FARMABIOS
Via Pavia,1 - 27027 Gropello Cairoli PV, Italy
Tel. +39 0382 819.1 - Fax +39 0382 815886

CERTIFICATE OF ANALYSIS

Product Name **FLUDROCORTISONE ACETATE MICRONIZED**

According to **Ph.Eur. - USP**

Batch Nr.	**2142AM0**	**B0022123**	**Manufacturing Date**	**01/OCT/2021**	**Expiration Date**	**01/OCT/2026**	
Analysis record Nr.	**202107676**	**Net weight**	**Nr. of packages**		**CoA Version**	**4.0**	

Appearance White to almost white, microcrystalline powder, practically insolubile in Water, sparingly soluble in Ethanol and Chloroform, slightly soluble in Ether.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR,TLC methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (after 3 hours at 105°C)	0.06	<= 1.0	%
WATER CONTENT (KF)	0.19	<= 1.0	%
SPECIFIC OPTICAL ROTATION (EP) (c = 1% in Dioxane)	+151.7	+148.0 - +156.0	° o.d.b.
SPECIFIC OPTICAL ROTATION (USP) (c = 0.5% in Acetone)	+132.7	+126.0 - +138.0	° o.d.b.
SPECIFIC ABSORBANCE (in Ethanol at about 238 nm)	401.3	393.0 - 417.0	A(1%,1cm) o.d.b.
RESIDUE ON IGNITION	0.00	<= 0.1	%
RELATED SUBSTANCES (HPLC method)			
Cortisone acetate	< 0.05	<= 0.15	% Vs Std
Any unspecified impurity	0.09	<= 0.10	% Vs Std
Total impurities	0.16	<= 1.5	%
ASSAY (HPLC method)	99.5	97.0 - 103.0	% *
ASSAY (Spectrophotometric method)	99.1	97.0 - 103.0	%
RESIDUAL SOLVENTS (HS-GLC methods)			
Methanol	N.D.	<= 200	ppm
Ethanol	< 26	<= 200	ppm
Methylene Chloride (*)	N.D.	<= 100	ppm
Ethyl Acetate	312	<= 2000	ppm
Tetrahydrofuran	637	<= 720	ppm
Pyridine	N.D.	<= 80	ppm
Dimethylformamide	N.D.	<= 500	ppm
(*)No potential for other "OVIs" USP <467> presence because not used in the process.			
COLOUR OF SOLUTION (c=10% in Dimethyl Sulfoxide w/v at 400 nm)	0.057	<= 0.100	A.U.

**** as C23H3FO6 on dried basis referred to the Std.***

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
18/FEB/2022	23/FEB/2022	VIVIANA BOTTIROLI	23/FEB/2022	SABRINA ABBIATI

"Certificate of Conformance (CoC)": The Qualified Person hereby confirm that that the API has been manufactured and packaged in compliance with cGMP, the product registration, applicable laws or regulations and tested according to the approved specifications.
This Certificate of analysis has been produced by a electronic validated system and it is valid without a signature.

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TESTS	RESULTS	SPECIFICATIONS	UNITS
MELTING POINT	230.4	226.0 - 236.0	° C
PARTICLE SIZE (Laser Scattering method)			
Particle <= 30 µm	100.0	>= 99.0	% of total volume
Particle <= 15 µm	100.0	>= 95.0	% of total volume
Particle <= 5 µm	89.0	>= 75.0	% of total volume

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