

## CERTIFICATE OF ANALYSIS

Product Name:	Prednisolone	CAS No. :	50-24-8
Molecular Formula:	C <sub>21</sub> H <sub>28</sub> O <sub>5</sub>	Molecular Weight:	360.45
Batch No:	ST210301	Quantity:	100KG
Manufacturing date:	2021.03.01	Expire date:	2024.03.01

Item	Specification	Results
Appearance	White to almost white crystalline powder	White crystalline powder
Identification	A: IR spectrum of sample corresponds to with that of reference standard	Conforms
	B: Absorptivities at 242nm, calculated on the dried basis, do not differ by more than 2.5%	Conforms
Specific rotation	+97° ~ +103°	+100°
Loss on drying	≤1.0%	0.46%
Residue on ignition	Negligible, from 100mg	Conforms
Selenium	≤0.003%	<0.003%
Related substances		
Any individual impurity	≤1.0%	0.74%
Total impurities	≤2.0%	0.74%
Assay	97.0%-102.0%	99.2%

Conclusion	The batch is in compliance with USP40.
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Hangzhou Sartort Chemical Co., LTD

QC:

May Liu

QA:

Cathy Shen

## CERTIFICATE OF ANALYSIS

Product Name:	Prednisolone	CAS No. :	50-24-8
Molecular Formula:	C <sub>21</sub> H <sub>28</sub> O <sub>5</sub>	Molecular Weight:	360.45
Batch No:	ST210122	Quantity:	134.50KG
Manufacturing date:	2021.01.22	Expire date:	2024.01.21

Item	Specification	Results
Appearance	white or almost white crystalline powder	almost white crystalline powder
Identification(IR,TLC)	complies with the standard	Conforms
Solubility	very slightly soluble in water, soluble in ethanol(96 per cent) and in methanol, sparingly soluble in acetone, slightly soluble in methylene chloride.	Conforms
Specific optical rotation	+113° ~ +119°	+116°
Loss on drying	≤1.0%	0.17%
Residual solvents		
Dichloromethane	≤3000ppm	Conforms
Methanol	≤600 ppm	Conforms
Related substances		
Impurity A	≤ 1.0%	0.40%
Impurity F	≤ 0.5%	<0.05%
Impurity B	≤ 0.3%	<0.05%
Impurity C	≤0.3%	<0.05%
Impurity J	≤0.3%	<0.05%
Any unspecified impurity	≤0.10%	0.08%
Total impurities	≤1.5%	0.53%
Assay	97%~103.0%	100.1%

Conclusion	The batch is in compliance with EP9.0.
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QC:

Maylin

Hangzhou Sartort Chemical Co., LTD

QA:

Cathy Shen