

Product Specification

medex

PHARMACEUTICALS · CHEMICALS

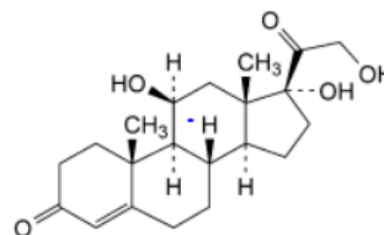
A HOBART COMPANY

PRODUCT Hydrocortisone EP/BP

CAS no. [50-23-7]

C₂₁H₃₀O₅

SYNONYMS Cortisol



CHARACTERISTICS White or almost white, crystalline powder.
Practically insoluble in water, sparingly soluble in acetone and in alcohol, slightly soluble in methylene chloride. It shows polymorphism.

TEST	SPECIFICATION																																	
Content	97.0% – 103.0% (dried basis)																																	
Identification	Complies with EP/BP tests																																	
Specific optical rotation	+162° to +168°																																	
Related Substances	<table><tbody><tr><td>Impurity A*</td><td>prednisolone</td><td>Maximum 0.2%</td></tr><tr><td>Impurity B*</td><td>cortisone</td><td>Maximum 0.2%</td></tr><tr><td>Impurity C*</td><td>hydrocortisone acetate</td><td>Maximum 0.5%</td></tr><tr><td>Impurity D*</td><td>6β-hydroxyhydrocortisone</td><td>Maximum 0.5%</td></tr><tr><td>Impurity E*</td><td>Δ6-hydrocortisone</td><td>Maximum 0.5%</td></tr><tr><td>Impurity F*</td><td>Reichstein's substance S</td><td>Maximum 0.3%</td></tr><tr><td>Impurity G*</td><td>hydrocortisone-21-aldehyde</td><td>Maximum 0.4%</td></tr><tr><td>Impurity H*</td><td>7α-hydroxyhydrocortisone</td><td>Maximum 0.15%</td></tr><tr><td>Impurity N*</td><td>hydrocortisonedimer</td><td>Maximum 0.15%</td></tr><tr><td>Unspecified impurities</td><td></td><td>Maximum 0.10%</td></tr><tr><td>Total impurities</td><td></td><td>Maximum 2.0%</td></tr></tbody></table>	Impurity A*	prednisolone	Maximum 0.2%	Impurity B*	cortisone	Maximum 0.2%	Impurity C*	hydrocortisone acetate	Maximum 0.5%	Impurity D*	6β-hydroxyhydrocortisone	Maximum 0.5%	Impurity E*	Δ6-hydrocortisone	Maximum 0.5%	Impurity F*	Reichstein's substance S	Maximum 0.3%	Impurity G*	hydrocortisone-21-aldehyde	Maximum 0.4%	Impurity H*	7α-hydroxyhydrocortisone	Maximum 0.15%	Impurity N*	hydrocortisonedimer	Maximum 0.15%	Unspecified impurities		Maximum 0.10%	Total impurities		Maximum 2.0%
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Loss on drying	Maximum 1.0%																																	

STORAGE Store in a well-closed airtight containers in a cool, dry place and protected from light.

PRODUCT NAMED ABOVE COMPLIES WITH THE SPECIFICATION OF THE EP/BP.



Hydrocortisone EP/BP