浩 信 药 业
HAOSUN PHARMA

湖北浩信药业有限公司
Hubei Haosun Pharmaceutical Co., Ltd.
No.20 Juxian Road, Gedian Economic &Technology Development Area, Hubei, China Post Code: 436070
Tel: +86-711-3811388, 5916663 Fax: +86-711-3813389

CERTIFICATE OF ANALYSIS

Check No.: FP-09-1204019

Product Name:	**Erythromycin Ethylsuccinate**	**Batch No.:**	**HS0920120410**
Quantity:	**460.0kg**	**Manufacturing Date:**	**2012-4-24**
Packing:	**20kg/Drum**	**Retest Date:**	**2016-4-23**
Test Standard:	**USP34**	**Report Date:**	**2012-4-26**

Items	Specifications	Results
Description	White powder or white crystalline powder,odorless,tasteless	White powder
Identification		
IR	The infrared absorption spectrum exhibits maximum only at the same wavelengths as that of the standard spectrum	Conform
Crystallinity	Meets the requirements	Conform
X-ray diffraction	Meets the requirements	Conform
Water	Not more than 3.0%	1.5%
Residue on ignition	Not more than 1.0%	0.1%
Related compounds		
Any individual related compound	Not more than 3.0%	0.8%
Erythromycin A enol ether	Not more than 3.0%	< LOD
Erythromycin N-ethylsuccinate	Not more than 3.0%	0.6%
Residual solvents		
THF	Not more than 720ppm	651ppm
Assay		
	On the anhydrous basis,erythromycin B is not more than 12 percent	1.2%
	On the anhydrous basis,erythromycin C is not more than 5 percent	0.9%
	The sum of the percentages of erythromycin A, erythromycin B, and erythromycin C is not less than 76.5 percent	81.8%

Conclusion: **The tests comply with the specification of USP34**

QC Manager: 2012年04月26日 **Rechecker :** 2012年04月26日 **Checker:** 2012年04月26日