SABINSA EUROPE GmbH

PRODUCT DATA SHEET

NILITIS SR TABLET

Finished product Specification

Issue No.3
January 15, 2015

NILITIS SR TABLET

Specification No. : FPS/ARD/364 (MAL)

Parameters	Limit	Reference
Physical		
Description	Orange yellow – yellow, oblong bilayered tablet	Visual
Average weight	1083mg ± 5%	USP
Thickness	6.4mm ± 0.2mm	By suitable calibrated Vernier caliper
Hardness	Not less than 5 Kg/cm^2	USP <1217>
Friability	Not more than 1.0%	USP <1216>
Loss on drying	Not more than 5.0% w/w	USP <731>
Chemical		
Composition :-		
Each tablet contains		
- Boswellin Super (Boswellia serrata extract) 30% AKBBA	200mg	
- Curcumin C3 Complex (Curcuma longa extract)	200mg	
- Ginger Soft SCF Extract 20%	150mg	
- Bioperine	5mg	
Assay:		
Each tablet contains		
-AKBBA	60mg ± 10%	SLL/STP-A-039*
-Curcuminoids	190mg ± 10%	SLL/STP-C-051*
-Bioperine	5mg± 10%	SLL/STP-C-051*
-Gingerols	30mg±10%	USP
Dissolution test		SLL/STP-D-014*
% Release of AKBBA		
- 1st hour	Not less than 10%	
- 2nd hour	Not less than 30%	
- 4th hour	Not less than 50%	
- 8th hour	Not less than 65%	
% Release of Curcuminoids		
- 1st hour	Not less than 25%	
- 2nd hour	Not less than 40%	
- 4th hour	Not less than 60%	
- 8th hour	Not less than 65%	
Others		
Total Heavy metals	Not more than 20ppm (µg/g)	USP <231> Method II
Lead	Not more than 3ppm (µg/g)	ICP-OES, SLL/STP-H-006**
Arsenic	Not more than 1ppm (µg/g)	ICP-OES, SLL/STP-H-006**
Cadmium	Not more than 0.3ppm (µg/g)	ICP-OES, SLL/STP-H-006**
Mercury	Not more than 0.1ppm (µg/g)	ICP-OES, SLL/STP-H-006**
Micro results		
Total aerobic microbial count	Not more than 5000cfu/g	USP <2021>
Total yeasts and molds count	Not more than 100cfu/g	USP <2021>
Escherichia coli	Negative/10g	USP <2022>
Salmonella	Negative/25g	EP 2.6.31
Staphylococcus aureus	Negative/10g	USP <2022>
Pseudomonas aeruginosa	Negative/10g	USP <62>
Bile tolerant gram negative bacteria	Not more than 100cfu/g	USP <2021>
Packing	60's – 120ml, white HDPE bottle	

*Inhouse developed and validated method

Prepared By:
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Checked By:
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Approved By:
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SABINSA EUROPE GmbH

PRODUCT DATA SHEET

NILITIS SR TABLET

Finished product Specification

Issue No. 2
January 5, 2015

STANDARDS AND LIMITS

NILITIS SR TABLETS

Specification No. : FPS/ARD/364 (PH)

Parameters	Limit	Reference
Physical		
Description	Orange yellow – yellow, oblong bilayer tablet	Visual
Average weight	1083mg ± 5%	USP
Thickness	6.4mm ± 0.2mm	By suitable calibrated Vernier caliper
Tablet Length	21.25mm± 0.3mm	By suitable calibrated Vernier caliper
Hardness	Not less than 5 Kg/cm^2	USP <1217>
Friability	Not more than 1.0% w/w	USP <1216>
Moisture content	Not more than 5.0% w/w	USP <921>
Chemical		
Composition :-		
Each tablet contains		
- Boswellin Super (Boswellia serrata extract) 30% AKBBA	200mg	
- Curcumin C3 Complex (Curcuma longa extract)	200mg	
- Ginger Soft SCF Extract 20%	150mg	
- Bioperine	5mg	
Assay:		
Each tablet contains		
-AKBBA	60mg ± 10%	SLL/STP-A-039*
-Curcuminoids	190mg ± 10%	SLL/STP-C-051*
-Gingerols	30mg± 10%	USP
-Bioperine	5mg± 10%	SLL/STP-C-051*
Dissolution test		SLL/STP-D-014*
% Release of AKBBA		
- 1st hour	Not less than 10%	
- 2nd hour	Not less than 30%	
- 4th hour	Not less than 50%	
- 8th hour	Not less than 65%	
% Release of Curcuminoids		
- 1st hour	Not less than 25%	
- 2nd hour	Not less than 40%	
- 4th hour	Not less than 60%	
- 8th hour	Not less than 65%	
Others		
Total Heavy metals	Not more than 20ppm (µg/g)	USP <231> Method II
Lead	Not more than 3ppm (µg/g)	ICP-OES, SLL/STP-H-006*
Arsenic	Not more than 0.3ppm (µg/g)	ICP-OES, SLL/STP-H-006*
Cadmium	Not more than 0.3ppm (µg/g)	ICP-OES, SLL/STP-H-006*
Mercury	Not more than 0.1ppm (µg/g)	ICP-OES, SLL/STP-H-006*
Total Aflatoxins	Not more than 20ppb (µg /kg)	SLL/STP-A-044*
Aflatoxin B1	Not more than 10ppb (µg /kg)	SLL/STP-A-044*

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	SABINSA EUROPE GmbH **PRODUCT DATA SHEET** **NILITIS SR TABLET**

Finished product Specification

Issue No. 2
January 5, 2015

STANDARDS AND LIMITS

NILITIS SR TABLETS

Specification No. : FPS/ARD/364 (PH)

Parameters	**Limit**	**Reference**
Micro results		
Total aerobic microbial count	Not more than 5000cfu/g	USP <2021>
Total yeasts and molds count	Not more than 100cfu/g	USP <2021>
Escherichia coli	Negative/10g	USP <2022>
Salmonella	Negative/10g	USP <2022>
Staphylococcus aureus	Negative/10g	USP <2022>
Pseudomonas aeruginosa	Negative/10g	USP <62>
Other Enterobacteria	Not more than 100cfu/g	USP <2021>
Packing	60's – 120ml, white HDPE bottle	

*Inhouse developed and validated method

Prepared By:	Checked By:	Approved By:
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Sr. Scientist – Analytical R&D	**Dy. Manager – Analytical R&D**	**Executive Vice President**

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SABINSA EUROPE GmbH

PRODUCT DATA SHEET

NILITIS SR TABLET

FINISHED PRODUCT SPECIFICATION

Product : NILITIS TABLET	
Specification No. : FPS/ARD/1089 (AY)	**Effective Date : 07/12/2015**
Issue No. : 1	**Review Date : 06/12/2018**
Supersedes : New Specification	**Grade : In-house**

Parameters	Limits	Reference method
Description	Yellow coloured round film coated tablet	Visual
Disintegration time	Not more than 30minutes	USP<701>
Average weight	450mg±5%	USP
Thickness	5.8mm±0.3mm	By suitable calibrated Vernier caliper
Hardness	Not less than 4kg/cm²	USP <1217>
Friability	Not more than 1%	USP <1216>
Composition		
Each tablet contains		
-Boswellin super (30% AKBBA)	100mg	
-Bioperine 40%	2.5mg	
-Curcumin C3 complex	100mg	
-Ginger extract (Gingerols 35%)	40mg	
Assay		
Each tablet contains		
-Acetyl Keto beta boswellic acid	Not less than 30mg	SLL/STP-B-002
-Piperine	1mg±10%	SLL/STP-C-051
-Curcuminoids	100mg±10%	SLL/STP-C-051
-Total Gingerols	14mg±10%	USP
Others		
Heavy metals		
Lead	Not more than 10ppm(µg/g)	ICP-OES, SLL/STP-H-006
Arsenic	Not more than 3ppm(µg/g)	ICP-OES, SLL/STP-H-006
Cadmium	Not more than 0.3ppm(µg/g)	ICP-OES, SLL/STP-H-006
Mercury	Not more than 1ppm(µg/g)	ICP-OES, SLL/STP-H-006
Aflatoxin		SLL/STP-A-044
B1	0.5 ppm(µg/g)	
B2	0.1 ppm(µg/g)	
G1	0.5 ppm(µg/g)	
G2	0.1 ppm(µg/g)	
Residual pesticides	Less than 1 ppm	SLL/STP-R-004
Microbiological profile		
Total bacterial count	Not more than 100000cfu/g	USP <2021>
Total yeasts and molds count	Not more than 1000cfu/g	USP <2021>
Escherichia coli	Absent	USP <2022>
Salmonella	Absent	USP <2022>
Staphylococcus aureus	Absent	USP <2022>
Pseudomonas aeruginosa	Absent	USP <62>

Prepared by	Checked by	Approved by
07/12/2015	07/12/2015	07/12/2015
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Confidential

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