

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13I 10-007

Director Técnico

BI 130853

精华制药集团南通有限公司检验报告

NANTONG JINGHUA PHARMACEUTICAL CO. LTD.

CERTIFICATE OF ANALYSIS

APIs.ADD: 2-02# Crossroad Between 3 Haibin Road and 2 Tonghai Road, Yanhai Economic

Development Zone, Rudong, Nantong Jiangsu China, 226407

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保 泰 松

PHENYLBUTAZONE

Batch No.	BTZ2013156	Manufacture Date	2013.7.19
Total Quantity	251.8KG	Report Date	2013.7.26
Commercial Quantity	250.0KG	Re-test Date	2016.7.18
Inspection No.	130400202		

TEST	SPECIFICATIONS (Ph.Eur.)	RESULTS
Characteristics	white or almost white, Crystalline powder	Complies
Identification	B. TLC C. IR D. chemical test	Complies
Melting Point	104~107°C	105.0-106.0°C
Appearance of solution	The solution is clear	Complies
Acidity or alkalinity	≤0.5ml of 0.01M NaOH, ≤0.6ml of 0.01MHCl by 0.5g sample	Complies
Absorbance	420nm, ≤0.20	0.08
Related substances	Impurity A ≤0.25% Impurity B ≤0.25% Impurity C ≤0.20% Impurity E ≤0.0005% Any other impurity ≤0.10% Total ≤0.5%	N.D. 0.16% 0.03% <LOD, LOD=0.00005% 0.01% 0.20%
Heavy metals	≤0.002%	<0.002%
Loss on drying	≤0.2%	0.08%
Sulphated ash	≤0.1%	0.07%
Assay	99.0~101.0%	100.33%
(Calculated on the dried basis)		

Conclusion The product meets the requirements of Ph.Eur. 7.0

Analyst

Supervisor

Chief of Laboratory

QA Release Date

2013.7.26

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