浙江华海药业股份有限公司
HUAHAI ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

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CERTIFICATE OF ANALYSIS

Product Name	Levetiracetam		
Batch No.	D5294-18-189	Batch Size	1554.56Kg
Batch Type	Commercial	Report Date	2018-8-28
Retest Date	2021-7	Storage Condition	Preserve in well-closed containers.
Manufacture Date	2018-8-21	Manufacture Site	Chuannan, Duqiao, Linhai, Zhejiang 317016, China.
Reference	USP		

Test Items	Specifications	Results
Description	White crystalline powder	White crystalline powder
Identification	1) The infrared absorption spectrum is concordant with the reference spectrum obtained with Levetiracetam RS.	Conform
	2)The retention time of the major peak for levetiracetam from the sample solution corresponds to that of the levetiractem S-enantiomer from the System suitability solution, as obtained in the test for Limit of levetiracetam R-enantiomer.	Conform
Water (KF)	≤0.5%	<0.1%
Residue on ignition	≤0.1%	<0.1%
R-enantiomer(HPLC)	≤0.8%	N.D
*Organic impurities (HPLC)	**Levetiracetam acid≤0.3%	<LOD(LOD:0.015%)
	Any individual unspecified impurity≤0.05%	<LOQ(LOQ:0.007%)
	Total impurities≤0.4%	<LOQ
Residual solvents (GC)	Acetone≤5000ppm	273ppm
	Dichloromethane≤600ppm	N.D
	Toluene≤890ppm	<LOD(LOD:0.3ppm)
Assay (HPLC)	98.0%~102.0% (Calculated on anhydrous and solvent-free basis)	100.3%
Conclusion	Complies with USP	

*Pyridin-2-ol, USP related compound A ((S)-N-(1-Amino-1-oxobutan-2-yl)-4-chlorobutanamide) and USP related compound B ((S)-2-aminobutanamide hydrochloride) are process related and are not possible to appear per Huahai's synthetic route, therefore no test required for these three process impurities for Huahai's Levetiracetam drug substance.
**Levetiracetam acid: (S)-2-(2-Oxopyrrolidin-1-yl)butanoic acid. Included in the Total impurities limit.

Signature: Fanglingxin (QC manager) Issued Date: 2018.08.28

Signature: Lijing (QA manager) Issued Date: 2018.08.29