



Record Code	Effective Date
AOP172-02R04	2025-08-29

Xianju Pharmaceutical Co., Ltd.
Certificate of Analysis

Product	Dexamethasone	Batch No.	QP111-251001
Amounts	67.30kg	Manufacture Date	2025-10-20
According To	USP 2025 And Customer Standard	Retest Date	2030-10-20

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White to almost white crystalline powder	Almost white crystalline powder
Identification	(A): Complies by IR	Conforms
Identification	(B): Complies by HPLC	Conforms
Specific Rotation	+72° ~ +80°	+76°
Related Substances	16 α -Methylprednisone \leq 0.15%	Not detected
Related Substances	Betamethasone \leq 0.15%	Not detected
Related Substances	Dexamethasone 7,9-diene \leq 0.10%	0.05%
Related Substances	Desoximetasone \leq 0.15%	Not detected
Related Substances	Dexamethasone acetate \leq 0.30%	Not detected
Related Substances	Any individual unspecified impurity \leq 0.10%	Not detected
Related Substances	Total impurities \leq 0.5%	0.05%
Loss On Drying	\leq 0.5%	0.4%
Residue On Ignition	\leq 0.2%	0.08%
Residual Solvents	Chloroform \leq 60ppm	Not detected
Residual Solvents	Methanol \leq 1000ppm	184ppm
Residual Solvents	Ethyl acetate \leq 300ppm	14ppm
Assay	Contains 97.0% to 102.0% of C ₂₂ H ₃₅ FO ₅ calculated on the dried basis	100.8%
Particle Size (Volume Method)	D90 $<$ 20 μ m	3 μ m

Conclusion: The Product Conforms To USP 2025(Official as of 2020-05-01) And Customer Standard.

Reported by: *汪如辰*

Date: *2025-12-05*

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Checked by: *林*

Date: *2025-12-05*