



Page 1 of 2

According to Ph. Eur. - USP current edition

Appearance	White to almost white crystalline powder. Practically insoluble in Water and Heptane; soluble in Methanol, anhydrous Ethanol and Acetone; slightly soluble in Ether and Chloroform. It melts at about 270°C, with decomposition.
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TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR, HPLC methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (after 3 hours at 100 - 105 °C)	0.45	<= 1.0	%
SPECIFIC OPTICAL ROTATION (E.P.) (c = 1% in Ethanol)	+101.7	+100.0 - +104.0	° o.d.b.
SPECIFIC OPTICAL ROTATION (USP) (c = 1% in Methanol)	+100.4	+98.0 - +108.0	° o.d.b.
SPECIFIC ABSORBANCE (at about 238 nm)	351.3	344.0 - 366.0	A(1%,1cm) o.d.b.
RELATED SUBSTANCES (HPLC method)			
17beta-Acid Analog (Imp. B - EP)	N.D.	<= 0.10	% Vs Std
Fluocinolone (Imp. C - EP)	N.D.	<= 0.10	% Vs Std
21-Acid Analog (Imp. A - EP)	N.D.	<= 0.10	% Vs Std
21-Aldehyde Analog (Imp. D - EP)	0.02	<= 0.2	% Vs Std
Triamcinolone Acetonide (Imp. H- EP)	0.10	<= 0.15	% Vs Std
Delta-14 Fluocinolone Acetonide (Imp. I - EP)	0.03	<= 0.15	% Vs Std
6alpha-Fluoro, 9,11-Epoxy Prednisolone 16,17 Acetonide (Imp. E - EP)	N.D.	<= 0.10	% Vs Std
Fluocinonide (Imp. M - EP)	N.D.	<= 0.10	% Vs Std
Flurandrenolide 21-Acetate (Imp. G - EP)	N.D.	<= 0.10	% Vs Std
Any unspecified impurity	0.01	<= 0.10	% Vs Std
Total impurities	0.15	<= 0.7	%
ASSAY (HPLC method)	99.9	97.5 - 102.0	% *
ASSAY (Spectrophotometric method)	99.0	97.0 - 102.0	%

* as C₂₄H₃₀F₂O₆ on dried basis referrend to the Std

Assay Date 16/02/2018	Print Date 20/02/2018	Q.C. department FABIO VECCHIO	Release Date 20/02/2018	Qualified Person SABRINA ABBIATI
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"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.



Page 2 of 2

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Analysis record Nr.	201800516	Net weight	Nr. of packages	CoA Version	1.0
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[illegible]

* as C₂₄H₃₀F₂O₆ on dried basis referrend to the Std

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
16/02/2018	20/02/2018	FABIO VECCHIO	20/02/2018	SABRINA ABBATI

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