

CERTIFICATE OF ANALYSIS

Product name	Dexamethasone BASE	Batch No.	20170114
Manuf. Date	2017-1-14	Expiry Date	2022-1-13
Quantity	50.5Kgs	Test Standard	EP9

TEST	SPECIFICATIONS	RESULTS
Description	A white or almost white powder	white powder
IDENTIFICATION	(1)complies by IR (2) complies by TLC	CONFORM CONFORM
SPECIFIC ROTATION	+86 ° ~ + 92°	+89.4°
Chromatographic purity	Impurity G ≤0.3% Impurity B ≤0.15% Impurity F ≤0.15% Impurity J ≤0.15% Impurity K ≤0.15% INDIVIDUAL UNKNOWN IMP. ≤0.10% TOTAL impurities ≤0.5%	0.02% 0.06% Undetected 0.01% Undetected 0.04% 0.20%
LOSS ON DRYING	≤0.5%	0.1%
ASSAY	97.0 ~ 103.0%	98.7%

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light

Conclusion: The product complies with the requirements of EP9 standard

Quality Manager:

朱永章

Rechecker:

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Analyst:

刘洪

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