

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: Feb. 25, 2024 Product: Niceway Enteric Coated Softgels
 Product Code: 201544 Lot No.: 22402752 Manufacture Date: Feb. 07, 2024

Active Ingredients <i>*Base on Input</i>	per unit	Result
Peppermint Oil (<i>Mentha arvensis L. var. piperascens Maliny</i>)	181.00 mg	*
Foeniculi Fructus Oil (<i>Foeniculum vulgare Mill.</i>)	19.30 mg	*
Ginger Oil	17.60 mg	*

Excipients: *Sun Flower Oil*

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	Transparent brown oval #6 enteric coated softgels containing a clear oil	Conforms	Visual
Filling Weight Variation	350.000 mg/per unit $\pm 10\%$	346.120 mg	USP <2091>
Shell Moisture Content	6% to 10%	Conforms	USP <731>
Disintegration	1) No unit disintegrates in gastric fluid within 60 minutes 2) All units disintegrate in intestinal fluid in no more than 60 minutes	1) Conforms 2) 12 min 48 sec	USP <2040>
Heavy Metals* Arsenic Cadmium Lead Mercury	NMT 0.14 mcg/kg b.w./day NMT 0.09 mcg/kg b.w./day NMT 0.14 mcg/kg b.w./day NMT 0.29 mcg/kg b.w./day	Conforms	ICP

Microbiological Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Total Aerobic Count	< 1000 cfu/g	Conforms	USP <2021>
Total Combined Mold and Yeasts Count	< 100 cfu/g	Conforms	USP <2021>
E. coli	Negative	Negative	USP <2022>
Salmonella spp.	Negative	Negative	USP <2022>
Staphylococcus aureus	Negative	Negative	USP <2022>
Pseudomonas aeruginosa	Negative	Negative	USP <62>



02/25/2024

Quality Control

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QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: Feb. 21, 2022 Product: Niceway Enteric Coated Softgels
 Product Code: 201544 Lot No.: 22201593 Manufacture Date: Jan. 25, 2022

Active Ingredients *Base on Input

	per unit	Result
Peppermint Oil (<i>Mentha arvensis</i> L. var. <i>piperascens</i> Maliny)	181.00 mg	*
Foeniculi Fructus Oil (<i>Foeniculum vulgare</i> Mill.)	19.30 mg	*
Ginger Oil	17.60 mg	*

Excipients: *Sun Flower Oil*

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	Transparent brown oval #6 enteric coated softgels containing a clear oil	Conforms	Visual
Filling Weight Variation	350.000 mg/per unit $\pm 10\%$	346.110 mg	USP <2091>
Shell Moisture Content	6% to 10%	Conforms	USP <731>
Disintegration	1) No unit disintegrates in gastric fluid within 60 minutes 2) All units disintegrate in intestinal fluid in no more than 60 minutes	1) Conforms 2) 12 min 47 sec	USP <2040>
Heavy Metals* Arsenic Cadmium Lead Mercury	NMT 0.14 mcg/kg b.w./day NMT 0.09 mcg/kg b.w./day NMT 0.14 mcg/kg b.w./day NMT 0.29 mcg/kg b.w./day	Conforms	ICP

Microbiological Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Total Aerobic Count	< 1000 cfu/g	Conforms	USP <2021>
Total Combined Mold and Yeasts Count	< 100 cfu/g	Conforms	USP <2021>
E. coli	Negative	Negative	USP <2022>
Salmonella spp.	Negative	Negative	USP <2022>
Staphylococcus aureus	Negative	Negative	USP <2022>
Pseudomonas aeruginosa	Negative	Negative	USP <62>



02/21/2022

Quality Control

Date

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: November 07, 2018 Product: Niceway Enteric Coated Softgels
Product Code: 201544 Lot No.: 21807238 Manufacture Date: August 01, 2018

Active Ingredients *Base on Input

	per unit	Result
Peppermint Oil (Mentha arvensis L. var. piperascens Maliny)	181.00 mg	*
Foeniculi Fructus Oil (Foeniculum vulgare Mill.)	19.30 mg	*
Ginger Oil	17.60 mg	*

Excipients: Gelatin (Pigskin) 、 Purified Water 、 Glycerol 、 Carob Powder (Ceratonia siliqua L.)

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	Transparent brown oval #6 enteric coated softgels containing clear oil	Conforms	Visual
Filling Weight Variation	350.000 mg/per unit $\pm 10\%$	346.000 mg/per unit CV=0.914%	USP <2091>
Shell Moisture Content	6%-10%	Conforms	USP <731>
Disintegration	1) No unit disintegrates in gastric fluid within 60 minutes 2) All units disintegrate in intestinal fluid in no more than 60 minutes	1) Conforms 2) Conforms	USP <2040>

Microbiological Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Total Aerobic Count	< 1000 cfu/g	Conforms	USP <2021>
Total Combined Mold and Yeasts Count	< 100 cfu/g	Conforms	USP <2021>
E. coli	Negative	Negative	USP <2022>
Salmonella spp	Negative	Negative	USP <2022>
Staphylococcus aureus	Negative	Negative	USP <2022>
Pseudomonas aeruginosa	Negative	Negative	USP <62>

Nutrition Values**

per unit

Energy	4.2 kcal
Carbohydrate	19.15 mg
Protein	246.7 mg
Fat(Oil)	350.3 mg
Sodium	0.6 mg

**** Estimated from Nutritional Value Database**



Quality Control

06/24/2019_____
Date