



CERTIFICATE OF ANALYSIS

PYRANTEL PAMOATE

MANUFACTURING SITE: MEXICO

ANALYTICAL SITE: MEXICO

BATCH : 1018200015.01

TEST:	RESULTS:	SPECIFICATION:
DESCRIPTION :	YELLOW SOLID	YELLOW TO TAN SOLID.
IDENTIFICATION:		
A) IR:	COMPLIES	THE INFRARED ABSORPTION SPECTRUM OF THE SAMPLE EXHIBITS MAXIMA AT THE SAME WAVELENGTHS OF THE SPECTRUM OF A SIMILAR PREPARATION OF THE PYRANTEL PAMOATE REFERENCE STANDARD.
B) UV:	COMPLIES	THE UV ABSORPTION SPECTRA OF THE TEST SOLUTION AND THE STANDARD SOLUTION EXHIBIT MAXIMA AND MINIMA AT THE SAME WAVELENGTHS.
C) HPLC:	COMPLIES	THE RETENTION TIME OF THE MAJOR PEAKS DUE TO PYRANTEL BASE AND PAMOIC ACID OF THE SAMPLE SOLUTION CORRESPOND TO THOSE OF THE STANDARD SOLUTION AS OBTAINED IN THE ASSAY
ASSAY BY HPLC:	100.3 %	97.0% - 103.0% w/w ON THE DRIED BASIS.
CONTENT OF PAMOIC ACID:	67.2 %	63.4% - 67.3%, CALCULATED ON THE DRIED BASIS.
LIMIT OF IRON:	<0.0075 %	0.0075 %
RESIDUE ON IGNITION :	0.0 %	NOT MORE THAN 0.5 %
ORGANIC IMPURITIES:		
PYRANTEL RELATED COMPOUND A:	0.0 %	NOT MORE THAN 0.5 %
IMPURITY B:	0.0 %	NOT MORE THAN 0.2 %
INDIVIDUAL UNSPECIFIED IMPURITIES:	0.0 %	NOT MORE THAN 0.1 %
TOTAL UNSPECIFIED IMPURITIES:	0.1 %	NOT MORE THAN 0.3 %
TOTAL IMPURITIES:	0.1 %	NOT MORE THAN 1.0 %
LOSS ON DRYING :	0.1 %	NOT MORE THAN 2.0 %
RESIDUAL SOLVENTS:		
METHANOL :	0.0 %	NOT MORE THAN 0.1%

REMARKS: According to USP specification

MANUFACTURING DATE: October 30, 2020

EXPIRY DATE : October 29, 2025

COMPLIES USP 42

REVIEWED:   
 NAME: ALEJANDRO ALFARO  
 TITLE: QUALITY CONTROL HEAD

APPROVED:   
 NAME: JAVIER ICAZA  
 TITLE: QUALIFIED PERSON

ISSUED BY: Judith Sedeño  
 DATE: November 09, 2020

ANEXO 1. Version 01. PNO-CAL-039