



CONTRACT PHARMACEUTICALS LIMITED
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Certificate of Manufacturing Compliance

To: Glasshouse Pharmaceuticals Limited Canada

Product:

Plastibase 55W

CPL Product No. 5003494

Customer SAP No. 1249353

Manufacturing Lot No. 105753

Date of Manufacture: November 15, 2017

Expiry Date: 10/20

Quantity Released (kg): 1500.0

Manufacturing Order Revision No.: 10

Deviation(s): Yes ☐

No ☒

Title: N/A

Incident Report(s):

Yes ☐

No ☒

Title: N/A

FINAL APPROVAL

The product specified above has been manufactured, packaged, tested and approved in accordance with Current Good Manufacturing Practices as outline in Part 210 and Part 211 (Title 21) of the Code of Federal Regulations and Bristol-Myers Squibb specifications. All current procedures have been followed.
All incoming materials have been evaluated and approved.
All quality inspections have met specifications.
All quality control testing has been completed, is acceptable and is approved.
All documentation has been reviewed for completeness accuracy.
Any discrepancies/deviations which may have occurred have been properly investigated, documented and approved by Quality Assurance.

Authorization:

Jolina

Title:

Production Quality Specialist II

Date:

November 28, 2017

Certificate of Analysis

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Client:	Glasshouse	Client Id:	1598	Run Date:	11/27/2017
Material Number:	5003494	IP #:	99526		
Testing PO#:	N/A	Tests Required:	FULL		
Specification Revision #:	4	COA Revision #:	0		
Product:	Plastibase 55W (excludes Japan) (Finished Product)				
Special Requests:	N/A				
Batch #:	105753	Lot #:	105753		
Test Started:	11/20/2017	Test Completed:	11/27/2017		

TEST/METHOD	SPECIFICATION/UNIT	RESULT/UNIT
Description GM-D1	Colorless to pale yellow in bulk. Translucent, ointment-like mass. It is odorless or has a faint, characteristic odor.	CONFORMS(Colorless in bulk, odorless.)
Identification-IR 220260(S)	Conforms	CONFORMS
Polyethylene Content 249796(S)	4.95-6.05 %	5.39 %
Acidity or Alkalinity 249799(S)	Complies	CONFORMS
Bleed Test 249797(S)	<= 0.100 g, The weight of the oil separated must not exceed 0.100g	0.021 g
Heat Stability 000732(S)	The sides of the cone must show no more than a slight curvature.	CONFORMS
Sulfated Ash 006C(G) (use a 1g sample)	<= 0.1%	0.0 %
Specific Gravity 249798 (S)	0.850-0.920	0.880
Metal Particles (Oint) 0282 (G)	<= 3 particles/sample	0,0,0 particles / sample
Consistency 0095 (G)	240-310	258
Reducing Substances 220261(S)	The permanganate color must not disappear	CONFORMS
Peroxide Content 220262(S)	<= 3 ppm	0 ppm

Reviewed by Quality

Jolina November 28, 2017

APPROVED BY:



DATE:

Nov 29, 2017

Authorized Signature / Date

Certificate of Analysis

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TEST/METHOD	SPECIFICATION/UNIT	RESULT/UNIT
Microbial Limits: Escherichia coli 5450A(G), 220259(S)	Absent in 1g	Absent in 1g
Microbial Limits: Pseudomonas aeruginosa 5450A(G), 220259(S)	Absent in 1g	Absent in 1g
Microbial Limits: Salmonella species 5450A(G), 220259(S)	Absent in 10g	Absent in 10g
Microbial Limits: Staphylococcus aureus 5450A(G), 220259(S)	Absent in 1g	Absent in 1g
Microbial Limits: Total Aerobic Microbial Count 5450A(G), 220259(S)	≤ 100 CFU/g	< 10 CFU/g
Microbial Limits: Total Yeasts and Mold Count 5450A(G), 220259(S)	≤ 100 CFU/g	< 10 CFU/g

Comments:

Composite Testing .Chemistry: 1B, 1M, 1E. Micro: 1B, 1M, 1E.

Reviewed by Quality

Jolina November 28, 2017

Authorized Signature / Date

APPROVED BY:



DATE:

Nov 28, 2017