



QUALITY CHEMICAL LABORATORIES

Specializing In Analytical & Synthetic Chemistries

Analysis Report

July 23, 2015

• • • Hydrolyzed Clinoptilolite Fragments Solution (CytoDetox) • • •

Project #: G2481
Lot # 190515
Sample # 1507785

Specifications:

Specifications were established by using option 1 from the ICH Guidelines Q3D. Option 1 assumes the daily intake of the drug product is 10 grams or less. The permissible daily limits used for the study was from the ICH Q3D and proposed revision of USP <232> Elemental Impurities – Limits. This option calculates a fixed common maximum concentration in micrograms per gram. The target limit for aluminum, titanium, magnesium, and calcium were based on a permissible daily limit of 100 µg/day. The 100 µg/day specification was based on the specification for the platinum-group elements. However, no specifications have been established for aluminum, titanium, magnesium, and calcium.

Results:

Metal	Target Limit (ppm)	Result (ppm)	% Recovered*
Mercury	3.0	0.0	96
Lead	0.5	0.0	101
Arsenic	1.5	0.2	108
Cadmium	2.5	0.0	99
Aluminum	10	0	95
Titanium	10	0	103
Magnesium	10	13	89
Calcium	10	37	136

*Accuracy study was performed at or below the 100% level.

Approval Signature:


Metals Manager, Michael D Gain

7/23/15
Date