Mitchell Group USA
1 S.E. 3rd Avenue, Suite 1860
Miami, FL 33131
United States

Evaluation of Test Results	
Item Description:	**Neoprosone Dark Spot Remover**
ASIN Number:	**B082ZPYLPM**
Sample Received Date:	**2/5/2025**
Issue Date:	**2/14/2025**
Expiration Date:	**2/14/2026**



Overall Rating: PASS	**Neoprosone Dark Spot Remover**

Label Verification: **PASS**
GMP Validation: **PASS**
FDA Facility Registration: **PASS**
FDA Product Listing: **PASS**
Microbiological Testing (USP 60/61/62): **PASS**
Heavy Metals Testing: **PASS**
Adulterants Testing: **PASS**

Signed for and on behalf of SGS North America, Inc.

Date: February 14, 2025

Joseph Scognamiglio
Director of Operations, C&H Laboratory

Prepared By:

Date: February 14, 2025

Aliyah Bobb
Regulatory Affairs Associate, C&H Laboratory

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LABELING REVIEW						
Scope	***Conformity***			***Present text on label***	***CORRECTIVE ACTION (Corrections marked in red)***	***COMMENTS (Reasons for changes) LEGISLATION***
PASS	***YES***	***NO***	***N/A***			
Statement of Identity	X					

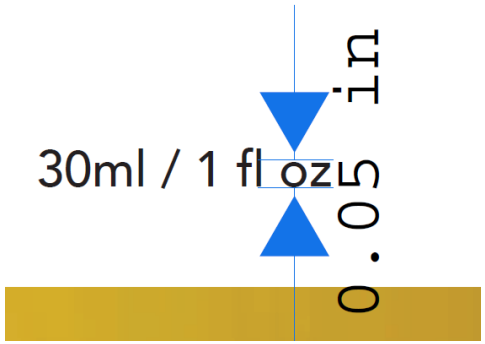
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	YES	***NO***	***N/A***			
PASS						
Statement of Responsibility Name and place of business of manufacturer, packer, or distributor	X			TECHNOPharma brand 12 M MADE IN USA MITCHELL BRANDS 6852 NW 77th Court Miami, FL 33166 PH: 1 888 726 6211 www.mitchellgroupinternational.com UK Distribution: Mitchell Cosmetics Inc. Ltd. 167-169 Great Portland Street Fifth Floor London W1W 5PF UK Toll Free 0 800 041 8158 EU Distribution: Mitchell Cosmetics Ltd. First Floor, Penrose 1, Penrose Dock, Cork, T23 KW81 | EU Toll Free 0 805 98 54 94		

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PASS	***YES***	***NO***	***N/A***			
Brand Owner Details	X			TECHNOPharma brand 12 M MADE IN USA MITCHELL BRANDS 6852 NW 77th Court Miami, FL 33166 PH: 1 888 726 6211 www.mitchellgroupinternational.com UK Distribution: Mitchell Cosmetics Inc. Ltd. 167-169 Great Portland Street Fifth Floor London W1W 5PF UK Toll Free 0 800 041 8158 EU Distribution: Mitchell Cosmetics Ltd. First Floor, Penrose 1, Penrose Dock, Cork, T23 KW81 | EU Toll Free 0 805 98 54 94		
Country of Origin	X			MADE IN USA		

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PASS	***YES***	***NO***	***N/A***			
Net Quantity of Contents and its type size requirement			X		If the PDP is ≥ 25 but ≤ 100 sq in. then the type size for net weight needs to be at least 3/16 in. (0.1875 in.) Type size is 0.05 in. PDP measures at 7.01 sq in.	21 CFR 701.13(i)(2): The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications… …Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches
Avoidable Hazards and Cautions			X	**Warnings:** For external use only. Avoid eye area.	Risk assessment was not conducted as part of the label review. If any concerns for the safe use of the product exist, the proper warnings, hazards and cautions should appear.	
Directions for use	X			**Directions:** Apply directly on dry, cleansed skin and massage in circular motions. Follow up with SPF daily.		

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PASS	***YES***	***NO***	***N/A***			
Ingredient Listing			X	**Ingredients:** Monopropylene Glycol, Alpha Arbutin, Vitamin A, Phenoxyethanol, Sodium Benzoate, Potassium Sorbate, Benzyl Alcohol,Tetrasodium EDTA.	Not Listed on UNII: Alpha Arbutin IMPROPER INCI Names: Monopropylene Glycol Alpha Arbutin	The following are PROPER INCI names: Propylene Glycol Alpha-Arbutin
Claims	X			Formulated in a light refreshing scent, **Neoprosone Complex Forte Brightening Gel Cream** reduces appearance of dark brown spots, evening out skin tone with brightening Arbutin Complex. Helps prevent premature aging, promoting a radiant youthful complexion.		

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FDA Review						
Scope	***Conformity***			***Specficiation***	***CORRECTIVE ACTION (Corrections marked in red)***	***Document Reference***
PASS	***YES***	***NO***	***N/A***			
FDA Registration REQUIREMENTS						
GMP Verification	**X**			Documentation of Good Manufacturing Practices from manufacturing facility according to ISO 22716:2007, NSF/ANSI 455-3 or equivalent. FDA Inspections are not considered a replacement for a GMP issuing body.		
Facility Registration	**X**			FDA Form 5066 must be provided and note expired.		
FDA Product Listing	**X**			FDA Form 5067 with product name and ingredients of ASIN must be provided.		

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MICROBIOLOGICAL AND ANALYTICAL REVIEW						
Scope	***Conformity***			***Specification***	***CORRECTIVE ACTION (Corrections marked in red)***	***Document Reference***
PASS	***YES***	***NO***	***N/A***			
FDA Registration REQUIREMENTS						
Microbial Limits Testing	**X**			≤1000 cfu/mL(g) - USP <60>,<61> Absence of specified organism (or negative) – USP <62>		
Heavy Metals Testing	**X**			Mercury: < 1ppm Lead: < 10ppm Arsenic: < 3ppm Cadmium: < 3 ppm		
Adulterants Testing	**X**			Hydroquinone: < 5ppm or ND Betamethasone dipropionate: < 5ppm or ND Betamethasone 17-valerate: < 5ppm or ND Betamethasone: < 5ppm or ND Clobetasol propionate: < 5ppm or ND Clotrimazole: < 5ppm or ND Halobetasol propionate: < 5ppm or ND Fluocinonide: < 5ppm or ND Fluocinolone: < 5ppm or ND Fluocinolone acetonide: < 5ppm or ND		

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Scope	***Conformity***			***Specification***	***CORRECTIVE ACTION (Corrections marked in red)***	***Document Reference***
	YES	***NO***	**N/A**			
PASS						
FDA Registration REQUIREMENTS						

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APPENDIX – GENERIC REMARK

(a) This evaluation is relevant solely to the conditions described herein. Any substitution of ingredients, increase in ingredient concentrations, or change in use pattern will necessitate a new evaluation.

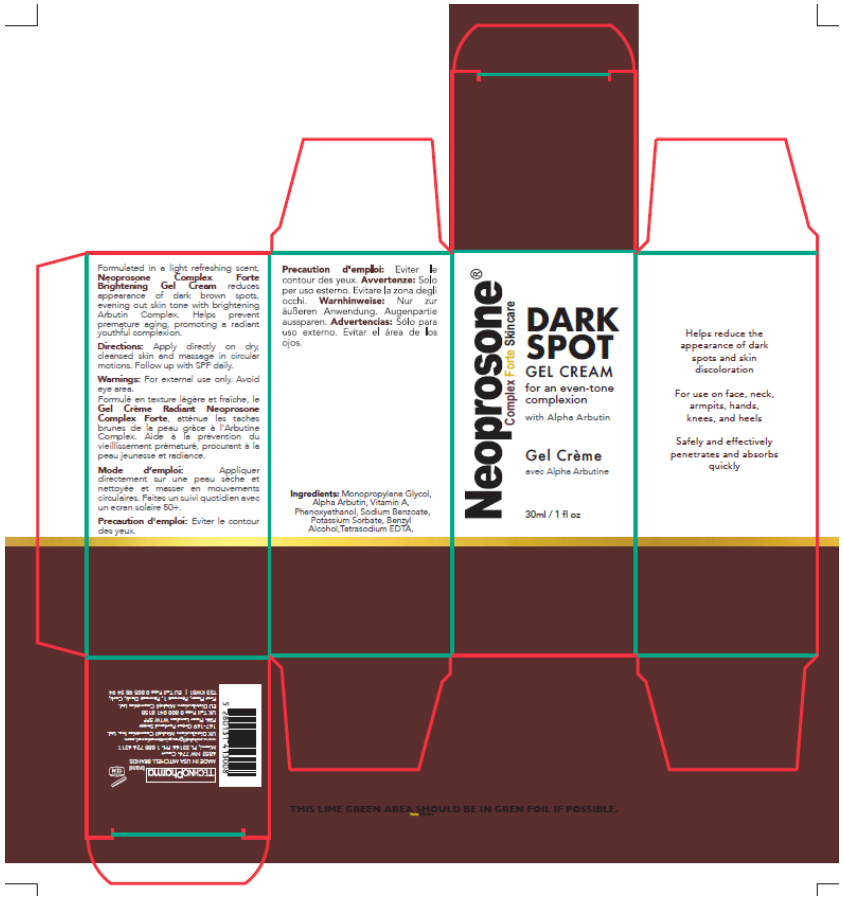
(b) Results reported on the submitted product label/label artwork are on an as received basis.

(c) Ingredients checked for INCI name only.

(d) Only content in English was reviewed in the assessment.

(e) All claims on the label(s) shall be truthful and verifiable.

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End of Report

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