

TORONTO REGION OPERATIONS

Title: **CERTIFICATE OF MANUFACTURE**

Form: **F-053** Revision: 27

SOP Reference: **OPS 1027**

Effective Date: 16-OCT-2017

**Certificate of Manufacture**

Establishment License Number: 100074-A

Manufactured, Packaged and/or Labeled at:		Tested at:		
<input checked="" type="checkbox"/> Patheon Inc. Toronto Region Operations 2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada Establishment License Number:100074-A	<input type="checkbox"/> Patheon Inc. Patheon Whitby Operations 111 Consumers Drive Whitby, Ontario L1N 5Z5 Establishment License Number:100074-F	<input checked="" type="checkbox"/> Patheon Inc. Toronto Region Operations 2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada	<input type="checkbox"/> Patheon Inc. Patheon Whitby Operations 111 Consumers Drive Whitby, Ontario L1N 5Z5 Canada	<input type="checkbox"/> Patheon Inc. Patheon Laboratory Services 977 Century Drive Burlington, Ontario L7L 5J8 Canada

Product Name:	SALAGEN (Pilocarpine HCL) tablets 5 mg, 100'S CA	Patheon Batch #:	CDYPN
Serialized Product:	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Client Batch #:	N/A
Quantity:	9600 bottles / 400 shippers / 1 skid	Marketing Auth. # (NDC, DIN, etc):	DIN 02216345
		Average Tablet or Capsule Weight:	N/A

Packaging Material #:	4000005132	Packaging Batch #:	CDYPN	Master #:	Bill of Materials:1 Label information: 1 Packaging Instructions: 2 Finished Product Sampling: 1
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Manufacturing Material #:	3000004205	Manufacturing Batch #:	CDYPM	Master #:	Dispensing: 1 Granulation:1 Compression:1 Coating:1
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Date of Manufacture:	14.Jan.2020	Fill Before Date:	22.Mar.2020	Expiry Date:	DEC/21
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Other Information:	N/A
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**Certification Statement:**

I hereby certify that the above information is authentic and accurate. This batch has been fabricated / manufactured, including packaging and quality control at the above-mentioned sites in full compliance with the GMP requirements of the local Regulatory Authority. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. If applicable, explanations for accepted deviations are attached.

Investigation(s) Required: Yes ☐ No ☒ Deviation Report Nos. N/A

Conclusion: Batch released.  
Complies with all specifications of the testing instruction.



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Form #: F-053  
Revision # 27

Material #: 4000005132

Batch #: CDYPN

**JOSE ALINO QA ASSOCIATE**

Print Name and Title of Authorized person

Jose B. Alino  
Signature of Authorized Person

**04 FEB 2020**  
Date Certificate Issued

Patheon Final Disposition

PATHEON  
QUALITY ASSURANCE

**04 FEB 2020**

FK

RELEASED

**PATHEON INC.**  
 FABRICATION, PACKAGING, LABELING and  
 FINAL PRODUCT SPECIFICATION TESTING  
 Toronto Region Operations (100074-A)  
 2100 Syntex Court, Mississauga, Ontario  
 L5N 7K9 Canada  
 (905) 821-4001

**CERTIFICATE OF ANALYSIS**  
**BULK/FINISHED PRODUCT**

**PRODUCT:** SALAGEN® 5MG FILM COATED TABLETS, 100'S - CANADA

**CLIENT:** AMDIPHARM, LTD. (ADVANZ PHARMA)

**BP MATERIAL NUMBER:** 3000004205

**FP MATERIAL NUMBER:** 4000005132

**BP BATCH NO:** CDYPM

**FP BATCH NO:** CDYPN

**DATE OF MANUFACTURE:** 14/JAN/2020

**EXPIRATION DATE:** DEC/21

ARF BP Rev NEW

ARF FP Rev NEW

CofA Rev NEW

**EFFECTIVE DATE:** 22/OCT/2019

TEST	SPECIFICATION	RESULTS
<b>PHYSICAL APPEARANCE</b>		
Visual / TM-015	White, round, biconvex, un-scored, film coated, polished tablet with debossed brand of "SAL" on one side and "5" on the other side.	White, round, biconvex, un-scored, film coated, polished tablet with debossed brand of "SAL" on one side and "5" on the other side.
<b>IDENTIFICATION</b>		
TM-013	Retention time corresponds to Pilocarpine HCl reference standard	Conforms
<b>POTENCY ASSAY</b>		
TM-013	95 - 105% of label claim	
	1)	101%
	2)	100%
	Avg:	100%
<b>CONTENT UNIFORMITY</b>		
TM-011 / USP <905>	Meets the requirements of USP<905> Uniformity of Dosage Units	Acceptance Value = 2.7
	Report Pass or Fail	Pass
<b>TOTAL RELATED COMPOUNDS</b>		
TM-013	Isopilocarpine HCl: NMT 1.0%	<0.1%
	Pilocarpic Acid: NMT 0.5%	<0.1%
	Isopilocarpic Acid: NMT 0.5%	ND
	Unidentified (any other) impurity: No individual more than 0.1%	<0.1%
	Total other than Isopilocarpine HCl: NMT 1.0%	<0.1%
	Total: NMT 2.0%	<0.1%

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TEST	SPECIFICATION	RESULTS
<b>DISSOLUTION</b>		
TM-012	Q = 75% in 45 minutes	
S1	Stage 1	
Each unit (n=6) is not less than Q+5%	1	99%
	2	97%
	3	99%
	4	100%
	5	99%
	6	98%
	AVG (6)	99%
S2	Stage 2	
The average of 12 units (S1 + S2) is equal to or greater than Q and no unit is less than Q-15%	7	NA
	8	NA
	9	NA
	10	NA
	11	NA
	12	NA
	AVG (12)	NA
S3	Stage 3	
The average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15%, and no unit is less than Q-25%	13	NA
	14	NA
	15	NA
	16	NA
	17	NA
	18	NA
	19	NA
	20	NA
	21	NA
	22	NA
	23	NA
	24	NA
	AVG (24)	NA

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TEST	SPECIFICATION	RESULTS
<b>MICROBIAL ENUMERATION TESTS AND TESTS FOR SPECIFIED MICROORGANISMS*</b>		
MM-1421		
USP <61><62> / Ph. Eur. (2.6.12 & 2.6.13)		
Total Aerobic Microbial Count (TAMC)	NMT 10 <sup>3</sup> cfu/g	<100 cfu/g
Total Yeasts and Moulds Count (TYMC)	NMT 10 <sup>2</sup> cfu/g	<10 cfu/g
E. Coli	Absent/g	Absent/g

\*One batch to be tested annually.

Comments:

N/A

REVIEWED AND APPROVED BY: \_\_\_\_\_

QC Manager Designate

DATE: \_\_\_\_\_

04 FEB 2020

PATHEON  
QUALITY ASSURANCE

04 FEB 2020

F.K  
ACCEPTED