

CERTIFICATE OF ANALYSIS



Generated Date:
Sep 11, 2023

ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc.
2605 E. KILGORE RD
KALAMAZOO, MI 49001 USA

Item: 10024436
Title: APOQUEL FCT 16MGX100BTX1 UA
Expiration Date: 05-2026
Date Of Manufacture: 22-JUN-2023
Market: 10024436 UKRAINE LIMIT
Lot Number: 689219 Associated Lots: 676795

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
APPEARANCE VISUAL	MEETS TEST	N/A	MEETS TEST
IDENTIFICATION UPLC	MEETS TEST	N/A	MEETS TEST
IDENTIFICATION PDA	MEETS TEST	N/A	MEETS TEST
ASSAY OCLACITINIB	95.0 - 105.0 % of Label Claim	%	98.4
MALEATE CONJUGATE	<= 2.0	%	< 0.3
INDIVIDUAL UNSPEC DEGRADATION<= 1.0 PRODUCTS		%	< 0.3
TOTAL DEGRADATION PRODUCTS	<= 4.0	%	< 0.3
DISSOLUTION @ 30 Minutes (Q = 75%)	Meets Criteria of USP <711>	N/A	MEETS TEST
WATER	<= 7.0	%	5.2
CONTENT UNIFORMITY	MEETS Ph Eur <2.9.40>	N/A	MEETS TEST
TOTAL AEROBIC MICROBIAL COUNT<= 2000		CFU/g	< 10

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<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
TOTAL YEAST & MOLD COUNT	<= 200	CFU/g	< 10
ABSENCE OF ESCHERICHIA COLI	MEETS TEST	N/A	MEETS TEST

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Lot Release Electronic Jonathan Evans

Lot Release System Timestamp: Aug 11, 2023 3:33:26 PM

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CERTIFICATE OF ANALYSIS



Generated Date:
Mar 30, 2022

ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc.
2605 E. KILGORE RD
KALAMAZOO, MI 49001 USA

Item: 10024435
 Title: APOQUEL FCT 5.4MGX100BTX1 UA
 Expiration Date: 12-2024
 Date Of Manufacture: 11-JAN-2022
 Market: 10024435 UKRAINE LIMIT
 Lot Number: 570468 Associated Lots: 556088

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
APPEARANCE VISUAL	MEETS TEST	N/A	MEETS TEST
IDENTIFICATION UPLC	MEETS TEST	N/A	MEETS TEST
IDENTIFICATION PDA	MEETS TEST	N/A	MEETS TEST
ASSAY OCLACITINIB	95.0 - 105.0 of Label Claim.	%	100.1
MALEATE CONJUGATE	<= 2.0	%	< 0.3
INDIVIDUAL UNSPEC DEGRADATION PRODUCTS	<= 1.0	%	< 0.3
TOTAL DEGRADATION PRODUCTS	<= 4.0	%	< 0.3
DISSOLUTION @ 30 Minutes (Q = 75%)	Meets criteria of USP <711>	N/A	MEETS TEST
WATER	<= 7.0	%	4.3
CONTENT UNIFORMITY	MEETS Ph Eur <2.9.40>	N/A	MEETS TEST
TOTAL AEROBIC MICROBIAL COUNT	<= 2000	CFU/g	< 10

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Title: APOQUEL FCT 5.4MGX100BTX1 UA
Expiration Date: 12-2024
Date Of Manufacture: 11-JAN-2022
Market: 10024435 UKRAINE LIMIT
Lot Number: 570468 Associated Lots: 556088

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
TOTAL YEAST & MOLD COUNT	<= 200	CFU/g	< 10
ABSENCE OF ESCHERICHIA COLI	MEETS TEST	N/A	MEETS TEST

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Lot Release Electronic Joel McGorman

Lot Release System Timestamp: Mar 25, 2022 7:23:17 PM

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