Hangzhou Huarong Pharmaceutical Co., Ltd.

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Product Name	Apixaban		
Batch No.	D5286-18-001M1	Batch Size	5.48kg
Batch Type	Commercial	Report Date	2018-11-21
Retest Date	2022-9	Storage Condition	Preserved in an airtight container
Manufacture Date	2018-10-2	Manufacture Site	Chuannan, Duqiao, Linhai, Zhejiang 317016, China
Reference	EDMF		
Test Items	Specifications		Results
Appearance	White to yellow crystalline powder.		Almost white crystalline powder
Identification	(1) The IR spectrum of the sample is in accordance with that of Apixaban reference standard.		Conform
	(2) The retention time of the major peak in the chromatogram of the Test solution corresponds to that in the chromatogram of the Standard solution,as obtained in the Assay.		Conform
Water	≤0.5%		0.1%
Sulfated ash	≤0.1%		<0.1%
Related Substances (HPLC)	Methyl ester impurity≤0.15%		<LOQ(LOQ:0.04%)
	Ethyl ester product≤0.15%		<LOD(LOD:0.01%)
	Any other impurity≤0.10%		<LOQ(LOQ:0.05%)
	Total impurities≤1.0%		<LOQ
Assay (HPLC)	98.0% - 102.0% (calculated on anhydrous basis)		100.3%
Residual solvents (GC)	Methanol≤3000ppm		146ppm
	Ethanol≤5000ppm		<LOD(LOD:19ppm)
	Acetonitrile≤410ppm		<LOD(LOD:12ppm)
	Ethyl acetate≤5000ppm		<LOD(LOD:4ppm)
Conclusion	Complies with EDMF		

Signature: huang xiaxia (QC manager) Issued Date: 2018.11.21

Signature: (QA manager) Issued Date: 2018.11.24

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. 杭州华镕医药有限公司 QC

*Means the document is under process
Product under patent is for R&D purpose.