

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: Apr. 17, 2023 Product: Ospastone Film Tablets
 Product Code: 400563 Lot No.: 42302130 Manufacture Date: Mar. 28, 2023

Active Ingredients	*Base on Input	per unit	Result
Dandelion Root Extract		60.00 mg	*
Olera Extract		50.00 mg	*
Rosehip Extract		50.00 mg	*
Golden Rod Extract		50.00 mg	*
Horsetail Extract		50.00 mg	*
Corn Silk Extract		50.00 mg	*
Cat's Whiskers Extract		50.00 mg	*
Calcium Phosphate, Dibasic		25.00 mg	*

Excipients: Microcrystalline Cellulose, Potassium Citrate, Magnesium Stearate, Titanium Dioxide

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	11.11 x 4.75 mm white coated round tablets	Conforms	Visual
Average Tablet Weight	540.750 mg $\pm$ 5%	525.950 mg	USP <2091>
Weight Variation	Meets USP requirements	Conforms	USP <2091>
Disintegration	NMT 60 minutes	26 mins 12 sec	USP<2040>
Hardness	NLT 9 kp	17.5 kp	USP<1217>
Friability	NMT 1%	0%	USP<1216>

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>



Quality Control

04/17/2023

Date

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: May 18, 2022 Product: Ospastone Film Tablets
Product Code: 400563 Lot No.: 42203127 Manufacture Date: April 27, 2022

Active Ingredients	*Base on Input	per unit	Result
Dandelion Root Extract		60.00 mg	*
Olera Extract		50.00 mg	*
Rosehip Extract		50.00 mg	*
Golden Rod Extract		50.00 mg	*
Horsetail Extract		50.00 mg	*
Corn Silk Extract		50.00 mg	*
Cat's Whiskers Extract		50.00 mg	*
Calcium Phosphate, Dibasic		25.00 mg	*

Excipients: *Microcrystalline Cellulose, Potassium Citrate, Magnesium Stearate, Titanium Dioxide*

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	11.11 x 4.75 mm white coated round tablets	Conforms	Visual
Average Tablet Weight	540.750 mg $\pm$ 5%	531.800 mg	USP <2091>
Weight Variation	Meets USP requirements	Conforms	USP <2091>
Disintegration	NMT 60 minutes	25min 49sec	USP<2040>
Hardness	NLT 9 kp	18 kp	USP<1217>
Friability	NMT 1%	0%	USP<1216>

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>



Quality Control

05/18/2022

Date

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: May 13, 2021 Product: Ospastone Film Tablets
Product Code: 400563 Lot No.: 42104123 Manufacture Date: April 23, 2021

Active Ingredients	*Base on Input	per unit	Result
Dandelion Root Extract		60.00 mg	*
Olera Extract		50.00 mg	*
Rosehip Extract		50.00 mg	*
Golden Rod Extract		50.00 mg	*
Horsetail Extract		50.00 mg	*
Corn Silk Extract		50.00 mg	*
Cat's Whiskers Extract		50.00 mg	*
Calcium Phosphate, Dibasic		25.00 mg	*

Excipients: Microcrystalline Cellulose, Potassium Citrate, Magnesium Stearate, Titanium Dioxide

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	11.11 x 4.75 mm white coated round tablets	Conforms	Visual
Average Tablet Weight	540.750 mg $\pm$ 5%	538.450 mg	USP <2091>
Weight Variation	Meets USP requirements	Conforms	USP <2091>
Disintegration	NMT 60 minutes	29min 29sec	USP<2040>
Hardness	NLT 9 kp	12 kp	USP<1217>
Friability	NMT 1%	0%	USP<1216>

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>



05/13/2021

Quality Control

Date

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QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: June 15, 2020 Product: Ospastone Film Tablets
Product Code: 400563 Lot No.: 42202121 Manufacture Date: June 02, 2020

Active Ingredients	*Base on Input	per unit	Result
Dandelion Root Extract		60.00 mg	*
Olera Extract		50.00 mg	*
Rosehip Extract		50.00 mg	*
Golden Rod Extract		50.00 mg	*
Horsetail Extract		50.00 mg	*
Corn Silk Extract		50.00 mg	*
Cat's Whiskers Extract		50.00 mg	*
Calcium Phosphate, Dibasic		25.00 mg	*

Excipients: Microcrystalline Cellulose, Potassium Citrate, Magnesium Stearate, Titanium Dioxide

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	11.11 x 4.75 mm white coated round tablets	Conforms	Visual
Average Tablet Weight	540.750 mg / per unit +/- 5%	538.000 mg/unit	USP <2091>
Weight Variation	Meets USP requirements	Conforms	USP <2091>
Friability	NMT 1%	Conforms	USP <1216>
Disintegration	NMT 30 minutes	26 minutes 24 seconds	USP <2040>
Hardness	NLT 9 KP	Conforms	USP <1217>

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>



Quality Control

06/15/2020

Date

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: June 11, 2019

Product: Ospastone Film Tablets

Product Code: 400563

Lot No.: 41905127

Manufacture Date: May 24, 2019

Active Ingredients **Base on Input*

	per unit	Result
Microcrystalline Cellulose	80.00 mg	*
Dandelion Root Extract	60.00 mg	*
Atractylodes Extract	50.00 mg	*
Rosehip Extract	50.00 mg	*
Solidago Virga-Aurea Extract	50.00 mg	*
Horsetail Extract	50.00 mg	*
Burdock Root Extract	50.00 mg	*
Cat's Whiskers Extract	50.00 mg	*
Potassium Citrate	30.00 mg	*
Di-Calcium Phosphate	25.00 mg	*
Magnesium Stearate	7.00 mg	*
Titanium Dioxide	0.25 mg	*

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	White coated round tablets	Conforms	Visual
Per Unit Size	Diameter: 11.11 mm +/- 10% Thickness: 4.75 mm +/- 10%	Conforms	In-House Tester
Weight Variation	546.00 mg / per unit +/- 5%	550.400 mg/unit CV=2.57%	USP <2091>
Friability	NMT 1%	Conforms	USP <1216>
Disintegration	NMT 30 minutes	25 minutes 35 seconds	USP <2040>
Hardness	NLT 15 KP	Conforms	USP <1217>

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	1.1 kcal
Carbohydrate	260.5 mg
Protein	10.0 mg
Fat (Oil)	5.0 mg
Sodium	0.2 mg



Quality Control

06/11/2019

Date

Certificate of Analysis

QUALITY CONTROL LABORATORY ANALYTICAL REPORT

Date: Mar. 15, 2017

Product: Ospastone Film Tablets

Product Code: 400373

Lot No.: 41612125

Manufacture Date: Jan. 30, 2017

Active Ingredients **Base on Input*

	per unit	Result
Microcrystalline Cellulose	80.00 mg	*
Dandelion Root Extract	60.00 mg	*
Atractylodes Extract	50.00 mg	*
Rosehip Extract	50.00 mg	*
Solidago Virga-Aurea Extract	50.00 mg	*
Horsetail Extract	50.00 mg	*
Burdock Root Extract	50.00 mg	*
Cat's Whiskers Extract	50.00 mg	*
Potassium Citrate	30.00 mg	*
Di-Calcium Phosphate	25.00 mg	*
Magnesium Stearate	7.00 mg	*
Titanium Dioxide	0.25 mg	*

Chemical /Physical Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Appearance	White coated round tablets	Conforms	Visual
Per Unit Size	Diameter: 11.11 mm +/- 10% Thickness: 4.75 mm +/- 10%	Length: 11.34 mm CV=0.24% Thickness: 5.05 mm CV=0.56%	In-House Tester
Weight Variation	546.00 mg / per unit +/- 5%	548.450 mg/unit CV=1.61%	USP <2091>
Friability	NMT 1%	0.0 %	USP <1216>
Disintegration	NMT 30 minutes	28 minutes 35 seconds	USP <2040>
Hardness	NLT 15 KP	20 KP	USP <1217>

Microbiological Analysis

ITEM	SPECIFICATION	RESULT	METHODS
Total Aerobic Count	< 1000 cfu/g	15 cfu/g	USP <2021>
Total Combined Mold and Yeasts Count	< 100 cfu/g	< 10 cfu/g	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	1.1 kcal
Carbohydrate	260.5 mg
Protein	10.0 mg
Fat (Oil)	5.0 mg
Sodium	0.2 mg



Quality Control

03/15/2017

Date