



# Hangzhou Huarong Pharmaceutical Co., Ltd.

ADD: Room1101, Hakim International Building, Gongshu District,

Hangzhou, Zhejiang Province, China.

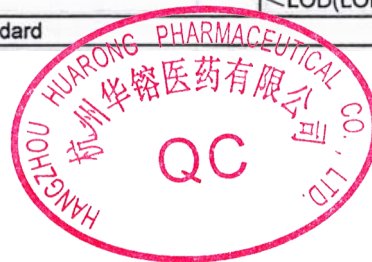
TEL: 0086-571-86758373

Website: [www.huarongpharm.com](http://www.huarongpharm.com)

## CERTIFICATE OF ANALYSIS

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Product Name		Brivaracetam	
Batch No.	D5391-23-003	Batch Size	77.12kg
Batch Type	Commercial	Report Date	2023-10-16
Retest Date	2025-08	Storage Condition	Preserve in well-closed containers
Manufacture Date	2023-09-26	Manufacture Site	Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
Reference	EDMF standard		
Test Items	Specifications	Results	
Appearance	White or almost white powder	White powder	
Identification	Infrared absorption spectrum corresponds to the spectrum obtained with the Brivaracetam RS.	Conforms	
	The retention time of the major peak in the chromatogram of the Sample solution corresponds to that in the chromatogram of the System suitability solution, as obtained in the Isomer	Conforms	
Water	≤0.50%	0.02%	
Sulfated ash	≤0.1%	<0.1%	
Appearance of solution	The solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY6.	Conforms	
Isomer (HPLC)	S,S-isomer ≤2.50%	0.35%	
	R,R-isomer ≤0.15%	<LOD(LOD=0.01%)	
	R,S-isomer ≤0.15%	<LOD(LOD=0.01%)	
Related substances(HPLC)	Any unspecified impurity ≤0.10%	<LOQ(LOQ=0.05%)	
	Total impurities ≤0.30%	<LOQ	
Assay(HPLC)	97.0%~102.0%(calculated on anhydrous substance)	99.1%	
Residual solvents(GC)	Methanol ≤3000ppm	<LOD(LOD=90ppm)	
	Isopropanol ≤5000ppm	<LOD(LOD=60ppm)	
	Dichloromethane ≤600ppm	<LOD(LOD=55ppm)	
	MTBE ≤5000ppm	27ppm	
	Tetrahydrofuran ≤720ppm	<LOD(LOD=11ppm)	
	Isopropyl acetate ≤5000ppm	<LOD(LOD=15ppm)	
	Heptane ≤5000ppm	<LOD(LOD=2ppm)	
Conclusion	Complies with EDMF standard		



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