

AbbVie, Inc.  
Dept. 055M, Bldg. AP16  
One North Waukegan Road  
North Chicago, IL 60064

CERTIFICATE OF ANALYSIS

12-SEP-2023

LIST	PRODUCT DESCRIPTION	LOT NUMBER	MFG DATE	EXP DATE
03956-2201	KALETRA, ORAL SOLUTION, 80 MG LOPINAVIR/ 20 MG RITONAVIR PER ML, SERIALIZED	1203624	17JUL2023	17JUL2025

(BULK LOT: 1197884)

TEST NAME	SPECIFICATION LIMIT	RESULT	UNIT
MICROBIAL, TOTAL AEROBIC MICROBIAL COUNT (TAMC)	LESS, EQUAL TO 100	<100	CFU/ML
MICROBIAL, TOTAL COMBINED YEAST/MOLD COUNT (TYMC)	LESS, EQUAL TO 20	<10	CFU/ML
MICROBIAL, E. COLI	ABSENT IN 1 ML	ABSENT	
ASSAY, LOPINAVIR, FINISHING	90.0 TO 110.0	101.3	%LA
ASSAY, RITONAVIR, FINISHING	90.0 TO 110.0	101.2	%LA
IDENTIFICATION, HPLC, LOPINAVIR	MEETS REQUIREMENT	MEETSREQ	
IDENTIFICATION, HPLC, RITONAVIR	MEETS REQUIREMENT	MEETSREQ	
ETHANOL	85.0 TO 115.0	101.0	%LA
PHYSICAL EXAMINATION	MEETS REQUIREMENT	MEETSREQ	
PHYSICAL EXAMINATION, COLOR	REPORT RESULTS	PASS (LIGHT YELLOW)	
RELATED SUBSTANCES, ANY UNSPECIFIED DEGRADANT, LOPINAVIR	LESS, EQUAL TO 0.2	NOTDET	%
RELATED SUBSTANCES, TOTAL (ICH), LOPINAVIR	LESS, EQUAL TO 0.5	NOTDET	%
RELATED SUBSTANCES, TOTAL (ICH), RITONAVIR	LESS, EQUAL TO 3.0	NOTDET	%
RELATED SUBSTANCES, ANY UNSPECIFIED DEGRADANT, RITONAVIR	LESS, EQUAL TO 0.2	NOTDET	%
RELATED SUBSTANCES, A-154446.0, MONOACYL VALINE	LESS, EQUAL TO 0.8	NOTDET	%
RELATED SUBSTANCES, A-163827.0, PROPYLENE GLYCOL (PG) ADDUCT	LESS, EQUAL TO 0.5	NOTDET	%
RELATED SUBSTANCES, A-86023.0, ACID HYDROLYSIS PRODUCT	LESS, EQUAL TO 0.4	NOTDET	%
RELATED SUBSTANCES, A-162199.0, ETHANOL ADDUCT	LESS, EQUAL TO 0.7	NOTDET	%
RELATED SUBSTANCES, A-136478.0, OXIDATION IMPURITY	LESS, EQUAL TO 0.3	NOTDET	%
RELATED SUBSTANCES, A-318874, GLYCERINE ADDUCT	LESS, EQUAL TO 0.2	NOTDET	%
RELATED SUBSTANCES, HYDROPEROXIDE	LESS, EQUAL TO 0.2	NOTDET	%
RELATED SUBSTANCES, A-160631, GEO-ISOMER	LESS, EQUAL TO 0.2	NOTDET	%
RELATED SUBSTANCES, A-124395, BASE CYCLIZED PRODUCT	LESS, EQUAL TO 0.2	NOTDET	%
IDENTIFICATION, TLC, LOPINAVIR	MEETS REQUIREMENT	MEETSREQ	
IDENTIFICATION, TLC, RITONAVIR	MEETS REQUIREMENT	MEETSREQ	
FINISHED PRODUCT INSPECTION	MEETS REQUIREMENT	MEETSREQ	
DELIVERABLE VOLUME, AVERAGE (10)	GREATER, EQUAL TO 100	101	%
INDIVIDUAL VOLUME (10)	GREATER, EQUAL TO 95	101	%
		101	
		101	
		102	
		101	
		101	
		101	
		101	
		102	

THE PRODUCT DOES NOT CONTAIN DETECTABLE LEVELS OF ETHYLENE GLYCOL OR DIETHYLENE GLYCOL.

THIS PRODUCT HAS BEEN MANUFACTURED AND TESTED IN CURRENT GOOD MANUFACTURING PRACTICES (cGMP) FACILITIES IN ACCORDANCE WITH APPROPRIATE REGULATIONS. THIS PRODUCT MEETS APPLICABLE SPECIFICATIONS AND, WHERE/AS APPROPRIATE, COMPENDIAL REQUIREMENTS. THE UNDERSIGNED CERTIFIES THIS TO BE A TRUE REPRESENTATION OF THE RESULTS, AS REPORTED AND DOCUMENTED BY THE APPLICABLE QA/QC FUNCTIONAL AREAS.

*Beth Neubauer* Electronically signed by: Beth  
Neubauer  
Reason: Approver  
Date: Sep 12, 2023 14:31 CDT

QUALITY ASSURANCE BETH NEUBAUER

*Nikki Valdecanas* Electronically signed by: Nikki  
Valdecanas  
Reason: Verifier  
Date: Sep 13, 2023 09:27 CDT

QUALITY ASSURANCE NIKKI VALDECANAS