

CERTIFICATE OF ANALYSIS

PRODUCT:	KOMBIFOL	GRADE:	NPN 80050952
CODE:	BAC160UKR	MANUFACTURE DATE:	2017-03
MANUFACTURED UNDER LOT:	BB 3227 (R09763)	EXPIRATION DATE:	2019-03
PACKED UNDER LOT :	14669		

VERSION: 03

Issued Date: 2017-04-13

Approved by: 

TEST	LIMITS	METHOD	RESULTS
IDENTITY			
Appearance:	Unscored, rond, uncoated tablet	Visual	Complies
Color:	From light yellow to light pink	Visual	Complies
Odor:	Odorless	Organoleptic	Complies
Average weight:	297 - 363 mg/tab	Gravimetric	328 mg/tab
Weight variation:	USP limits	USP <2091>	Complies
Disintegration :	≤ 30 minutes	USP <2040>	< 3min
ACTIVITY			
Vitamin B6 (pyridoxine HCL)	90 - 150 mg/tab (Target: 100 mg /tab)	HPLC	105 mg/tab
Vitamin B12 (cyanocobalamin)	450 - 750 µg/tab (Target: 500 µg /tab)	HPLC	684 µg/tab
Folique acide	720 - 1 200 µg/tab (Target: 800 µg /tab)	HPLC	872 µg/tab
PURITY			
Total aerobic microbial count	< 3 000 cfu/g	USP <2021>	< 10 cfu/g
Yeasts / Moulds	< 300 cfu/g	USP <2021>	< 10 cfu/g
Escherichia coli	Absence	USP < 2022>	Absence
Salmonella spp.	Absence	USP <2022>	Absence
Staphylococcus aureus	Absence	USP <2022>	Absence
Arsenic	< 9.8 µg /tab	ICP/MS	0,3 µg /tab
Cadmium	< 6.3 µg /tab	ICP/MS	< 0.1 µg /tab
Lead	< 9.8 µg /tab	ICP/MS	< 0.1 µg /tab
Mercury	< 20.3 µg /tab	ICP/MS	< 0.1 µg /tab
Residual solvents ⁽¹⁾	USP limits	USP <467>	Complies

⁽¹⁾ Tested according to SOP CQ025

VERIFIED BY:



QUALITY CONTROL (QC)
2017-04-20

DATE

APPROVED FOR USE BY:



QUALITY ASSURANCE (QA)
2017-04-21

DATE