

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

Phenylephrine Hydrochloride USP37			
Batch Number	01-040-1602	Particle size	40
Manufacturing Date	2016-01-06	Expiration Date	2019-01-05
Quantity	160.0 kg	Date of Analysis	2016-01-07

Test Items	Specification	Results
Characteristic	White or almost white, crystalline powder	White crystalline powder
Identification A	Positive identification	Complies
Identification B	Positive identification	Complies
Melting point	140° to 145°	142.2°~143.2°
Specific Rotation	-42° to -47.5°	-46.2°
Chromatographic purity	Individual impurity ≤0.5 % Sum of impurities ≤ 1.0%	Complies
Limit of Ketones	No deeper than the control solution	Complies
Sulfates	Not more than 0.20%	Complies
Loss on Drying	Not more than 1.0 %	0.02%
Residue on Ignition	Not more than 0.2 %	0.03%
Chloride content	17.0% to 17.7%	17.4%
Assay	97.5% to 102.5 %	99.9%
Particle Size	98% past 40 Mesh	Complies
Residual Solvents	Methanol ≤3000 ppm	130ppm
	2-Propanol ≤5000 ppm	120 ppm
	Ethanol ≤5000 ppm	40 ppm
Package and Storage	Preserve in tight and light-resistant containers. Store at 25°C. Excursion permitted between 15°C to 30°C	
Conclusion	The product meets the requirements of USP37	

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