

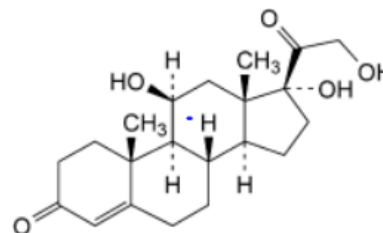
# Product Specification

## PRODUCT Hydrocortisone EP/BP

CAS no. [50-23-7]

C<sub>21</sub>H<sub>30</sub>O<sub>5</sub>

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 border="0"> <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></td> <td>Unspecified impurities</td> <td>Maximum 0.10%</td> </tr> <tr> <td></td> <td>Total impurities</td> <td>Maximum 2.0%</td> </tr> </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.**

