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CERTIFICATE OF ANALYSIS

Product Name	Levodropropizine	CAS No.	99291-25-5
Batch No.	P010363017A	Mfg. Date	Mar. 03, 2017
Packing	25kg/Drum	Retest Date	Mar. 02, 2019
Quantity	500kg	Report Date	Mar. 16, 2017
Specification	EP8.0		

ITEM	SPECIFICATION	RESULT
Assay(HPLC, dried basis)	98.5%~101.0%	99.70%
Appearance	White or almost white powder	Complies
Solubility	Slightly soluble in water, freely soluble in dilute acetic and methanol, soluble in ethanol	Complies
Identification	By IR, To match with the reference standard	Complies
Specific Optical Rotation	-30.0° ~ 33.5°	-33.2°
pH	9.0~10.2	9.7
Loss on Drying	≤1.0%	0.11%
Sulphated Ash	≤0.2%	0.09%
Related Substances		
Impurity B and Related Substances	Impurity B≤0.5%	<0.1%
	Any Other Impurity≤0.1%	<0.1%
	Total Impurities≤0.6%	<0.1%
Impurity C	≤5ppm	<5ppm
Impurity A	≤2%	0.1%
Conclusion	Comply with EP8.0.	
Storage	Preserve in tight containers, protected from strong light and high heat. Store in dry cool place.	

Analyst:

QC Manager:

QA: