



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241783

Product:	18B-GLYCYRRHETIC ACID (ENOXOLONE)
Lot:	241783
Expiry date:	04/04/2029
Reference:	Cumple PhEur11.5
Synonyms:	Acido glicirretínico.
Formula:	C30H46O4
Molecular weight:	470,67 g/mol

Assay	Result	Specification
Identification	Conform (A)	Test RFE/Ph. Eur.
Organoleptic properties	Conform	RFE/Ph. Eur.
Appearance of solution	Conform	
Related substances (HPLC)	Conform	Test RFE/Ph. Eur.
Heavy metals	<= 20 ppm	<= 20 ppm
Specific rotation	+149	(+145) - (+154)
Loss on drying	0,12 %	<= 0,5 %
Sulphated ashes	0,1 %	<= 0,2%
Assay	99,3 %	98,0 - 101,0 %
Impurity A	0,03 %	<= 0,15%
Impurity B	0,2 %	<= 0,7 %
Impurity C	0,04 %	<= 0,15%
Unspecified Impurities	0,05 %	<= 0,10%
Total impurities	0,4 %	<= 1,0 %

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 19/09/2024

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Product	Name	Capacity	Batch
1102340	AC.GLICIRRETICO 18B-ENOXOLONA	500 g	241783-O-1
1102340	AC.GLICIRRETICO 18B-ENOXOLONA	500 g	241783-O-2
1102341	AC.GLICIRRETICO 18B-ENOXOLONA	100 g	241783-J-1
1102341	AC.GLICIRRETICO 18B-ENOXOLONA	100 g	241783-J-2
1102343	AC.GLICIRRETICO 18B-ENOXOLONA	5 g	241783-E-1
1102343	AC.GLICIRRETICO 18B-ENOXOLONA	5 g	241783-E-2

1102344	AC.GLICIRRETICO 18B-ENOXOLONA	25 g	241783-G-1
1102344	AC.GLICIRRETICO 18B-ENOXOLONA	25 g	241783-G-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

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