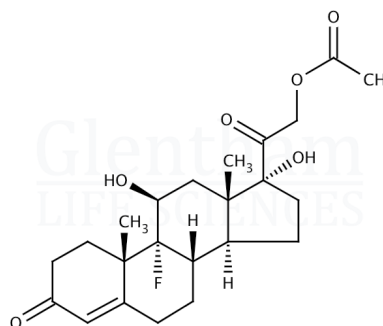


Product Specification

Product Name	Fludrocortisone acetate, Ph. Eur., USP grade
Glentham Code	GL6401
CAS Number	514-36-3
EINECS	208-180-4
MDL Number	MFCD00864160
Molecular Weight	422.49
Molecular Formula	$C_{23}H_{31}FO_6$
Storage Temp.	+20°C



Property	Specification
Physical Description	White to almost white crystalline powder
Identification	IR, TLC
Solubility	Practically insoluble in water, sparingly soluble in ethanol and chloroform
Specific Optical Rotation	+148.0 - +156.0 ° (Ph. Eur. test, c=1%, dioxane)
Specific Optical Rotation	+126.0 - +138.0 ° (USP test, c=0.5%, acetone)
Specific Absorption (E1%/1cm)	393.0 - 417.0 (ethanol, ~238nm)
Any Individual Impurity (HPLC)	≤ 0.15%
Total Impurities (HPLC)	≤ 1.5%
Residue on Ignition	≤ 0.1%
Melting Point	226.0 - 236.0 °C
Water (KF)	≤ 1.0%
Loss on Drying	≤ 1.0% (3h, 105°C)
Assay (HPLC)	97.0 - 103.0 %
Assay (spectrophotometry)	97.0 - 103.0 %
Pharmacopoeia Specification(s)	Ph. Eur., USP

Specification Version	- v1.0
Date Created	- 2017-01-25

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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