

CERTIFICATE OF ANALYSIS

PRODUCT:	PROBIOX	GRADE:	NPN 80025502
CODE:	YOG6MM30UKR	MANUFACTURE DATE:	2017-03
MANUFACTURED UNDER LOT:	50RB199 (R09770)	EXPIRATION DATE:	2019-03
PACKED UNDER LOT:	14659		

VERSION: 03

Issued Date: 2016-12-02

 Approved by: 

TEST	LIMITS	METHOD	RESULTS
IDENTITY			
Appearance:	Natural, hard capsule, clear vegetable #2	Visual	Complies
Color:	Ivory to beige powder with some darker grains	Visual	Complies
Odor:	Characteristic	Organoleptic	Complies
Average gross weight:	362 - 442 mg/caps	Gravimeter	404 mg/caps
Weight variation:	USP limits	USP <2091>	Complies
Disintegration:	≤ 45 minutes	USP <2040>	Complies
ACTIVITY			
<i>Lactobacillus rhamnosus</i> (HA-111)	73 - 150 × 10 ⁹ cfu/caps ^a (target > 30 × 10 ⁹ cfu/caps) ^b	Input	Complies
<i>Lactobacillus paracasei</i> (HA-196)	64 - 132 × 10 ⁹ cfu/caps ^a (target > 27 × 10 ⁹ cfu/caps) ^b	Input	Complies
<i>Lactobacillus acidophilus</i> (HA-122)	073 - 150 × 10 ⁹ cfu/caps ^a (target > 30 × 10 ⁹ cfu/caps) ^b	Input	Complies
<i>Lactobacillus bulgaricus</i> (HA-137)	002 - 004 × 10 ⁹ cfu/caps ^a (target > 10 × 10 ⁸ cfu/caps) ^b	Input	Complies
<i>Streptococcus thermophilus</i> (HA-110)	015 - 030 × 10 ⁹ cfu/caps ^a (target > 6 × 10 ⁸ cfu/caps) ^b	Input	Complies
Total bacteriological count	14.5 - 30.0 × 10 ⁶ cfu/caps	In house method	21 × 10 ⁶ cfu/caps
PURITY			
Total aerobic microbial count	< 10 000 cfu/g	USP<2021> modified	Complies
Yeasts / Moulds	< 100 cfu/g	USP<2021> modified	Complies
<i>Enterobacteriaceae</i>	< 100 MPN/g	USP<2021> modified	Complies
<i>Escherichia coli</i>	Absence	USP<2022> modified	Absence
<i>Salmonella</i> spp.	Absence	USP<2022> modified	Absence
<i>Staphylococcus aureus</i>	Absence	USP<2022> modified	Absence
Heavy Metals (As, Cd, Pb, Hg)	According to NHPD	ICP-MS	Complies

^aAccording to release date of bulk ^bIdentification at beginning of manufacturing ^cConcentration at expiration date

VERIFIED BY:


 QUALITY CONTROL (QC)

2017-04-18

DATE

APPROVED FOR USE BY:


 QUALITY ASSURANCE (QA)

2017-04-19

DATE