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**REPORT
FOR
SUITABILITY OF METHOD FOR
MICROBIAL ENUMERATION TESTS
AND
TEST FOR SPECIFIED MICRO-ORGANISMS.**

Product/Material Name: Sofosbuvir and Velpatasvir Film-coated
Tablets 400mg/100 mg.

Batch No : 2012394.

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1.0 OBJECTIVE:

The objective of this Report is to document efforts carried out for the suitability of method used for quantitative enumeration of Total aerobic microbial count and Total yeast and mold count and the recovery method used for detection of Specified microorganisms as per Ph. Eur, USP and JP harmonized method.

2.0 PURPOSE

The Validity of result for microbial enumeration test and test for specified microorganisms depends largely on adequacy of demonstration that the test specimens to which they are applied do not of themselves inhibit the multiplication of microorganism, under test conditions. The inhibition can be neutralized by addition of neutralizing agents or by using higher dilution factor. The purpose of this study is to validate method for quantitative enumeration of mesophilic Bacteria and fungi and recovery method for detection of Specified Microorganisms as per Ph. Eur, USP and JP harmonized method

3.0 SCOPE:

The scope of this report is limited to the suitability of method for microbial enumeration test and test for specified microorganism for

Product/Material Name: Sofosbuvir and Velpatasvir Film-coated

Tablets 400mg/100mg.

Batch No: 2012394.

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4.0 EXPERIMENTAL PLAN

4.1 Media Preparation:

4.1.1 Record the Load No. of Media used during validation activity in following table:

Sr. No.	Media	Load No/Validity
1.	Soyabean Casein Digest Medium (SCDM)	652a / 23/11/16 655a / 24/11/16
2.	Soyabean Casein Digest Medium w/Tween 80 and Lecithin (SCDM + TS)	NA
3.	Soyabean Casein Digest Agar (SCDA)	652a / 24/11/16
4.	Sabouraud Chloramphenicol Agar (SCA)	NA
5.	Sabouraud dextrose agar (SDA)	652c / 24/11/16
6.	Enterobacteria Enrichment Broth Mossel (EEB)	529b / 22/11/16
7.	Violet Red Bile Glucose Agar (VRBGA)	mp2401 / march 2017
8.	MacConkey Broth (MB)	657a / 25/11/16
9.	MacConkey Agar (MA)	mp2479 / April 2017
10.	Peptone Water (PW)	624b / 31/10/16
11.	Rappaport Vassiliadis Salmonella Enrichment Broth (RVS)	16M767 / march 2018
12.	Xylose Lysine Deoxycholate Agar (XLDA)	mp2469 / Nov 2016
13.	Triple-Sugar-Iron Agar (TSI)	632c / 22/11/16
14.	Cetrimide Agar (CA)	mp2400 / march 2017
15.	Mannitol Salt Agar (MSA)	mp2443 / march 2017

4.2 Preparation of Test Strains:

4.2.1 Record the inoculum details used in the validation activity in following table:

Sr. No	Micro-organism	Type	Lot No/ Validity	No. of Organism per vial
1.	<i>Staphylococcus aureus</i>	NCTC 10788	B3255 / 25/08/17 B3546 / 17/05/18	11580.0 cfu 546.0 cfu
2.	<i>Pseudomonas aeruginosa</i>	NCTC 12926	B3278 / 15/09/17 B3543 / 16/05/18	9372.0 cfu 557.8 cfu
3.	<i>Bacillus subtilis</i>	NCTC 10400	B3236 / 11/08/17	11112.0 cfu
4.	<i>Candida albicans</i>	NCPF 3179	B3280 / 16/09/17	8970.0 cfu
5.	<i>Aspergillus brasiliensis</i>	NCPF 2275	B3373 / 09/12/17	8776.0 cfu
6.	<i>Escherichia coli</i>	NCTC 9001 NCTC 12923	B3131 / 18/05/17 B3529 / 10/05/18	9432.0 cfu 573.5 cfu
7.	<i>Salmonella abony</i>	ACM 5080	B3583 / 15/06/18	30.0 cfu

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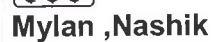
4.3 Microbiological Examination of Non-sterile products: Microbial Enumeration Tests:

4.3.1 Preparation of Samples:

Prepare all the samples as per protocol MLN/QC/MMVP/03

*Pretreatment of Sample: NA

NEGATIVE PRODUCT CONTROL (NPC)	POSITIVE PRODUCT CONTROL (PPC)	NEGATIVE CONTROL (NC)	POSITIVE CONTROL (PC)
11.11 g sample + 90 ml SCDM (NPC-A1)	sample (ppc-A1) + 90 ml SCDM + bioball containing 10,000 cfu of test strain (Added individually)	100 ml SCDM (NC-A1)	100 ml SCDM + (pc-A1) bioball containing xmt 10,000 cfu of test strains (Added individually)
	11.09 g sample + B. subtilis (5050.90cfu) (ppc-A1:BS1)		B. subtilis (5050.90cfu) (pc-A1:BS1)
	11.00 g sample + p. aeruginosa (4260 cfu) (ppc-A1:PA1)		p. aeruginosa (4260 cfu) (pc-A1:PA1)
	11.09 g sample + S. aureus (5263.63 cfu) (ppc-A1:SA1)		S. aureus (5263.63 cfu) (pc-A1:SA1)
	11.08 g sample + C. albicans (4077.27 cfu) (ppc-A1:CA1)		C. albicans (4077.27 cfu) (pc-A1:CA1)
	11.12 g sample + A. baumannii (3989.09cfu) (ppc-A1:AB1)		A. baumannii (3989.09cfu) (pc-A1:AB1)



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Prepared By: *[Signature]*
Date: *27/10/16*

Checked By: 
Date: 28.10.16

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4.3.2 Observation:

4.3.2.1 Total Aerobic Microbial Count:

1 ml of preparation + 15-20 ml of SCDA medium.

Incubate the plates at 30°C to 35°C for 3 to 5 days.

Incubator No.: FOC 263 incubation started time: 23:00 Date: 27/11/16 Sign: [Signature]
incubation completed time: 13:00 Date: 01/11/16 Sign: [Signature]

Description	Plate I	Plate II	Mean	Observed by	Checked by
NPC	0	0	0	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PPC (B.Subtilis)	48	52	50	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PPC (S.aureus)	45	51	48	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PPC (P.aeruginosa)	38	42	40	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PPC (C.albicans)	36	41	39	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PPC (A.brasiliensis)	29	34	32	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
NC	0	0	0	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PC (B.Subtilis)	56	63	60	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PC (S.aureus)	54	58	56	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PC (P.aeruginosa)	55	59	57	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PC (C.albicans)	56	62	59	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16
PC (A.brasiliensis)	46	50	48	<u>[Signature]</u> 01/11/16	<u>[Signature]</u> 02/11/16

4.3.2.2 Total Combined Molds and Yeast Count:

1 ml of preparation + 15-20ml of SDA/~~SCA~~ medium.

Incubate the plates at 20°C to 25°C for 5 to 7 days.

Incubator No.: FOC 186 Incubation started time: 23:02 Date: 27/11/16 Sign: [Signature]
Incubation completed time: 21:00 Date: 03/11/16 Sign: [Signature]

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Description	Plate I	Plate II	Mean	Observed by	Checked by
NPC	0	0	0	03/11/16	P 04.11.16
PPC (C.albicans)	37	43	40	02/11/16	P 02.11.16
PPC (A.brasiliensis)	27	33	30	02/11/16	P 02.11.16
NC	0	0	0	03/11/16	P 04.11.16
PC (C.albicans)	56	60	58	02/11/16	P 02.11.16
PC (A.brasiliensis)	41	45	43	02/11/16	P 02.11.16

4.3.3 Estimation of Recovery of Number of Viable Microorganisms:

Name of Organism	Dilution	No. of Colony in Negative product control (A)	No. of Colony in Positive product control (B)	No. of Colony in Positive control (C)	Percent Recovery = $\frac{(B-A)}{C} \times 100$
Total Aerobic Microbial Count					
<i>Staphylococcus aureus</i> (NCTC 10788)	1:10	0	48	56	85.71 %
<i>Pseudomonas aeruginosa</i> (NCTC 12924)	1:10	0	40	57	70.17 %
<i>Bacillus subtilis</i> (NCTC 10400)	1:10	0	50	60	83.33 %
<i>Candida albicans</i> (NCPF 3179)	1:10	0	39	59	66.10 %
<i>Aspergillus brasiliensis</i> (NCPF 2275)	1:10	0	32	48	66.66 %
Total Combined Molds and Yeast Count					
<i>Candida albicans</i> (NCPF 3179)	1:10	0	40	58	68.96 %
<i>Aspergillus brasiliensis</i> (NCPF 2275)	1:10	0	30	43	69.76 %
Recovery calculated by : 03/11/16				Verified by : P 04.11.16	

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4.4 Microbiological Examination of Non-sterile Products: Tests For Specified

Microorganisms

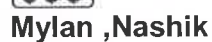
4.4.1 Preparation of Samples:

Prepare all the samples as per protocol MLN/QC/MMVP/03

*Pretreatment of Sample:

PA

NEGATIVE PRODUCT CONTROL (NPC)	POSITIVE PRODUCT CONTROL (PPC)	NEGATIVE CONTROL (NC)	POSITIVE CONTROL (PC)
11.09 g sample + 90 ml SCDM (NPC-A2)	sample + 90 ml SCDM (PPC-A2) + bioball containing 1000 cfu of organism (Added individually)	100 ml SCDM (NC-A2)	100 ml SCDM (PC-A2) + bioball containing nmt 1000 cfu of organism (Added individually)
	11.08 g sample + E.coli (573.5 cfu) (PPC-A2:EC1)		E.coli (573.5 cfu) (PC-A2:EC1)
	11.06 g sample + P.aeruginosa (551.8 cfu) (PPC-A2:PA2)		P.aeruginosa (551.8 cfu) (PC-A2:PA2)
	11.14 g sample + S.aureus (546.0 cfu) (PPC-A2:SA2)		S.aureus (546.0 cfu) (PC-A2:SA2)
	For BTGNB 11.01 g sample + E.coli (573.5 cfu) (PPC-A2:EC2)		For BTGNB E.coli (573.5 cfu) (PC-A2:EC2)
			P.aeruginosa (551.8 cfu) (PC-A2:PA3)



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Reviewed By: 
Date: 28.10.16

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4.4.2 Bile-Tolerant Gram-Negative Bacteria:

4.4.2.1 Qualitative Evaluation:

Incubate negative product control, Positive product control, Positive control and negative control at 20°C to 25°C for 2 to 5 hours.

Incubator No.: EEC184 :

Incubation details	Negative product control	Positive product control	Negative control	Positive Control
Incubation started date/time	<u>27/10/16/20:10</u>	<u>27/10/16/20:10</u>	<u>27/10/16/20:10</u>	<u>27/10/16/20:10</u>
Incubation completed date/time	<u>27/10/16/22:12</u>	<u>27/10/16/22:12</u>	<u>27/10/16/22:12</u>	<u>27/10/16/22:12</u>

Transfer 10 ml of enriched broth to 100 ml of EE broth.

Incubate at 30°C to 35°C for 24 to 48 hour

Incubator No.: EEC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>27/10/16/23:00</u>	<u>27/10/16/23:00</u>	<u>27/10/16/23:00</u>	<u>27/10/16/23:00</u>
Incubation completed date/time	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>

Subculture on plates of VRBGA.

Incubate the plates at 30°C to 35°C for 18 to 24 hours.

Incubator No.: EEC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>
Incubation completed date/time	<u>30/10/16/12:05</u>	<u>30/10/16/12:05</u>	<u>30/10/16/12:05</u>	<u>30/10/16/12:05</u>

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Observations:

Dilution	Observation	Observed by	Checked by
Negative product control	No growth	30/10/16	P 02-11-16
Positive product Control (<i>Escherichia coli</i>)	Red colonies	30/10/16	P 02-11-16
Positive product Control (<i>Pseudomonas aeruginosa</i>)	Red colonies	30/10/16	P 02-11-16
Positive Control (<i>Escherichia coli</i>)	Red colonies	30/10/16	P 02-11-16
Positive Control (<i>Pseudomonas aeruginosa</i>)	Red colonies	30/10/16	P 02-11-16
Negative Control	No growth	30/10/16	P 02-11-16

4.4.2.2 Quantitative Evaluation :

Sample preparation: Take 1.2 gm sample add into 100 ml of SCDM and inoculate

inoculum containing NMT 10,000 cfu of E.coli.

Take 1.3 gm sample add into 100 ml of SCDM and inoculate

inoculum containing NMT 10,000 cfu of P.aeruginosa.

Incubate negative product control, Positive product control , Positive control and negative control at 20°C to 25°C for 2 to 5 hours.

Incubator No.: EEC184 :

Incubation details	Negative product control	Positive product control	Negative control	Positive Control
Incubation started date	27/10/16 / 20:10	27/10/16 / 20:10	27/10/16 / 20:10	27/10/16 / 20:10
Incubation completed date	27/10/16 / 22:12	27/10/16 / 22:12	27/10/16 / 22:12	27/10/16 / 22:12

Procedure: Inoculate quantities of sample equivalent to 0.1g or ml, 0.01 g or ml and 0.001 g or ml in EE broth for E.coli and P.aeruginosa separately.

I) Add 10 ml or gm quantity of sample equivalent to 0.1g or ml in EEB for E.coli and P.aeruginosa separately.

II) Add 0.1 ml or gm quantity of sample equivalent to 0.01g or ml in EEB for E.coli and P.aeruginosa separately.

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III) Add 0.1 ml or gm quantity of sample equivalent to 0.001g or ml in EEB for E.coli and P.aeruginosa separately.

Incubate at 30°C to 35°C for 24 to 48 hours.

Incubator No.: E00267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>29/10/16/23:00</u>	<u>29/10/16/23:00</u>	<u>29/10/16/23:00</u>	<u>29/10/16/23:00</u>
Incubation completed date/time	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>	<u>29/10/16/11:05</u>

Subculture on surface of VRBGA

Incubate the plates at 30°C to 35°C for 18 to 24 hours.

Incubator No.: E00267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>	<u>29/10/16/15:28</u>
Incubation completed date/time	<u>30/10/16/12:00</u>	<u>30/10/16/12:00</u>	<u>30/10/16/12:00</u>	<u>30/10/16/12:00</u>

Observations:

Sample details	Observation			
	Result of Each Quantity of product			Probable Number of Bacteria Per Gram or ml of Product
	0.1 g or ml	0.01 g or ml	0.001 g or ml	
Negative product control	-	-	-	<10
Positive product Control (<i>Escherichia coli</i>)	+	+	+	>10 ³
Positive product Control (<i>Pseudomonas aeruginosa</i>)	+	+	+	710 ³
Positive Control	+	+	+	710 ³



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(*Escherichia coli*)

+

+

+

 7×10^3

Positive Control

+

+

+

 $> 10^3$ (*Pseudomonas aeruginosa*)

-

-

-

 < 10

Negative Control

Observed by:

M
30/10/16

Checked by:

P
02/11/16

Remark:

sample shows no inhibition

4.4.3 *Escherichia coli*:Transfer 10 ml from solution NP1-A2, PP1-A2: EC1, PI-A2: EC1, M-A2

Incubate Negative product control, Positive product control, Positive control and Negative control at 30° to 35°C for 18 to 24 hrs.

Incubator No.: ECC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	27/10/16/20:30	27/10/16/20:30	27/10/16/20:30	27/10/16/20:30
Incubation completed date/time	28/10/16/14:30	28/10/16/14:30	28/10/16/14:30	28/10/16/14:30

Shake the container and transfer 1 ml of enriched medium to 100 ml MacConkey Broth and incubate at 42 to 44°C for 24 to 48 hours. Incubator No.: ECC266 B

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	28/10/16/15:32	28/10/16/15:32	28/10/16/15:32	28/10/16/15:32
Incubation completed date/time	M 30/10/16/07:40	M 29/10/16/07:40	M 30/10/16/07:40	M 29/10/16/07:40

Subculture loopful of enriched media on plates of MacConkey agar, incubate at 30 to 35°C for 18 to 72 hours. Incubator No.: ECC267

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Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<i>m</i> 30/10/16/12:00	<i>m</i> 29/10/16/15:28	<i>m</i> 30/10/16/12:00	<i>m</i> 29/10/16/15:28
Incubation completed date/time	<i>m</i> 02/11/16/12:05	<i>m</i> 30/10/16/12:00	<i>m</i> 02/11/16/12:05	<i>m</i> 30/10/16/12:00
Observation	no growth	Brick Red colonies	no growth	Brick Red colonies
Checked by	<i>P</i> 02.11.16	<i>P</i> 02.11.16	<i>P</i> 02.11.16	<i>P</i> 02.11.16

Test for the presence of Indole:

Transfer the suspected positive colonies to 5 ml of peptone water and incubate at 30-35°C for 24 hrs.

Incubator No.: E00267 Incubation start date/time: 12:00 / 30/10/16 *m*
Incubation completed date/time: 12:50 / 01/11/16 *R*

Add 0.5mL of Kovac's reagent to the peptone water tube shake well and allow to stand for 1 minute.

If red color develops in the reagent layer, Indole is present, which indicates the presence of *E. coli*.

Sample description	Observation	Observed by / date	Checked by/date
Positive product Control	Red colour ring formation	<i>P</i> 01/11/16	<i>P</i> 02.11.16
Positive Control	Red colour ring formation	<i>P</i> 01/11/16	<i>P</i> 02.11.16
Negative Control (Tube containing 5 ml of peptone water)	no red colour ring formation	<i>P</i> 01/11/16	<i>P</i> 02.11.16

Remark: Results meets acceptance criteria.

4.4.4 Salmonella:

Incubate Negative product control, Positive product control, Positive control and Negative control at 30° to 35°C for 18 to 24 hrs.

Incubator No.: E00267

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Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	27/10/16/20:30	27/10/16/20:30	27/10/16/20:30	27/10/16/20:30
Incubation completed date/time	28/10/16/14:30	28/10/16/14:30	28/10/16/14:30	28/10/16/14:30

Transfer 0.1 ml of enriched solutions of all dilutions to 10 ml of RVS broth.

Incubate at 30°C to 35°C for 18 to 24 hours.

Incubator No.: EQC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	28/10/16/15:30	28/10/16/15:30	28/10/16/15:30	28/10/16/15:30
Incubation completed date/time	29/10/16/11:15	29/10/16/11:15	29/10/16/11:15	29/10/16/11:15

Subculture the enriched RVS medium on plates of XLDA

Incubate the plates at 30°C to 35°C for 18 to 48 hours.

Incubator No.: EQC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	29/10/16/15:28	29/10/16/15:28	29/10/16/15:28	29/10/16/15:28
Incubation completed date/time	01/11/16/13:00	30/10/16/12:05	01/11/16/13:00	30/10/16/12:05
Observation	no growth	Red colonies	no growth	Red colonies
Checked by	<u>P</u> 02-11-16	<u>P</u> 02-11-16	<u>P</u> 02-11-16	<u>P</u> 02-11-16

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
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Transfer suspected colonies on TSI agar slants.

Incubate at 30°C to 35°C for 18 to 24 hours.

Incubator No.: ERC267 Incubation start date/time: 12:00 / 30/10/16
Incubation completed date/time: 10:00 / 01/11/16 R

Observation:

Sample description	Observation	Observed by / Date	Checked by/date
Positive product Control	Black ButH formation	R 01/11/16	R 02-11-16
Positive Control	Black ButH formation	R 01/11/16	R 02-11-16
Negative Control (streaked with sterile loop)	no Black butH formation	R 01/11/16	R 02-11-16

Reamrk: Results meets acceptance criteria

4.4.5 *Pseudomonas aeruginosa*:

Transfer 10 ml from solution NPL-A2, PPL-A2, PA2, P1-A2:PA2, MC-A2

Incubate Negative product control, Positive product control, Positive control and Negative control at 30° to 35°C for 18 to 24 hrs. Incubator No: ERC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>27/10/16 / 20:30</u>	<u>27/10/16 / 20:30</u>	<u>27/10/16 / 20:30</u>	<u>27/10/16 / 20:30</u>
Incubation completed date/time	<u>28/10/16 / 16:30</u>	<u>28/10/16 / 16:30</u>	<u>28/10/16 / 16:30</u>	<u>28/10/16 / 16:30</u>

Subculture on CA

Incubate at 30°C to 35°C for 18 to 72 hours. Incubator No.: ERC267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>28/10/16 / 15:30</u>	<u>28/10/16 / 15:30</u>	<u>28/10/16 / 15:30</u>	<u>28/10/16 / 15:30</u>

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
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Incubation completed date/time	<u>M</u> 30/10/16 / 11:30	<u>M</u> 29/10/16 /11:15	<u>M</u> 30/10/16 / 11:30	<u>M</u> 29/10/16 /11:15
Observations	no growth	greenish colonies with fluorescence	no growth	greenish colonies with fluorescence
Checked by	<u>P</u> 02-11-16	<u>P</u> 02-11-16	<u>P</u> 02-11-16	<u>P</u> 02-11-16

Transfer suspected colonies from CA to Oxidase Disc.

Observations:

Sample description	Observation	Observed by	Checked by
Positive product Control	purple colour formation	30/10/16	<u>P</u> 02-11-16
Positive Control	purple colour formation	30/10/16	<u>P</u> 02-11-16
Negative Control	no purple colour formation	30/10/16	<u>P</u> 02-11-16

Remark: Results meets acceptance criteria

4.4.6 Staphylococcus aureus:

Transfer 10 ml from solution MP-A2, pPC-A2-CA2, PC-A2:SA2, NC-A2

Incubate Negative product control, Positive product control, Positive control and Negative control at 30° to 35°C for 18 to 24 hrs. Incubator No.: E00267

Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	<u>24/10/16 /20:30</u>	<u>24/10/16 /20:30</u>	<u>24/10/16 /20:30</u>	<u>24/10/16 /20:30</u>
Incubation completed date/time	<u>28/10/16 /14:30</u>	<u>28/10/16 /14:30</u>	<u>28/10/16 /14:30</u>	<u>28/10/16 /14:30</u>

Subculture on MSA

Incubate at 30°C to 35°C for 18 to 72 hours.

Incubator No.: E00267

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
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Incubation details	Negative product control	Positive product control	Negative control	Positive control
Incubation started date/time	28/10/16 /15:30	28/10/16 /15:30	28/10/16 /15:30	28/10/16 /15:30
Incubation completed date/time	30/10/16 /11:30	29/10/16 /11:15	30/10/16 /11:30	29/10/16 /11:15
Observations	no growth	yellow colonies with yellow zones	no growth	yellow colonies with yellow zones
Checked by	P 02.11.16	P 02.11.16	P 02.11.16	P 02.11.16

Coagulase Test:

Transfer Suspect colonies to 0.5 ml of mammalian plasma Incubate in water-bath (ID No. 66c17h) at 37°C examining the tubes at 3 hour and subsequently at suitable intervals up to 24 hours.

Incubation details	Positive product control	Positive control	Negative control (mammalian plasma only)
Incubation started date/time	30/10/16 /08:05	30/10/16 /08:05	30/10/16 /08:05
Incubation completed date/time	30/10/16 /11:10	30/10/16 /11:10	01/11/16 /10:00
Observations	coagulatin observed	coagulatin observed	no-agulatin observed
Checked by	P 02.11.16	P 02.11.16	P 02.11.16

Remark: Results meets acceptance criteria

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
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4.4.7 Results for Estimation of Recovery of Specified Microorganisms:

Test	Observation			
	Negative Product Control	Product Positive Control	Negative control	Positive control
Bile-Tolerant Gram-Negative Bacteria	no growth observed	Red colonies observed	no growth observed	Red colonies observed
<i>Escherichia coli</i>	no growth observed	Brick Red colonies observed	no growth observed	Brick Red colonies observed
<i>Salmonella sp.</i>	no growth observed	Red colonies observed	no growth observed	Red colonies observed
<i>Pseudomonas aeruginosa</i>	no growth observed	Greenish colonies with fluorescence observed	no growth observed	Greenish colonies with fluorescence observed
<i>Staphylococcus aureus</i>	no growth observed	yellow colonies with yellow zones observed	no growth observed	yellow colonies with yellow zones observed

Prepared By: 
Date: 02/11/16

Reviewed By: 
Date: 04.11.16

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
Reference Protocol No.	MLN/QC/MMVP/03	Page No.	21 of 22
Report No.	MLN/QC/MMVR/161002.		

5.0 ACCEPTANCE CRITERIA

- 5.1 The negative control should not show any growth.
- 5.2 All the Positive cultures used in recovery of specified microorganisms should show positive results for all the tests.
- 5.3 The average number of colony forming units recovered from the challenged product (Positive product Control) should not differ by a factor of 2 (Not Less than 50% to Not more than 200%) of that from the Positive control

Prepared By: 

Date: 03/11/16

Reviewed By: 

Date: 04.11.16

 Mylan ,Nashik	Report for Suitability of Method for Microbial enumeration Tests and Tests for specified microorganism	Department	Quality Control
Reference Protocol No.	MLN/QC/MMVP/03	Page No.	22 of 22
Report No.	MLN/QC/MMVR/161002.		

6.0 SUMMARY,EVALUATION OF DATA AND CERTIFICATION:

Summary:- method suitability study was performed for sofosbuvir and velpatasvir film coated tablets 400mg/100 mg. batch no: 2012394. for microbial enumeration test and test for specified microorganism. the study was performed as per protocol no. MLN/QC/MMVP/03.

Evaluation of data:- the sofosbuvir and velpatasvir film coated tablets 400 mg/100 mg was analyzed at 1:10 dilution along with test preparation with spiking of *S.aureus*, *B.subtilis*, *P.aeruginosa*, *C.albicans*, *A.brasiliensis*. for enumeration test. the recovery were evaluated and found the results were well within the acceptance criteria.

for test for specified microorganism the sample was tested at 1:10 dilution the spiked microorganism were detected in the positive control and positive product control. for test for *Escherichia coli*, *Salmonella* spp. *Pseudomonas aeruginosa*, *Staphylococcus aureus* and Bile tolerant Gram negative bacteria (BTGNB).

certification:- As the results meets acceptance criteria. the test used for analysis shall be certified as validated. the routine testing of sofosbuvir and velpatasvir film coated tablets 400 mg/100 mg and lower strength shall be analyzed using 1:10 dilution.

Description	Prepared By	Reviewed By	Approved By
Name	Tushar Kulkarni	Rupali Kothawade	Manohar Suryawanshi
Sign and date	 03/11/16	 04/11/16	 08/11/16



Mylan, Nashik

PRINTOUTS ATTACHMENT SHEET

Product / Material Name:

*Sofosbuvir & velpatasvir film coated
tab 400/100mg*

B.No. / A.R. No.:

2012394

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IQC272
Date: 27/10/2016
Start: 19:56:01

0.00 g
1.24 g

Signature:

[Signature] 27/10/16

B. No. : *2012394*

A. R. No. *NA*

Test: *mt suitability*

[Signature] Wt. Of: *BTGB NPL*
28.10.16 Sunhitahe test

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IQC272
Date: 27/10/2016
Start: 20:00:07

0.00 g
1.21 g

Signature:

[Signature] 27/10/16

[Signature] B. No. : *2012394*
A. R. No. *NA*
28.10.16 : *mt suitability*
28.10.16 : *BTGB*
Sunhitahe test

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IQC272
Date: 27/10/2016
Start: 19:58:07

0.00 g
1.34 g

Signature:

[Signature] 27/10/16

B. no *2012394*
A. R. no *NA*
Test: *mt suitability*
Wt. Of: *BTGB*

Sunhitahe test
placemugimosa *[Signature]*
28.10.16

MLLNSK-SOP-QC-GLP-0001 A02-02-07-16

		PRINTOUTS ATTACHMENT SHEET	
Mylan, Nashik			
Product / Material Name: <i>Sofosbuvir & velpatasvir film coated tab 500 / 100 mg</i>		B.No. / A.R. No.: <i>201239h</i>	
Mylan Laboratories Ltd. Sinnar. Model: GP3202 ID: 100272 Date: 27/10/2016 Start: 19:47:02 0.00 g 11.09 g Signature: <i>[Signature]</i> 27/10/16 B. No. : 201239h A. R. No. : <i>mt</i> Test : <i>mt suitability</i> Wt. Of : <i>ppc-A3</i> <i>P</i> 28.10.16		Mylan Laboratories Ltd. Sinnar. Model: GP3202 ID: 100272 Date: 27/10/2016 Start: 19:50:13 0.00 g 11.06 g Signature: <i>[Signature]</i> 27/10/16 B. No. : 201239h A. R. No. : <i>mt</i> Test : <i>mt suitability</i> Wt. Of : <i>ppc-A3 SA B1</i> <i>P</i> 28.10.16	

MLLNSK-SOP-QC-GLP-0001 A02-02-07-16



Mylan, Nashik

PRINTOUTS ATTACHMENT SHEET

Product / Material Name:

Sotabonir f nelpatossr kinn ceed
fah 100/100 mg

B.No. / A.R. No.:

2012393

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:21:57

0.00 g
11.09 g

Signature:

B. No.: NA 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:44:28

0.00 g
11.13 g

Signature:

B. No.: 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

28.10.16

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:24:23

0.00 g
11.08 g

Signature:

B. No.: NA 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:32:10

0.00 g
11.14 g

Signature:

B. No.: 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

28.10.16

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:26:12

0.00 g
11.06 g

Signature:

B. No.: NA 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:37:51

0.00 g
11.01 g

Signature:

B. No.: 2012393
A. R. No. NA
Test: mlt suitability
Wt. Of: PPL-A2

28.10.16

MLLNSK-SOP-QC-GLP-0001 A02-02-07-16



Mylan, Nashik

PRINTOUTS ATTACHMENT SHEET

Product / Material Name:

Sofabonir velpakuvay him coated
bub hoo 100mg

B.No. / A.R. No.:

201239h

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:04:52

0.00 g
11.11 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:14:29

0.00 g
11.09 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1: SA1

28.10.16

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:07:38

0.00 g
11.09 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1: BS1

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:16:28

0.00 g
11.08 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1: CA1

28.10.16

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:12:58

0.00 g
11.00 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1: PA1

Mylan Laboratories Ltd.
Sinnar.

Model: GP3202
ID: IOC272
Date: 27/10/2016
Start: 19:19:00

0.00 g
11.12 g

Signature:

B. No. : 201239h
A. R. No. NA
Test: MTT suitability
Wt. Of: PPL-A1: AB1

28.10.16

MLLNSK-SOP-QC-GLP-0001 A02-02-07-16

Lot Number: B3373

Reference Material Data

Organism: *Aspergillus brasiliensis*
Designation: NCPF 2275
Reference: 413776 10 Vials
56049 20 Vials
BTF Internal Reference: B-AN2275-10K-10
B-AN2275-10K-20
Date of Manufacture: 10 December 2015
Expiry Date: 9 December 2017
Extended Expiry Date*: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu SD

8776.0 900.0

95% Prediction Interval

Lower Limit Upper Limit

6640.8 10911.2

For an explanation of the Prediction Interval
see the BioBall Instructions For Use on the
BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: DRBC
Plate Incubation Time (hrs): counted at 18, 24 and 42+/-2hrs
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Linh Le

Linh Le

12 January 2016



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer

Accreditation Number: 14993

Site Number: 15276

Strain sourced from NCPF (National Collection of Pathogenic Fungi)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cota.php to determine whether or not the shelf life of your BioBall batch has been extended.

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Sydney Australia
Tel. 61 (0) 2 8877 9150
Fax. 61 (0) 2 8877 9101
www.btfbio.com

Sales and General enquiries:

bioMérieux S.A.
69280 Marcy l'Etoile - France
Tel. 33 (0) 4 78 87 20 00
Fax. 33 (0) 4 78 87 20 90
www.biomerieux-industry.com



BTF
A BIOMÉRIEUX COMPANY



Issue: 8 - May 2012

attached for reference purpose
reconstitute the bioball with 220ul of bioball rehydration fluid. spike
100ul of above suspension in ppc and 100ul of suspension in pc which
contain 3989.09cfu. 27/11/16
28.10.16

Lot Number: B3280

Reference Material Data

Organism: *Candida albicans*
Designation: NCPF 3179
Reference: 413778 10 Vials
56050 20 Vials
BTF Internal Reference: B-CA3179-10K-10
B-CA3179-10K-20
Date of Manufacture: 17 September 2015
Expiry Date: 16 September 2017
Extended Expiry Date*: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu	SD
8970.0	445.7

95% Prediction Interval

Lower Limit	Upper Limit
7912.5	10027.5

For an explanation of the Prediction Interval
see the BioBall Instructions For Use on the
BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 40 - 48
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Fiona Pollock

Fiona Pollock

8 October 2015



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 16276

Strain sourced from NCPF (National Collection of Pathogenic Fungi)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cofa.php to determine whether or not the shelf life of your BioBall batch has been extended.

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Issue: 8 - May 2012



13/05/16

attached for reference purpose

Reconstitute the bioball with 220ul of bioball rehydration fluid. spike
100ul of above suspension in PPC and 100ul of suspension in PC which
contains 4077.27 chv 27/10/16 P 20.10.16

Lot Number: B3236

Reference Material Data

Organism: *Bacillus subtilis*
Designation: NCTC 10400
Reference: 413777 10 Vials
56143 20 Vials
BTF Internal Reference: B-BS10400-10K-10
B-BS10400-10K-20
Date of Manufacture: 12 August 2015
Expiry Date: 11 August 2017
Extended Expiry Date#: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®
Mean cfu SD

11112.0 699.7

95% Prediction Interval

Lower Limit Upper Limit

9452.1 12771.9

For an explanation of the Prediction Interval
see the BioBall Instructions For Use on the
BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Linh Le

4 September 2015



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cofa.php to determine whether or not the shelf life of your BioBall batch has been extended.

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Fax. 33 (0) 4 78 87 20 90
www.biomerieux-industry.com



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Issue: 8 - May 2012

attached for reference purpose
reconstitute the bioball with 220ul of bioball rehydration fluid. spike
100ul of above suspension in PPC and 100ul of suspension in pc which
contains 5050 gc ch 9/24/16
28.10.16

Lot Number: B3278

Reference Material Data

Organism: *Pseudomonas aeruginosa*
Designation: NCTC 12924
Reference: 413831 10 Vials
56144 20 Vials
BTF Internal Reference: B-PA12924-10K-10
B-PA12924-10K-20
Date of Manufacture: 16 September 2015
Expiry Date: 15 September 2017
Extended Expiry Date*: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu	SD
9372.0	658.9

95% Prediction Interval

Lower Limit	Upper Limit
7808.8	10935.2

For an explanation of the Prediction Interval
see the BioBall Instructions For Use on the
BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Linh Le

2 October 2015



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cofa.php to determine whether or not the shelf life of your BioBall batch has been extended.

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Fax. 33 (0) 4 78 87 20 90
www.biomerieux-industry.com



BTF
A BIOMÉRIEUX COMPANY



Issue: 8 - May 2012

attached for reference purpose
Reconstitute the bioBall with 220 ul of bioBall rehydrant fluid
spike level of above suspension in PPC and 100 ul of suspension in PC
which contain 4260 cfu 2/21/16
2.8.10.16

Lot Number: B3255

Reference Material Data

Organism: *Staphylococcus aureus*
Designation: NCTC 10788
Reference: 56159 10 Vials
56055 20 Vials
BTF Internal Reference: B-SA10788-10K-10
B-SA10788-10K-20
Date of Manufacture: 26 August 2015
Expiry Date: 25 August 2017
Extended Expiry Date#: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu	SD
11580.0	629.0

95% Prediction Interval

Lower Limit	Upper Limit
10087.8	13072.2

For an explanation of the Prediction Interval see the BioBall Instructions For Use on the BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Fiona Pollock

Fiona Pollock

17 September 2015



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cofa.php to determine whether or not the shelf life of your BioBall batch has been extended.

Manufactured by:

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Sydney Australia
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www.btfbio.com

BTF
A BIOMÉRIEUX COMPANY

Sales and General enquiries:

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69280 Marcy l'Etoile - France
Tel. 33 (0) 4 78 87 20 00
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Issue: 8 - May 2012

attached for reference purpose
Reconstitute the bioball with 22ml of bioball rehydration fluid
spike 100ul of above suspension in PPC and 100ul of suspension in PC
which contain 5263.63 cfu

A 27/10/16

P
28-10-16

Lot Number: B3278

Reference Material Data

Organism: *Pseudomonas aeruginosa*
Designation: NCTC 12924
Reference: 413831 10 Vials
56144 20 Vials
BTF Internal Reference: B-PA12924-10K-10
B-PA12924-10K-20
Date of Manufacture: 16 September 2015
Expiry Date: 15 September 2017
Extended Expiry Date*: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®
Mean cfu SD
9372.0 658.9

95% Prediction Interval
Lower Limit Upper Limit
7808.8 10935.2

For an explanation of the Prediction Interval
see the BioBall Instructions For Use on the
BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

.....
Linh Le

2 October 2015

NATA

Accredited for compliance with ISO Guide 34

TECHNICAL
COMPETENCE

Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

*BTF regularly extends the expiry dates on standard BioBall products. Please check the BTF website www.btfbio.com/cofa.php to determine whether or not the shelf life of your BioBall batch has been extended.

Manufactured by:
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24/08/16

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attached for reference purpose
27/10/16

Issue 8 - May 2012

28-10-16

Lot Number: B3543

Reference Material Data

Organism: *Pseudomonas aeruginosa*
Designation: NCTC 12924
Reference: 56007 10 Vials
56017 20 Vials
BTF Internal Reference: B-PA12924-550-10
B-PA12924-550-20
Date of Manufacture: 16 May 2016
Expiry Date: 16 May 2018
Extended Expiry Date[#]: N/A

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

.....
Linh Le

10 June 2016

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Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall[®]
Mean cfu SD
551.8 27.1

Quantification Data
cfu Count per 100µl aliquot*

Mean cfu SD
50.2 7.4

95% Prediction Interval
Lower Limit Upper Limit
35.1 65.2

For an explanation of the Prediction Interval see the BioBall Instructions For Use on the BioBall website - www.bioball.com



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Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

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* QC data using BioBall Re-Hydration Fluid (ref 56021)

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24/08/16



Issue: 10 - May 2012

attached for reference purpose

24/10/16

28.10.16

Lot Number: B3544

Reference Material Data

Organism: *Staphylococcus aureus*
Designation: NCTC 10788
Reference: 56009 10 Vials
56019 20 Vials
BTF Internal Reference: B-SA10788-550-10
B-SA10788-550-20
Date of Manufacture: 17 May 2016
Expiry Date: 17 May 2018
Extended Expiry Date*: N/A

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Linh Le

14 June 2016



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Accredited Reference Material Producer

Accreditation Number: 14993

Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

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* QC data using BioBall Re-Hydration Fluid (ref 56021)

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21/03/16

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Issue: 10 - May 2012

attached for reference purpose
27/10/16
28.10.16

Lot Number: B3583

Reference Material Data

Organism: *Salmonella abony*
Designation: ACM 5080
Reference: 413841 10 Vials
56042 20 Vials
BTF Internal Reference: B-SA5080-30-10
B-SA5080-30-20
Date of Manufacture: 15 June 2016
Expiry Date: 15 June 2018
Extended Expiry Date*: N/A

Quantification Data	
(Method Ref: BB-001)	
cfu Count per BioBall®	
Mean cfu	SD
30.0	2.2
95% Prediction Interval	
Lower Limit	Upper Limit
25.5	34.5
For an explanation of the Prediction Interval see the BioBall Instructions For Use on the BioBall website - www.bioball.com	

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Fiona Pollock

4 August 2016



Accredited for compliance with ISO Guide 34

Accredited Reference Material Producer

Accreditation Number: 14993

Site Number: 15276

Strain sourced from ACM (Australian Collection of Microorganisms)

*BTF occasionally extends the expiry dates on standard BioBall products. Please check the BioBall website <http://bioball.com/bioball/certificate-of-analysis/> to determine whether or not the shelf life of your BioBall batch has been extended.

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4/10/16



attached for reference purpose
27/10/16

28/10/16

Lot Number: B3131

Reference Material Data

Organism: *Escherichia coli*
Designation: NCTC 9001
Reference: 56160 10 Vials
56053 20 Vials
BTF Internal Reference: B-EC9001-10K-10
B-EC9001-10K-20
Date of Manufacture: 19 May 2015
Expiry Date: 18 May 2017
Extended Expiry Date*: N/A

Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu	SD
9934.0	567.8

95% Prediction Interval

Lower Limit	Upper Limit
8586.9	11281.1

For an explanation of the Prediction Interval see the BioBall Instructions For Use on the BioBall website - www.bioball.com

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:



Linh Le

17 June 2015



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Accredited Reference Material Producer

Accreditation Number: 14993

Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

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attached for reference purpose
24/10/16
28.10.16
Issue: 8 - May 2012

Lot Number: B3529

Reference Material Data

Organism: *Escherichia coli*
Designation: NCTC 12923
Reference: 56006 10 Vials
56016 20 Vials
BTF Internal Reference: B-EC12923-550-10
B-EC12923-550-20
Date of Manufacture: 4 May 2016
Expiry Date: 4 May 2018
Extended Expiry Date[#]: N/A

Culture Information

No. of Passages: 4
QC Media: Nutrient agar
Plate Incubation Time (hrs): 14 - 24
Plate Incubation Temp °C: 37 Aerobic

Note: Number of passages are indicated from the original strain assuming original strain is zero.

Strain Confirmation

Bacteria strains are confirmed by genetic typing. Yeast and Mould strains are confirmed by Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Quality Officer:

Lin Le

14 June 2016

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Quantification Data

(Method Ref: BB-019)

cfu Count per BioBall®

Mean cfu	SD
573.5	28.5

Quantification Data

cfu Count per 100µl aliquot*

Mean cfu	SD
52.1	7.3

95% Prediction Interval
Lower Limit Upper Limit
37.4 **66.9**

For an explanation of the Prediction Interval see the BioBall Instructions For Use on the BioBall website - www.bioball.com

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Accredited Reference Material Producer
Accreditation Number: 14993
Site Number: 15276

Strain sourced from NCTC (National Collection of Type Cultures)

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