

南通精华制药股份有限公司检验报告

NANTONG JINGHUA PHARMACEUTICAL CO. LTD.

CERTIFICATE OF ANALYSIS

APIs.ADD:43 Yaogang Road,Nantong Jiangsu China

Tel:86-513-85609405/85609406

苯巴比妥

PHENOBARBITAL

Batch No.	BBT2012100	Manufacture Date	2012.6.1
Total Quantity	502.0KG	Report Date	2012.6.5
Commercial Quantity	500.0KG	Re-test Date	2015.5.31
Inspection No.	120100226		

TEST	SPECIFICATIONS		RESULTS
	(Ph.Eur)	(USP)	
Characteristics	A white, crystalline Powder or colourless crystals	White, odorless, glistening Small crystals, or white, crystalline powder	Complies
Identification	B. IR C.TLC D. chemical test	A. IR B. HPLC	Complies
Melting Point	≈176°C (≤2°C)	174~178°C (≤2°C)	175.5~176.5°C(0.5°C)
Appearance of Solution	Clear, ≤Y6		<Y6
Acidity	Complies		Complies
Related substances(HPLC)	Impurity A	≤0.15%	N.D.
	Impurity B	≤0.15%	N.D.
	unspecified impurities	≤0.10%	0.05%
	Total	≤0.2%	0.06%
Loss on drying	≤0.5%	≤1.0%	0.16%
Sulphated ash	≤0.1%		0.05%
Residue on ignition		≤0.15%	0.05%
Assay	99.0~101.0% 100.16%	98.0~101.0%	99.08%

(Calculated on the dried basis)

Conclusion The product meets the requirements of Ph.Eur.7.4 /USP 34

Analyst *[Signature]*
2012.6.5

Supervisor *[Signature]*
2012.6.5

Chief of Laboratory *[Signature]*
QA Release Date *[Signature]* 2012.6.5

