

QUALITY CERTIFICATE

Product name: PREDNISOLONE
Quality: Ph.Eur.11.0.
Package: 2 g
Formula: $C_{21}H_{28}O_5$
Rel. mol. weight: 360,44
Lot No.: GE5056054
Manufacturing date: 07.2023.
Expiry date: 30.06.2025. (DMY)
Anal. No.: 15508H56054

	REQUIRED	MEASURED
Appearance:	white or almost white hygroscopic crystalline powder	white hygroscopic powder
Identity (IR)	identical	identical
Specific optical rotation (20 °C)(dried substance)	(+113) - (+119)	+115,1
Solubility	very slightly soluble in water, soluble in ethanol (96 per cent) and in methanol	very slightly soluble in water, soluble in ethanol (96 per cent) and in methanol
Related substances (HPLC)	passes test	megfelel
Impurity A	max.1,0 %	0,57 %
Impurity B	max.0,3 %	<0,05 %
Impurity C	max.0,3 %	<0,05 %
Impurity F	max.0,5 %	<0,05 %
Impurity J	max.0,3 %	<0,05 %
Unspecified impurities	max.0,1 %	0,06 %
Total impurities	max.1,5 %	0,63 %
Loss on drying (105 °C)	max.1,0 %	0,1 %
Assay (HPLC)	96,5-102,0 %	101,4 %

The Product complies with the requirements of Ph.Eur.11.0.

Kiállítva: Halásztelek, 2023.10.03.


Nagy Balázs

minőségbiztosítási vezető

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