

CYCLAVANCE 100MG/ML BELS.OLDAT 15ML
Gysz: 2020-04/308915 Lej: 2022-07-31
Kisz: 1X Me: Doboz
SZÉKELY KFT részére

Szállító:
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CERTIFICATE OF ANALYSIS



Product: CYCLAVANCE

Analysis type: Finished Product

Code: 11035285

Production Date: 20/07/2020

Analysis Number: 54.930 (64157,64158)

Expiry Date: 07/2022

Result: Within specifications

Bibliography: S.O.P. No. 106021

Batch: 2020-04

Registry: 1015047

Batch size: 600 L

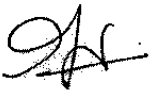

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Analysis date: 07/09/2020

Format: 15 ml

Test	Specification	Result
- Description: Liquid	Clear and slightly yellow solution.	Complies
- Identification by H.P.L.C.	Ciclosporin: Rt corresponds to reference standard	Complies
- Identification by H.P.L.C.	Alpha-tocopherol: Rt corresponds to reference standard	Complies
- Identification by H.P.L.C./D.A.D.	Ciclosporin: UV spectrum corresponds to reference standard	Complies
- Identification by H.P.L.C./D.A.D.	Alpha-tocopherol: UV spectrum corresponds to reference standard	Complies
- Clarity of the solution	Clear solution	Complies
- Colour of the solution	Y3 - Y4	Complies
- Relative Density	0.98 - 1.02	1.00
- Extractable Volume	>= 15 ml	Complies
- Assay by H.P.L.C.	Ciclosporin: 95.0 - 105.0 mg/ml	103.2 mg/ml
- Assay by H.P.L.C.	Alpha-tocopherol: 0.90 - 1.10 mg/ml	0.97 mg/ml
- Total Aerobic Microbial Count	<= 1000 cfu/ml	<1 cfu/ml
- Total Yeast and Moulds Count	<= 100 cfu/ml	<1 cfu/ml
- Escherichia coli	Absence/ml	Complies

GMP tested

Reviewed by Quality Control Anna Puig Ruiz  Date: 07/09/2020	Approved by Qualified Person Luisa Reyes Alcalde  Date: 07/09/2020
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Date: 07/09/2020/10:42:02 From: LWLIMS7

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