

Batch Release Document

Product: *Activyl Tick plus Lg Dog 4x600mg 301, Batch: 41120B0*

Material number: 118261
Batch class: FPP_PHA
Fill Volume: 4 ML
Batch quantity: 6,784 TB
Production date: Nov-2014
Expiration date: Oct-2017
Name and address of releasing site:
Merck Animal Health
2667 West Dual
BATON ROUGE LA 70814-4906
USA

Inspection lot: 40641871
Status of UD: UD Made

Inspection Characteristics:

to be tested	accepted	rejected	skipped	defects
19	3	0	0	0

Batch current stage status: OK
Batch internal release status: Rel for Quarantine shipment
Batch is released for the following countries: AT, DE, HU
Ship to party: -
Sold to party: -

Authorised Instructions used for all manufacturing steps Yes No N/A
Significant Deviations Yes No
Batch is: released for next manufacturing step restricted released
released rejected

Comments: TESTING PERFORMED AT BULK LEVEL. RELEASE FDR BATCH 41120
IS ATTACHED. SHIPPED UNDER QUARANTINE.

Signature and Date QP: *Carl Kessel* 08-JAN-2015

Proposal for Stock posting: to release 6,784
to sample usage 0

Comments: _____

Signature and Date SAP Transaction *Carl Kessel* 08-JAN-2015

FPP

This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site in full compliance with the specifications of the Marketing Authorization of the importing country. The batch processing and the analysis records were reviewed and found to be in compliance with GMP.

Certificate of Analysis

Product: *BULK INDOXACARB/PERMETHRIN OIL SOL FORM, Batch: 41120*

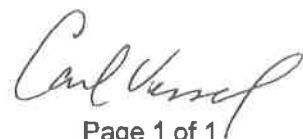
Intervet Material Number: 047431 Manufacturing Date: 19-Nov-2014
Storage Conditions: Under N2 gas, 15-25°C Expiry Date: Oct-2017

Results of Analysis

<u>Test</u>		<u>Result</u>
Description	No Visible Particulate Matter US	Complies
Color	Colorless to yellow or brown	Complies
Assay Indoxacarb	13.0 - 14.4	13.5 %
Assay Permethrin	41.6 - 46.0	43.3 %
Indoxacarb % of Label Claim	95.0 - 105.0	98.5 %
Permethrin % of Label Claim	95.0 - 105.0	98.8 %
ID UHPLC-RT Indoxacarb and Permethrin	Conform	Complies
ID UHPLC-UV Indoxacarb and Permethrin	Conform	Complies
Total degradation, Indoxacarb	=<1.0	0.0 %
Total degradation, Permethrin	=<1.0	0.3 %
Propyl gallate, % of label claim	75.0 - 125.0	96.3 %
Related compounds, specified (3-PBA)	=<1.0	0.1 %
Related compounds, unspecified	=<1.0	0.7 %
Water Content	=<0.5	0.0 %

This is to certify that the above batch has been manufactured and packed according to the current standard of Good Manufacturing Practices and Corporate Quality. For products for sale within the EU market, this certificate does not constitute final release.

Released by:



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