

CERTIFICATE OF ANALYSIS

PRODUCT:	<u>SONMELAT FORTE</u>	GRADE:	<u>NPN 80044500</u>
CODE:	<u>MELA10TR30UKR</u>	MANUFACTURE DATE:	<u>2017-03</u>
MANUFACTURED UNDER LOT:	<u>F-62210 (R09608)</u>	EXPIRATION DATE:	<u>2020-03</u>
PACKED UNDER LOT :	<u>14580</u>		

VERSION: 02

Issued Date: 2017-01-17

 Approved by: 

TEST	LIMITS	METHOD	RESULTS
IDENTITY			
Appearance:	Oval shape, film-coated tablet	Visual	Complies
Color:	Gray to greenish with speckles, bilayer with one lighter and one darker layer	Visual	Complies
Odor:	Characteristic	Organoleptic	Complies
Average weight :	546 - 668 mg/tab	Gravimeter	601 mg/tab
Weight variation:	USP limits	USP <2091>	Complies
Dissolution :	1 h : 0 - 6.0 mg	USP <2040>	4,4 mg
	4 h : 5.0 - 9.0 mg		6,7 mg
	8 h : 7.0 - 12.0 mg		8,6 mg
ACTIVITY			
Melatonin	8 - 12 mg/tab (Target: 10 mg/tab)	Current USP	10 mg/tab
PURITY			
Total aerobic microbial count	≤ 10 000 cfu/g	USP <2021>	< 10 cfu/g
Yeasts / Molds	≤ 500 cfu/g	USP <2021>	< 10 cfu/g
<i>Escherichia coli</i>	Absence	USP <2022>	Absence
<i>Salmonella</i> spp.	Absence	USP <2022>	Absence
<i>Staphylococcus aureus</i>	Absence	USP <2022>	Absence
Arsenic	< 9.8 µg/tab	ICP/MS	0,00 µg/tab
Cadmium	< 6.3 µg/tab	ICP/MS	0,00 µg/tab
Lead	< 9.8 µg/tab	ICP/MS	0,00 µg/tab
Mercury	< 20.3 µg/tab	ICP/MS	0,03 µg/tab
Residual solvents ⁽¹⁾	USP limits	USP <467>	Complies
Pesticides ⁽¹⁾	USP limits	USP <561>	Complies

⁽¹⁾ Tested according to SOP CQ025

VERIFIED BY:



 QUALITY CONTROL (QC)
 2017-03-30

 DATE

APPROVED FOR USE BY:



 QUALITY ASSURANCE (QA)
 2017-04-13

 DATE