

# Kalchem International

## Chemicals & Compounding Supplies

### Certificate of Analysis

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

|   |   |   |   |
|---|---|---|---|
| <b>Item:</b> 684393<br><b>Lot:</b> 1508130002 | <b>Item:</b> 684394<br><b>Lot:</b> 1508130003 | <b>Item:</b> 690869<br><b>Lot:</b> 1508130004 | <b>Item:</b> 694020<br><b>Lot:</b> 1508130005 |
|---|---|---|---|

|  |                               |                                 |
|--|-------------------------------|---------------------------------|
| <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 Kelson

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