## **Product Specification**



## **PRODUCT** Hydrocortisone Acetate Ph. Eur.

CAS no. [50-03-3]

CHARACTERISTICS White or almost white, crystalline powder.

Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride.

TEST	SPECIFICATION	
Assay	97.0% - 102.0% (dried basis)	
Identification	Conforms to Ph. Eur. tests	
Specific rotation	+158° to +167°	
Loss on drying	Not more than 0.5%	
Related substances	Impurity C (prednisolone acetate)	Not more than 0.6%
	Impurity A (hydrocortisone)	Not more than 0.4%
	Impurity B (oxenol)	Not more than 0.3%
	Impurity D (cortisone acetate)	Not more than 0.3%
	Impurity E*	Not more than 0.3%
	Impurity G**	Not more than 0.15%
	Unspecified impurities	Not more than 0.10%
	Total impurities	Not more than 1.0%

<sup>\*</sup> impurity E: 17-hydroxy-3,20-dioxopregna-4,9(11)-dien-21-yl acetate

**ENQUIRY** 

<sup>\*\*</sup> impurity G: 17-hydroxy-3,20-dioxopregn-4-ene-11β,21-diyl diacetate