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浙江海森药业有限公司检验报告书

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ZHEJIANG HAISEN PHARMACEUTICAL CO., LTD.
CERTIFICATE OF ANALYSIS

产品名称 Product Name	安乃近 Analgin - METAMIZOL SODICO		
批　号 Batch No.	20110705-5	数量/规格 Quantity/Spec.	1000kg/25kg/drum
生产日期 Manufacturing Date	2011.07.05	有效期至 Expiry Date	2015.07.04
报告编号 Report No.	201107027	报告日期 Report Date	2011.07.07

项　目 Contents	标　准：EP6 Standard: EP6	检验结果 Results of analysis
性状 Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	类白色结晶性粉末 Almost white crystalline powder
溶液性状 Appearance of solution	符合规定 Meets the requirements	符合 Conform
鉴别 Identification	A.红外光吸收图谱与对照品图谱相一致。 Comparing with the spectrum obtained with CRS. B.呈正反应 Positive. C.呈正反应 Positive. D.呈正反应 Positive.	符合 Conform 符合 Conform 符合 Conform 符合 Conform
硫酸盐 Sulfate	≤0. 1% Not more than 0. 1%	<0. 1%
酸碱度 Acidity or alkalinity	符合规定 Meets the requirements	符合 Conform
重金属 Heavy metals	≤0. 002% Not more than 0. 002%	<0. 002%
相关物质 Related substances	杂质 C　≤0. 5% Impurity C not more than 0. 5% 其它杂质 ≤0. 2% Any other impurity not more than 0. 2% 总杂质　≤0. 5% Total impurity not more than 0. 5%	未检出 Negative 0.14% 0.17%
干燥失重 Loss on drying	4. 9%～5. 3%	5. 2%
含量(以干品计) Assay (on drying)	99. 0%～100. 5%	99. 5%

结论：符合 EP6
Conclusion: Conforming to EP6

浙江海森药业有限公司
ZHEJIANG HAISEN PHARMACEUTICAL CO.,LTD.

DIRECTOR OF QC DEPT　WANG ZONGDAO
CHECKER　CAI YUEJUN
TECHNICIAN OF QC DEPT　LI YAFEN

GMP ISSUE DATE AND VALIDITY：11/28/2009 AND 11/27/2014
BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP NUMBER: 浙K0714
BATCH PRODUCTION RECORD CHECKED AND APPROVED, NO DEVIATION, NO REWORKING AND REPROCESSING
MANUFACTURERS NAME & FULL ADDRESS: ZHEJIANG HAISEN PHARMACEUTICAL CO., LTD & LIUSHI TOWN,DONGYANG CITY,ZHEJIANG 322104,CHINA