Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

LETCO MEDICAL: Item/Lot Number(s)			
Item: 684393 **Lot:** 1602230160	**Item:** 684394 **Lot:** 1602230161	**Item:** 690869 **Lot:** 1602230162	

Description:	Acetaminophen Powder USP	**Source Lot:**	1511706	**Expiration Date:**	10/26/2019
Date of MFG:	10/27/2015	**Specification:**	USP38		

Tests	Specification	Test Reference	Results
Characteristic	White, odorless, crystalline powder; having a slightly bitter taste. Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide	USP monograph for Acetaminophen	Conforms
Identification * (IR)	A & B should be positive	USP Monograph for Acetaminophen	Conforms
Loss on drying	≤0.5%	USP <731>	0.07%
Residue on Ignition	≤0.1%	USP <281>	0.04%
Heavy Metals	≤10ppm	USP <231> method II	<10ppm
Limit of free 4-Aminophenol	≤0.005%	USP Monograph for Acetaminophen, HPLC method	5.9ppm
Organic Impurity	Related compound B: ≤0.05% (N-(4-Hydroxypenyl) propanamide)	USP Monograph for Acetaminophen, HPCL method	0.009%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		0.008%
	Related compound D: ≤0.05% (N-Phenylacetamide)		0.027%
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND*
	Individual unspecified impurity: ≤0.05%		0.001%
	Total Impurities: ≤0.1%		0.04%
Assay	98.0-102.0% (on the dried basis)	HPLC method	99.8%
Residual Solvents	Glacial acetic acid is used in Acetaminophen production, and it can be determined by Loss on Drying not more than 0.5%		
Conclusion	It conforms to USP 38.		

*ND means not detected

Letco Medical QA Review By/Date: Latonyia Owens Digitally signed by Latonyia Owens DN: cn=Latonyia Owens, o=Letco Medical LLC, ou=QA, email=lowens@letcomedical.com, c=US Date: 2016.03.07 15:06:37 -06'00'

Kalchem International, Inc
224 South Main Street - Lindsay, OK 73052
Toll Free 888-298-9905 | FAX: 405-756-2373