



American
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Shenzhen Happy Pharmaceuticals Ltd.

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PO# P102608-2

ITEM# PHED-001

CERTIFICATE OF ANALYSIS

Phenylephrine Hydrochloride USP31			
Batch Number	01-200-1043	Particle size	200-mesh
Manufacturing Date	2010-12-04	Expiration Date	2013-12-03
Quantity	40.0 kg	Date of Analysis	2010-12-04

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°~144°
Specific Rotation	-42° to -47.5°	-45.5°
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 2000 ppm	Complies
Loss on Drying	Not more than 1.0 %	0.07%
Residue on Ignition	Not more than 0.2 %	0.02%
Chloride content	17.0% to 17.7%	17.4%
Assay	97.5% to 102.5 %	99.9%
Particle Size	97% past 200 Mesh	Complies
Residual Solvents	Methanol ≤ 3000 ppm	210 ppm
	2-Propanol ≤ 5000 ppm	30 ppm
	Ethanol ≤ 5000 ppm	100 ppm
Package and Storage	Preserve in tight and light-resistant containers. Store at 25°C. Excursion permitted between 15°C to 30°C	
Conclusion <i>For and on behalf of</i>	The product meets the requirements of USP31	

Shenzhen Happy Pharmaceuticals Ltd.

QC Manager:

Inspector:

Operator:

Authorized Signature(s)

American International Chemical, Inc. Verifies that the information contained herein is true and correct to the best of our knowledge.
Verified by:
Date: 12/30/10
Phone: 800-238-0001