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CERTIFICATE OF ANALYSIS

Product Name: Phenylephrine hydrochloride Batch/Lot No.: PEH-140714C

Manufacturing date: 18. July, 2014 Date of Analysis: 18. July, 2014

Date of Release: 01. Aug. 2014

Test	Specification	Result
Characters		
(Visual test)	White or almost white crystalline powder;	
(solubility test)	Freely soluble in water and in alcohol.	Complies
Identification		
(A) Specific optical rotation		
(Polarimetry)	Corresponding with specific optical rotation	Complies
(B) IR Spectrum		
(Spectrophotometry)	Corresponding to reference spectrum	Complies
(E)Test for chloride		
(Presioitation)	Positive	Complies
Melting Point		
(Capillary method)	About 143℃	142～144℃
Specific optical rotation		
(Polarimetry)	-43～ -47°	-45.3°
Loss on Drying		
(Weighing)	≤1.0%	0.02%
Sulphated ash		
(Weighing)	≤0.1%	0.05%
Sulfates		
(Limit test)	≤0.05%	Complies
Ketones		
(Limit test)	Not deeper than obtained solution	Complies

Related substances		
(HPLC)	Impurities C:≤0.1%	Not detected
	Impurities E:≤0.1%	Not detected
	Unspecified impurity: ≤0.10%	0.05%
	Total impurities: ≤0.2%.	0.11%
Appearance of solution		
(Visual test)	Clear and colourless	Complies
Acidity or alkalinity		
(Colour reaction)	Comply with the test of acidity and alkalinity	Complies
Assay		
(Titration)	98.5～101.0% (calculated on the dried basis)	99.3%
Chloride content		
(Titration)	17.0～17.7% (calculated on the dried basis)	17.4%
Residual Solvents		
(Gas chromatography)	≤0.5%(Isopropanol)	0.1%
	≤0.3%(Methanol)	Not detected
Particle Size		
(Sieve test)	≥90%(by 50 mesh)	98.3%

Packaging and storage: Preserve in tight, light-resistant containers.

Remarks: The expiry date is 17 July, 2017.(to be understood as recommended date of etesting)

Evaluation:Product corresponds with the requirement of EP7.0 and USP36.

Director:	Reviser:	Inspector:
(Quality Director)	(QA)	(QC)
(signature/date)	(signature/date)	(signature/date)