Hangzhou Huarong Pharm Co.,Limited

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CERTIFICATE OF ANALYSIS

Product : Ezetimibe
Quantity : 112.3Kg
Batch NO. : ZTB-705-221013-1
Manufacturing Date : Sep.27,2022
Retest Date : Sep.27,2024

Tests	Specifications	Results
Appearance	White powder	White powder
Specific Rotation	-25.0°～-30.0°	-27.7°
Identification	A. IR: similar to Reference Substance	Complies
	B. The retention time ratio of the major peak of the Sample solution to that of the the ezetimibe peak from the system suitability in Organic Impurities,Procedure 2 is between 0.97 and 1.03.	Complies
Water	≤0.6%	0.16%
*Residue on ignition	≤0.1%	0.06%
Organic Impurities, Procedure 1	Desfluoroaniline analog≤0.2%	Not Detected
	o-Fluorobenzene isomer≤0.2%	Not Detected
	m-Flouroaniline analog≤0.2%	Not Detected
	Ezetimibe ketone≤0.1%	Not Detected
	Any unspecified impurity≤0.10%	Not Detected
	Total achiral impurities(exclude Ezetimibe diastereomer)≤0.6%	Not Detected
Organic Impurities, Procedure 2	S,S,S -Ezetimibe≤0.2%	Not Detected
	R,R,R-Ezetimibe≤0.1%	Not Detected
	R,R,S -Ezetimibe≤0.4%	Not Detected
	S,S,R -Ezetimibe≤0.1%	Not Detected
	R,S,R -Ezetimibe≤0.1%	Not Detected
	Total chiral impurities≤0.5%	Not Detected
	Total impurities≤0.9%	Not Detected
*Residual solvents	Methanol≤3000ppm	Not Detected
	Isopropanol≤5000ppm	194ppm
	Chlorobenzene≤360ppm	Not Detected
Assay	98.0%～102.0%(Calculated on the anhydrous and solvent-free basis)	100.4%

Note： * - are in-house standard.
The results above meet all requirements under **Ezetimibe** in **USP and In-House Standard.**

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