

Retain Stability Report

Page 1 of 2

Department: Quality

Product: SPF 50 Body Stick; Formula F132-121.CC

Prepared By Amy Caudle QA/QC Manager  20 Jun 22	Reviewed By Madison Beane Assistant QC Manager  20 Jun 22	Approved By Miryam Bost Quality and Regulatory Manager  20 Jun 22	Effective Date:	JUN 20 2022
			Report No.	SR-2022-004R.00
			Supersedes:	N/A

1.0 INTRODUCTION/BACKGROUND

- 1.1 The objective of this stability study is to provide evidence of the quality and potency of the active ingredients in SPF 50 Body Stick products under the influence of ambient storage conditions for 3 years. This study was performed with retain samples that had been stored at ambient conditions for a minimum of 3 years. This study provides documented evidence that the drug product is stable, and packaging is not reactive, additive, or absorptive so that the identity, strength, quality, and purity of the drug product are unaffected.
- 1.2 This study was conducted with the purpose of determining and or validating that shelf-life stability of this product is 3 years.
- 1.3 Components used for this stability study of formula number F132-121.CC are documented under executed batch record and packaging record.

2.0 PRODUCT STUDY RESULTS

2.1 Product Specification and test results:

2.1.1 Specifications

Test Description	Specification Range
Appearance	Off white to pale yellow solid
Odor	Faint
Assay, Avobenzone	2.7%-3.3%
Assay, Homosalate	13.5%-16.5%
Assay, Octisalate	4.5%-5.5%
Assay, Octocrylene	9.0%-11.0%

2.1.2 Results

Test Description	Specification Range	3 years	3 years, 3 months
Appearance	Off white to pale yellow solid	Pale yellow solid	Pale yellow solid
Odor	Faint	Faint	Faint
Assay, Avobenzone	2.7%-3.3%	3.1%	2.9%
Assay, Homosalate	13.5%-16.5%	15.0%	14.8%
Assay, Octisalate	4.5%-5.5%	4.9%	4.8%
Assay, Octocrylene	9.0%-11.0%	10.0%	9.9%

3.0 DEVIATIONS/INVESTIGATIONS – N/A

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Product: SPF 50 Body Stick; Formula F132-121.CC	

4.0 PACKAGING INFORMATION

4.1 This product was packaged in a 50 g stick composed of polypropylene (PP). This can be seen in the attached packaging diagram for FTP-157 and FTP-158.

5.0 CONCLUSION

5.1 All results were within specification and the shelf-life is validated to be 3 years.

5.2 The drug product will be placed on a real-time stability schedule as allowable by production and stability schedules.

6.0 ATTACHMENT

6.1 Test results

6.2 Packaging Information

7.0 REFERENCES

7.1 Executed batch and packaging records, lot number 53B19.

Revision History:

Version Number	Effective Date	Description of Revision
00	JUN 20 2022	Original Version

Testing of Retain Samples for Stability

Department: Quality		Form No.: FRM-Q-046		Version: 02		Reference: SOP-Q-011	
Prepared By:	Miryam Bost Quality and Regulatory Manager	Approved By:	Amy Caudle QA/QC Manager	Effective Date:			
Date:	M 20 Oct 21	Date:	07 Oct 21	NOV 09 2021			

Product:	SPF 50 Body Stick
Formula Number:	F132-121.CC
FP Specs:	R&D-2019-008.00
Batch Number:	53B19
Expiration:	02/21

Tests to be Conducted by In-house Laboratory

Tests	Specifications	Method	Results	Tested By	Date
Appearance	Off white to pale yellow solid	SOP-L-002	pale yellow solid	VJ	10 May 22
Odor	Faint	SOP-L-002	Faint	VJ	10 May 22
Checked By/Date:				AC 16 Jun 22	

Testing to be Conducted by External Laboratory*

Tests	Specifications	Method	Results	Documented By	Date
Assay, Avobenzone	2.7-3.3%	Outside Laboratory	① 2.9% 2.89%	SM	23 MAY 22
Assay, Homosalate	13.5-16.5%	Outside Laboratory	14.8%	SM	23 MAY 22
Assay, Octisalate	4.5-5.5%	Outside Laboratory	4.8%	SM	23 MAY 22
Assay, Octocrylene	9.0-11.0%	Outside Laboratory	9.9%	SM	23 MAY 22
Checked By/Date:				AC 16 Jun 22	

*Attach results obtained by external laboratory

① ME: SM 23 MAY 22

Revision History:

Version	Effective Date	Comment
00	11 Feb 20	New Form
01	11 Feb 20	Updated with page number as footer
02	NOV 09 2021	Updated header and logo

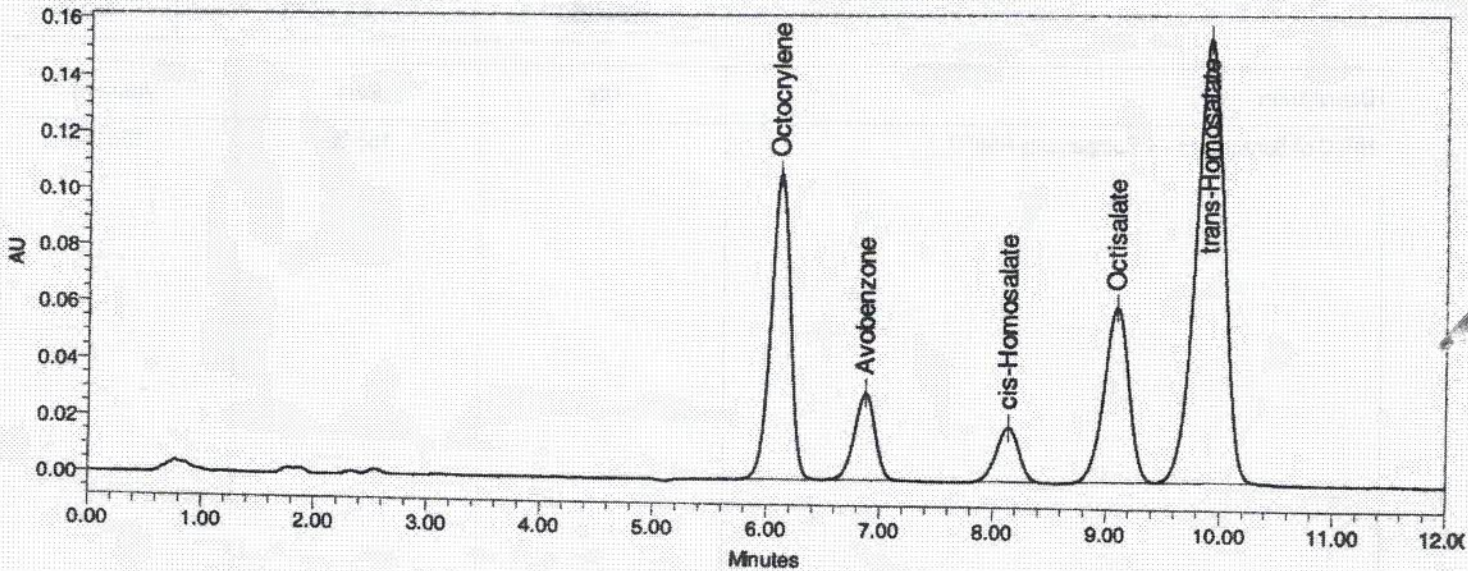
Custom Analytics LLC

Certificate of Analysis

5/13/2022

53B19 Ex: 02/21 Sheer Tough SPF 50 Body Stick COMP

NB Reference: 2115-17209	Acquired By: cgrier
Sample Type: Unknown	Date Acquired: 5/13/2022 2:59:08 PM EDT
Sample Weight: 0.14300 Dilution: 5.00000	Acq. Method Set: 15024
Injection Volume: 5.00 ul Vial 21	Date Processed: 5/13/2022 3:15:27 PM EDT
Run Time: 12.0 Minutes	Processing Method: 15024
Sample Set Name: 15024	Channel Name: 235 nm
	Sampling Rate: 1 per sec Calibration Id 9183



	Analyte	RT	Area	% Area	Height	Wt. %
1	Homosalate		2823284	52.87	171431	14.81
2	Octocrylene	6.113	1239841	23.22	106317	9.85
3	Avobenzene	6.870	372235	6.97	29767	2.89
4	cis-Homosalate	8.133	253119	4.74	18443	
5	Octisalate	9.090	904823	16.94	59260	4.78
6	trans-Homosalate	9.904	2570165	48.13	152988	

Chover



Testing of Retain Samples for Stability				
Department: Quality		Form No.: FRM-Q-046	Version: 02	Reference: SOP-Q-011
Prepared By:	Miryam Bost Quality and Regulatory Manager	Approved By:	Amy Caudle QA/QC Manager	Effective Date:
Date:	M 20 Oct 21	Date:	07 Oct 21	NOV 09 2021

Product:	SPF 50 Sheer Touch Body Stick
Formula Number:	F118-026-EE-2 F132-121
FP Specs:	R&D-2018-006.01
Batch Number:	53R19 53B19
Expiration:	02/21

Tests to be Conducted by In-house Laboratory

Tests	Specifications	Method	Results	Tested By	Date
Appearance	Off white to pale yellow solid	SOP-L-002	Pale yellow solid	MRB	05 Feb 22
Odor	Faint	SOP-L-002	Faint	WJ	08 Feb 22
Checked By/Date:				AC 23 Feb 22	

Testing to be Conducted by External Laboratory*

Tests	Specifications	Method	Results	Documented By	Date
Assay, Avobenzone	2.7-3.3%	Third Party Lab	3.1	Pass	22/16 Feb 22
Assay, Homosalate	13.5-16.5%	Third Party Lab	15.0	Pass	22/16 Feb 22
Assay, Octisalate	4.5-5.5%	Third Party Lab	4.9	Pass	22/16 Feb 22
Assay, Octocrylene	9.0-11.0%	Third Party Lab	10.0	Pass	22/16 Feb 22
Assay, Zinc Oxide	1.8-2.2%	Third Party Lab			
Micro	USP <61>, <62>	Third Party Lab	2.10	Pass	22/16 Feb 22
Checked By/Date:				AC 23 Feb 22	

*Attach results obtained by external laboratory

① EE MRB 16 Feb 22

② Incorrect formula was provided. On the correct formula, zinc oxide is not present. MRB 22 Feb 22

Version	Effective Date	Comment
00	11 Feb 20	New Form
01	11 Feb 20	Updated with page number as footer
02	NOV 09 2021	Updated header and logo

Custom Analytics LLC

Certificate of Analysis
 Total Aerobics, Total Coliforms and Yeast & Mold
 MC4005-2 Revision 3 2/11/2019

02/16/2022 13:16:09

Start Incubation: 02.11.2022 1:00:00 pm

Stop Incubation: 02.14.2022 1:00:00 pm

Stop Incubation: 02.16.2022 1:00:00 pm

35 C Incubator ≤ 3 Days

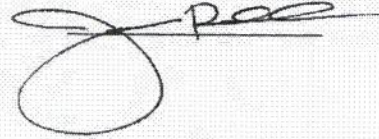
25 C Incubator ≤ 5 Days

Sample	Lot	Log #	TSA Total Aerobics			Endo LES Total Coliforms		PDA Yeast & Mold		
			Colonies	cfu / gram	Mean cfu/gram	Colonies	cfu / gram	Colonies	cfu / gram	Mean cfu/gram
53B19 Ex: Q2/21 Sheer Touch SPF 50 Body Stick Comp	53B19	22-01172	0	<10	<10	0	<10	0	<10	<10
			0	<10				0	<10	

NB Ref: 2111-125.6

MC4005-2 Revision 3 2/11/2019

Approved By:



Custom Analytics LLC

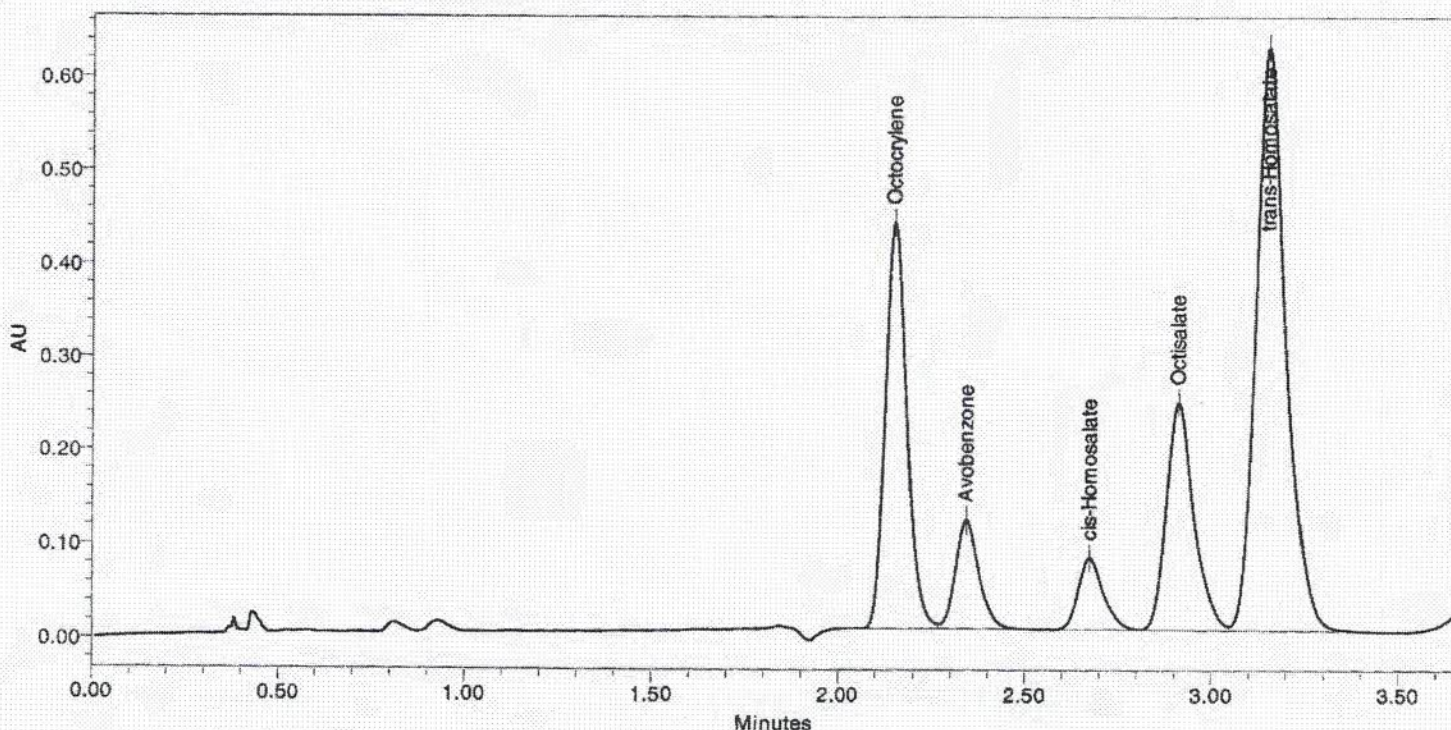
Certificate of Analysis

2/16/2022

Sheer Touch SPF 50 Body Stick BME Comp 53B19 Ex:02/21

NB Reference: 2204-04803
Sample Type: Unknown
Sample Weight: 0.18260 Dilution: 5.00000
Injection Volume: 2.00 ul Vial 1:D,4
Run Time: 6.0 Minutes
Sample Set Name: 15024A

Acquired By: jones
Date Acquired: 2/9/2022 11:25:16 AM EST
Acq. Method Set: 15024A
Date Processed: 2/9/2022 12:47:03 PM EST
Processing Method: 15024A
Channel Name: 235 nm
Sampling Rate: 40 per sec



	Analyte	RT	Area	% Area	Response	Wt. %
1	Homosalate		3799408	52.45	3799408.248	14.98
2	Octocrylene	2.151	1709019	23.59	1709019.388	9.96
3	Avobenzone	2.342	502116	6.93	502115.986	3.09
4	cis-Homosalate	2.673	354457	4.89	354457.259	
5	Octisalate	2.911	1232767	17.02	1232766.694	4.91
6	trans-Homosalate	3.153	3444951	47.56	3444950.989	

FillTech USA Batch Record Cover Sheet

Product:	SPF 50 Body Stick, F132-121.CC
FP Specs:	R&D-2019-008.00
Batch No. (Lot #):	531319
Expiration:	
Batch Size in pounds:	
Total Waste in pounds	
Bulk Left Over in Pounds	
Total Bottles	

N/A
22 Feb 22
MRB

BULK PRODUCT TESTING

Tests	Specifications	Method	Results
Appearance	Off white to pale yellow solid.	SOP-L-002	Pale yellow solid MRB 22 Feb 22 Pass ①
Odor	Faint	SOP-L-002	Faint Pass MRB 22 Feb 22 Pass ①
Avobenzone	2.7 - 3.3%	Analytical	3.1% pass MRB 22 Feb 22
Homosalate	13.5 - 16.5%	Analytical	15.0% pass MRB 22 Feb 22
Octisalate	4.5 - 5.5%	Analytical	4.9% pass MRB 22 Feb 22
Octocrylene	9.0 - 11.0%	Analytical	10.0% pass MRB 22 Feb 22
Checked by/date:			AC 23 Feb 22

YIELD CALCULATION (yield NLT 95%):

total amount in lbs = $\left(\frac{\# \text{ of sticks} \times \text{ave wt in g}}{453.6} \right) =$ _____ =

% yield = $\left(\frac{(\text{total amt in lbs} + \text{waste})}{\text{Theoretical in lbs}} \right) \times 100 =$ _____ * 100 =

Performed By/Date: _____ Checked By/Date: _____

Yield Approved By: _____ Date: _____

① Transcribed from cover sheet attached due to incorrect formula.
MRB 22 Feb 22

② micro documented on attached coversheet
MRB 22 Feb 22

Revision History

Date	Version	Description
02/19/19	00	Initial
20 May 2020	01	Added the yield calculation and changed batch approved by to yield approved by.

FillTech USA Batch Record Cover Sheet

Product:	Sheer Touch SPF 50 Body Stick, F118-026.CC
FP Specs:	R&D-2018-006.01
Batch No. (Lot #):	53B19 53B19 TE MEB 23Feb22
Expiration:	02/21 23Feb22
Batch Size in pounds:	
Total Waste in pounds	
Bulk Left Over in Pounds	N/A
Total Bottles	MEB 08Feb22

BULK PRODUCT TESTING

Tests	Specifications	Method	Results
Appearance	Off white to pale yellow solid.	SOP-L-002	Pale yellow solid MEB 08Feb22 Pass
Odor	Faint	SOP-L-002	Pass vs faint 08Feb22.
FINISHED PRODUCT TESTING			
Avobenzone	2.7 - 3.3%	Analytical	3.1% pass vs 23Feb22
Homosalate	13.5 - 16.5%	Analytical	15.0% pass vs 23Feb22
Octisalate	4.5 - 5.5%	Analytical	4.9% pass vs 23Feb22
Octocrylene	9.0 - 11.0%	Analytical	10.0% pass vs 23Feb22.
① Zinc Oxide	^{MICRO} salmonella 100 CFU/g TRAC, 100 CFU/g, S.aureus absent, P.aeruginosa absent 1.8 - 2.2% ①	USP 4017 Pass Analytical	100 CFU/g absent pass vs 23Feb22
Tested by/date: NB reference:	vs 20Feb22	Checked by/date:	Ac 23Feb22

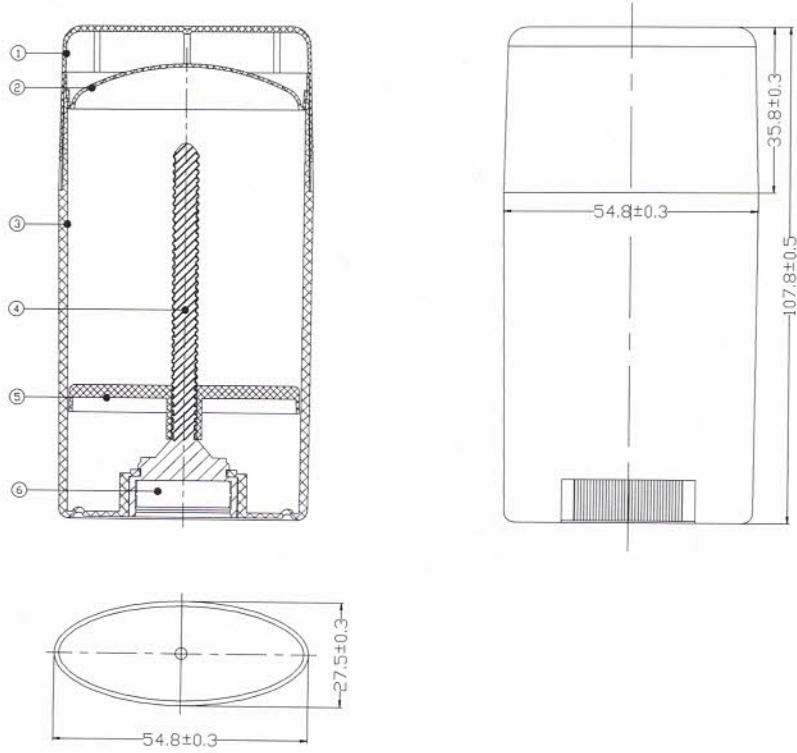
Batch Approved By: _____ Date: _____

Revision History

Date	Version	Description
06FEB18	00	Initial ELC 06FEB18

① ZINC not tested for - wrong formula vs 23Feb22.

50G DEODORANT CONTAINER



序号	名称	材料
①	外盖	PP
②	内盖	PP
③	瓶身	PP
④	螺杆	PP
⑤	活塞	PP
⑥	底座	PP

制图		材料						图样标记	
校对		重量		产品名称	50ML男士体香剂				
核准		比例							
日期									

MJS PACKAGING
130 BLAKELY ROAD
SIMPSONVILLE, SC 29680
P: 864-627-9546 F: 864-627-9548