1 ppm	0 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Zirconium	06Jan2023	Maximum 0.1 ppm	0.0 ppm	Conforms
3.1.5 Extractable Heavy Metals	19Jan2023	Maximum 2.5 ppm	Not more than 2.5 ppm was found.	Conforms
EP 3.1.5 Sulphated Ash	17Jan2023	Not more than 1.0 percent, determined on 5.0 g. This limit does not apply to material that has been opacified with titanium dioxide.	0.0 % determined on 5.0 g.	Conforms

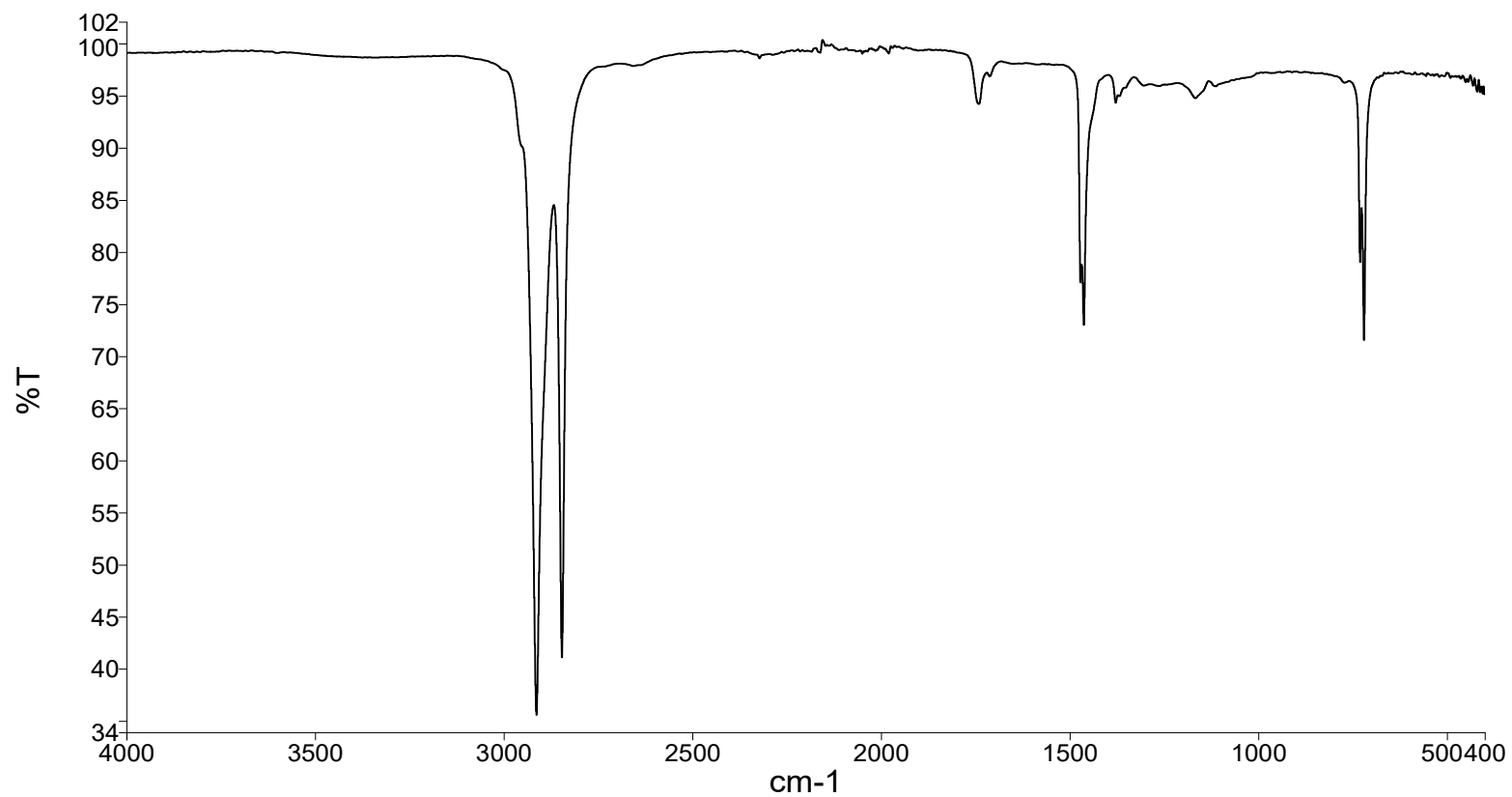
Sample ID: 9713431957.2, EM-4925-AAH				
Test	Date Started	Acceptance Criteria	Result	Comment
EP 3.1.5 ID A: IR Spectrum	20Jan2023	Absorption maxima at some of the following wavenumbers (tolerance: ± 5 cm^{-1}): at 2915 cm^{-1} , 2848 cm^{-1} , 1471 cm^{-1} , 1465 cm^{-1} , 729 cm^{-1} and 719 cm^{-1} . The spectrum obtained is identical to that obtained with the material selected for the type sample.	Absorption maxima at the following wavelengths: at 2915 cm^{-1} , 2847 cm^{-1} , 1472 cm^{-1} , 1462 cm^{-1} , 730 cm^{-1} and 719 cm^{-1} . The spectrum obtained is identical to that obtained with the material selected from the type sample USP HDPE RS Lot # R1490K0.	Conforms
EP 3.1.5 Appearance of Solution	18Jan2023	Solution S1 is clear and colourless.	Solution S1 is clear and colourless.	Conforms
EP 3.1.5 Acidity/Alkalinity	18Jan2023	NMT 1.5 mL of 0.01 M NaOH is required to change the colour of the indicator to blue. Not more than 1.0 mL of 0.01 M HCl is required to initiate the colour change of the indicator from yellow to orange.	0.2 mL of 0.01M NaOH was required to change the colour of the indicator to blue and 0.1 mL of 0.01 M HCl was required to initiate the colour change of the indicator from yellow to orange.	Conforms
EP 3.1.5 Absorbance	18Jan2023	Maximum 0.2, between wavelengths 220 nm to 340 nm on solution S1.	The maximum absorbance on solution S1 was 0.0, @220 nm.	Conforms
EP 3.1.5 Reducing Substances	18Jan2023	The difference between the titration volumes is not greater than 0.5 mL.	The difference between the titration volumes is 0.1 mL.	Conforms

Sample ID: 9713431957.2, EM-4925-AAH				
Test	Date Started	Acceptance Criteria	Result	Comment
EP 3.1.5 / TM-33 Extractable Aluminum	06Jan2023	Maximum 1 ppm	0 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Chromium	06Jan2023	Maximum 0.05 ppm	0.00 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Titanium	06Jan2023	Maximum 1 ppm	Less Than 1 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Vanadium	06Jan2023	Maximum 0.1 ppm	0.0 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Zinc	06Jan2023	Maximum 1 ppm	Less Than 1 ppm	Conforms
EP 3.1.5 / TM-33 Extractable Zirconium	06Jan2023	Maximum 0.1 ppm	Less Than 0.1 ppm	Conforms
EP 3.1.5 Extractable Heavy Metals	19Jan2023	Maximum 2.5 ppm	Not more than 2.5 ppm was found.	Conforms
EP 3.1.5 Sulphated Ash	17Jan2023	Not more than 1.0 percent, determined on 5.0 g. This limit does not apply to material that has been opacified with titanium dioxide.	0.0 % determined on 5.0 g.	Conforms

Laboratory Review:	Quality Assurance Approval:

Analyst
Date

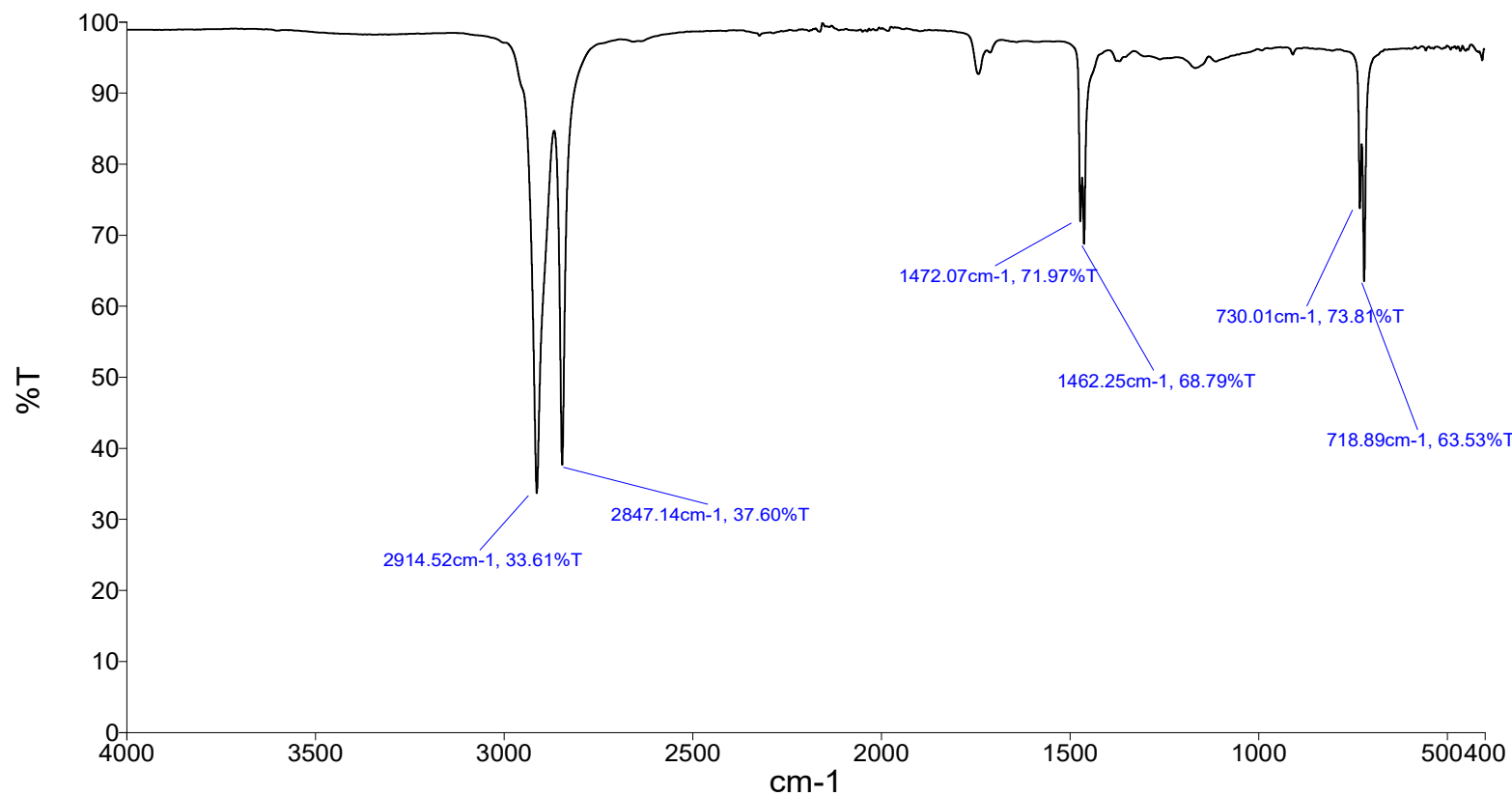
Clarence Clamor
Friday, January 20, 2023 4:22 PM



9713431957.1 20JAN2023 Sample 003 By CSANALYTICAL\clarence.clamor Date Friday, January 20 2023

Analyst
Date

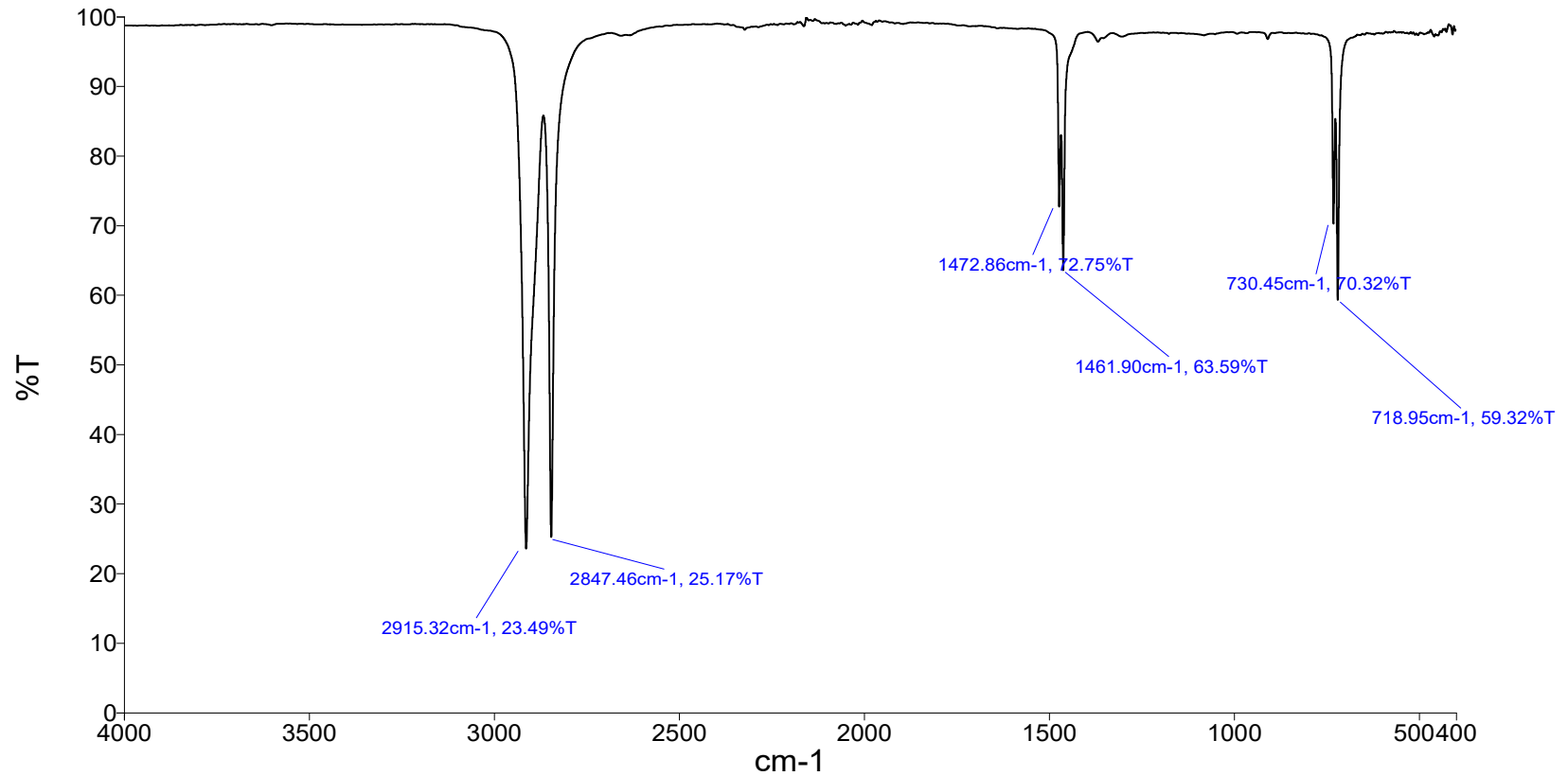
Clarence Clamor
Tuesday, January 24, 2023 1:52 PM



9713431957.2 20JAN2023 Sample 004 By CSANALYTICAL\clarence.clamor Date Friday, January 20 2023

Analyst
Date

Clarence Clamor
Tuesday, January 24, 2023 1:55 PM



USP HDPE RS Lot#R149K0 Sample 001 By CSANALYTICAL\clarence.clamor Date Thursday, March 24 2022