

Fagron Services B.V.
 Molenwerf 13
 Uitgeest, 1911 DB
 NL

Client Account Number: A00497292BNI
 Eurofins Quote Number: IOQ6PH19016880

General Method Reference: DAC Alfatradiol 2021/2

Eurofins Sample Number JJ22AA0436-1	
Original Received Date:	17-Jan-2022
Description:	Estradiolum (17 alfa-) Estradiolum (alfa-) DAC; 500246
Lot Number:	22A10-F02
Containers Submitted:	1 Container
Client Sample ID:	M001


Eurofins Sample Number JJ22AA0436-2	
Original Received Date:	17-Jan-2022
Description:	Estradiolum (17 alfa-) Estradiolum (alfa-) DAC; 500246
Lot Number:	22A10-F02
Containers Submitted:	1 Container
Client Sample ID:	M002

Eurofins Sample Number JJ22AA0436-3	
Original Received Date:	17-Jan-2022
Description:	Estradiolum (17 alfa-) Estradiolum (alfa-) DAC; 500246
Containers Submitted:	1 Container
Client Sample ID:	pool sample from M001+M002

Analysis/Sample	Specification	Result	Unit
Characters Appearance			
JJ22AA0436-1	White to almost white powder	Meets Requirements-White powder	----
JJ22AA0436-2	White to almost white powder	Meets Requirements-White powder	----
Method: DAC			
Analysis Date 09-Feb-2022 to 09-Feb-2022 for JJ22AA0436-1 through JJ22AA0436-2			

SPECIFICATIES
 GECONTROLEERD
 EN CONFORM

DATUM
 07-03-2022

PARAAF


Analysis/Sample	Specification	Result	Unit
Identity B			
JJ22AA0436-1	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those of the reference.	Meets Requirements	----
JJ22AA0436-2	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those of the reference.	Meets Requirements	----
Method: DAC 2.2.24 Analysis Date 09-Feb-2022 to 10-Feb-2022 for JJ22AA0436-1 through JJ22AA0436-2			
Optical rotation			
JJ22AA0436-3	+51 to +56	55	°
Method: Current Ph Eur (2.2.7) Analysis Date 09-Feb-2022 to 09-Feb-2022 for JJ22AA0436-3			
Related substances 1p/1i (UV detector)			
JJ22AA0436-3			
Impurity A	≤ 0.2	0.1	%
Impurity B	≤ 0.15	not detected	%
Impurity C	≤ 0.2	not detected	%
Impurity D	≤ 0.3	0.1	%
Any other impurity	≤ 0.10	< 0.05	%
Total impurities	≤ 1.0	0.2	%
Method: Current Ph Eur (2.2.29) and (2.2.46) Analysis Date 10-Feb-2022 to 11-Feb-2022 for JJ22AA0436-3			
Loss on drying			
JJ22AA0436-3	≤ 0.5	0.0	%
Method: Current Ph Eur (2.2.32) Analysis Date 08-Feb-2022 to 09-Feb-2022 for JJ22AA0436-3			
Sulfated ash			
JJ22AA0436-3	≤ 0.1	0.0	%
Method: Current Ph Eur (2.4.14) Analysis Date 17-Feb-2022 to 21-Feb-2022 for JJ22AA0436-3			

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 PARAF. *[Signature]*

Analysis/Sample	Specification	Result	Unit
Assay 1p/1i (LC/UV detector)			
JJ22AA0436-3			
Dried substance	97.0 - 102.0	100.2	%
Method: Current Ph Eur (2.2.29) and (2.2.46)			
Analysis Date 10-Feb-2022 to 11-Feb-2022 for JJ22AA0436-3			
Ph Eur Identification and Control of Residual Solvents Class 1,2 Procedure i and ii, System A			
JJ22AA0436-3			
Methanol	≤ 3000	Not detected	ppm
Tetrahydrofuran	≤ 720	Not detected	ppm
Method: Current EP 2.4.24			
Analysis Date 10-Feb-2022 to 17-Feb-2022 for JJ22AA0436-3			
Sample Compliance Assessment			
Samples JJ22AA0436-1 through JJ22AA0436-3 meet the requirement(s) for all listed test(s) where specifications were applied.			

Contracted Company: PROXY Laboratories Chemistry and Biochemistry

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Questions about this report should be directed to your project manager or the general email listed above.

