

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 <i>*Base on Input</i>	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 ±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