

BODYBIO

SOP# 02-008.12	Standard Operating Procedure	Written/Revised by/Date: <i>[Signature]</i> 01-16-2024
Effective Date: JAN 16 2024	General Manufacturing Equipment Cleaning	Approved by/Date: <i>[Signature]</i> 01/16/24
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1. Purpose

- 1.1. To summarize and ensure that each piece of equipment used in manufacturing BodyBio products are cleaned in compliance with current Good Manufacturing Practices (cGMP) at both facilities: 45 Reese Rd and 25 Driskill St.

2. Responsibility

- 2.1. Manufacturing Manager, Demand and Logistics Manager or Designee, and Sanitation are responsible for the following procedure.

3. Procedure

- 3.1. Cleaning procedures for each major group of equipment as per their respective attachments:
 - 3.1.1. Cleaning of Carboys, Tanks, or Fittings - Water Based (Attachment 1)
 - 3.1.2. Cleaning of Filler SKF 4000 (Attachment 2)
 - 3.1.3. Cleaning of SKF 5000 (Attachment 3)
 - 3.1.4. Cleaning of CVC SC204 Capsule Counter (Attachment 4)
 - 3.1.5. Cleaning of Diaphragm Pumps (Attachment 5)
 - 3.1.6. Cleaning of Ktron Powder Feeders K1-K3 (Attachment 6)
 - 3.1.7. Cleaning of Carboy or Oil Batch Tank- Oil Based (Attachment 7)
 - 3.1.8. Cleaning of the Diaphragm Pump- Oil Based (Attachment 8)
 - 3.1.9. Cleaning of Stainless Steel Rod Hose Attachments (Attachment 9)
 - 3.1.10. Cleaning of Mixing Paddles, Reusable Weigh Buckets (Attachment 10)
 - 3.1.11. Cleaning of Aesus Filler (Attachment 11)

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3.1.11.1. AESFILL Aesus Filler

3.1.11.1.1 Model AF1-C Single Head Gear Pump Filler Ser. No. P78734-40

3.1.11.2. AESUS High Viscosity Filler

3.1.11.2.1. Model AES Fill AFPI Ser. No. 12-12-348

3.1.12. Cleaning of CC60 Capsule Counter (Attachment 12)

3.1.13. Cleaning of Blender Model CD11 (Attachment 13)

3.1.14. Cleaning of In-Line Filler (Attachment 14)

3.1.14.1. Serial Number: 23618

3.1.14.2. Model: FOF NT C1 D2 Group D

3.1.14.3. Pump 1 Serial Number: W1212061385

3.1.14.4. Pump 2 Serial Number: 23954

3.1.15. Cleaning of Oden PC Filler (Attachment 15)

3.1.15.1. Serial Number: 4058

3.1.15.2. Model: Servo/Fill

3.1.16. Cleaning of SPC16P3 Capsule Counter (Attachment 16)

3.1.16.1. Serial Number: M1205

3.1.16.2. Model: Swiftpack SPC16P3

3.1.17. Cleaning of Oven Espec PV331-M (Attachment 17)

3.1.17.1. Serial Number: 221005546

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3.1.17.2. Model: Espec PV331-M

3.1.18. Cleaning of 15 cu ft Blender Paul O. Abbe (Attachment 18)

3.1.18.1. Serial Number: 21151033RB

3.1.18.2. Model: RB15

3.1.19. Cleaning of Eriez Metal Detector (Attachment 19)

3.1.19.1. Serial Number: 401823

3.1.19.2. Model: Eriez Xtreme

3.1.20. Cleaning of Duster Polisher CPX111 (Attachment 20)

3.1.20.1. Serial Number: 010265

3.1.20.2. Model: CPX111

3.1.21. Cleaning of Oven Light Armor LA10K (Attachment 21)

3.1.21.1. Serial Number: LA10K

3.1.22. Cleaning of Totes and Drying Trays (Attachment 22)

3.1.23. Cleaning of Capsule Filling Machine United UAF 1200c (Attachment 23)

3.1.23.1. Serial Number: 2931

3.1.23.2. Model: UAF 1200c

3.1.24. Cleaning of Hobart Mixer H-600 DT (Attachment 24)

3.1.24.1. Serial Number: 11-460-448

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3.1.24.2. Model: V1401D0 and H-60DT

3.1.25. Hobart Parts Washer (Attachment 25)

3.1.25.1. Model: UW50

3.1.26. Fitzpatrick Hammer Mill (Attachment 26)

3.1.27. Cooper Oven (Attachment 27)

3.1.27.1. Model 72222

3.1.28. Brew Built Mixer (Attachment 28)

3.1.28.1. Model Hot Liquor Tank

3.1.29. ConeMill (Attachment 29)

3.1.29.1 ConeMill 197 Ser. No. 051210642

3.1.30 Cleaning of SC202

3.1.30.1 Serial Number: 112z3535

3.2. If the equipment is not used within 30 days after cleaning, re-clean the equipment before use.

3.3. Documentation

3.3.1. All attachments will be filled out and filed in the Cleaning File Folder. Logbooks of equipment will be filled out after cleaning operations.

3.4. Equipment Status

3.4.1. All equipment shall have a status label of "Hold to be Cleaned" or "Cleaned". (Figure 1)

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Figure 1

CLEANED	
DESCRIPTION _____	
CLEANED BY _____	DATE _____
CHECKED BY _____	DATE _____

HOLD TO BE CLEANED	
Description _____	
Cleaned by _____	Date Cleaned _____
APPROVE BEFORE USE	
Signature _____	Date _____

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Revision History

Date	Revision	Change Control Number	Comments
09/21/2010	New		New SOP
01/18/2011	1		Revised Attachment 11
12/16/2013	2		New Attachment 8.1
03/25/2014	3		New Attachment 12
03/26/2015	4		New Attachment 13
06/15/2016	5		Revised SOP
02/01/2017	6		Revised SOP
07/23/2020	7		Updated format. Changed Plant Manager to Manufacturing Manager, Supervisor or designee. Added Cleaned and Hold to be Cleaned labels as Figure 1. Updated format of all attachments.
02/26/2021	8		Added new equipment, SPC16P3 capsule counter, to section 3. Added attachment 16.
12/16/2021	9		Added both facilities. Added attachments 17-26 for equipment located at 25 Driskill St.
09/30/2022	10		Added new equipment 27 and 28 at Driskill
06/01/2023	11		Added new equipment. 3.1.29 & 3.1.11.1
JAN 16 2024	12	2383	Added new equipment in section number 3.1.30 Revised attachment 4 and added SC202