



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis Nº: 260086

Product:	ADAPALENE
Lot:	260086
Expiry date:	30/10/2030
Reference:	Cumple PhEur12.1
Synonyms:	Adapalene, Adapalenum
Formula:	C28H28O3
Molecular weight:	412.5 g/mol

Assay	Result	Specification
Identification	Conform	
Organoleptic properties	Conform	
Appearance of solution	Conform	
Related substances (HPLC)	Conform	
Loss on drying	0,09 %	<= 0,5 %
Sulphated ashes	0,05 %	<= 0,1 %
Assay (HPLC)	99,9 %	98,0 - 102,0 %
Impurity A	< 0,05 %	<= 0,3 %
Impurity D	< 0,05 %	<= 0,2 %
Impurity C	< 0,05 %	<= 0,15 %
Unspecified Impurities	< 0,05 %	<= 0,10 %
Total impurities	< 0,05 %	<= 0,5 %
Elemental impurities	Conform	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm
Nitrosamine impurities	Conform	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm
Residual solvent: Methyl ethyl ketone	< 5000 ppm	<= 5000 ppm
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm
Residual solvent: Toluene	< 890 ppm	<= 890 ppm
Residual solvent: Dimethyl sulfoxide	< 5000 ppm	<= 5000 ppm

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, sparingly soluble in tetrahydrofuran, practically insoluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/01/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00146 BAL PHARMA LIMITED

Manufacturer batch: 1501052511003

Product	Name	Capacity	Batch
1115230	ADAPALENO	1 g	260086-D-1
1115231	ADAPALENO	5 g	260086-E-1

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.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 20/02/2026

