

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.: GM8859813
Manufacturing date: 02.2024.
Expiry date: 08.04.2027. (DMY)
Anal. No.: 17940H59813

	REQUIRED	MEASURED
Appearance:	white or almost white hygroscopic crystalline powder	fehér, higroszkópos, kristályos por
Identity (IR)	identical	identical
Specific optical rotation (20 °C)(dried substance)	(+113) - (+119)	+116,0
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	passes test
Impurity A	max.1,0 %	<1,0 %
Impurity B	max.0,3 %	<0,3 %
Impurity C	max.0,3 %	<0,3 %
Impurity F	max.0,5 %	<0,5 %
Impurity J	max.0,3 %	<0,3 %
Unspecified impurities	max.0,1 %	<0,1 %
Total impurities	max.1,5 %	<1,5 %
Loss on drying (105 °C)	max.1,0 %	0,1 %
Assay (HPLC)	96,5-102,0 %	99,3 %

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

Kiállítva: Halásztelek, 2024.04.30.


Nagy Balázs

minőségbiztosítási vezető

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