

# Kalchem International

## Chemicals & Compounding Supplies

### Certificate of Analysis

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#### LETCO MEDICAL: Item/Lot Number(s)

<b>Item:</b> 684393 <b>Lot:</b> 1508130002	<b>Item:</b> 684394 <b>Lot:</b> 1508130003	<b>Item:</b> 690869 <b>Lot:</b> 1508130004	<b>Item:</b> 694020 <b>Lot:</b> 1508130005
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<b>Description:</b> Acetaminophen Powder USP	<b>Source Lot:</b> CW-1505111	<b>Expiration Date:</b> 04/2020
<b>Date of MFG:</b> 05/2015	<b>Specification:</b> USP38	

Test Criteria	Result	Specification
Characters	Conforms	A white or almost white crystal.
Identification		
A: IR *	Conforms	A: Infrared Absorption USP<197K>
B: HPLC	Conforms	B: The retention time of the major peak of the sample solution corresponds to that of the Standard solution, as obtained in the Assay
Free 4-aminophenol	<0.005%	≤0.005%
Organic Impurities		
Acetaminophen related compound B	0.02%	≤0.05%
Acetaminophen related compound C	<0.01%	≤0.05%
Acetaminophen related compound D	<0.01%	≤0.05%
Acetaminophen related compound J	<0.001%	≤0.001%
Individual unspecified impurity	0.02%	≤0.05%
Total Impurities	0.06%	≤0.1%
Heavy Metals	<0.001%	≤10ppm USP <231>
Residue on Ignition	<0.0%	≤0.1% USP <281>
Loss on Drying	<0.0%	≤0.5% USP <731>
Assay	98.9%	98.0~102.0% (on the dried basis)
Residue Solvents: Acetic Acid	<0.5%	≤0.5% USP (467)
<b>Comments:</b> Comply with the requirements of USP38		

Letco Medical QA Review By/Date: Amanda Kelsoe

Digitally signed by Amanda Kelsoe  
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