

<b>Department</b>	<b>Micro Laboratory</b>	<b>Document no</b>	<b>MICLAB – METHOD 007</b>
<b>Title</b>	<b>Microbiological Test result acceptance criteria for raw materials and finished products</b>		
Prepared by:		Date:	Supersedes:
Checked by:		Date:	Date Issued:
Approved by:		Date:	Review Date:

NO.	RAW MATERIAL/ PRODUCT	ITEM NUMBER	MICROBIOLOGICAL TEST RESULTS ACCEPTANCE CRITERIA							
			TPC cfu/g	Yeast & Mould cfu/g	Pseudomonas spp / 10g	S.aureus /10g	Coliforms/ 10g	E.coli /1g	Salmonella/ 10g	Enterobacteriaceae cfu/g
1	Acacia Gum	WRRM00040	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
2	Alginate Acid (Kelacid)	WRRM00030	<200	<200	N/A	N/A	N/A	ND	ND	N/A
3	70% Alcohol	WRRM00440	<1/400mL	<1/400mL	ND/400mL	ND/400mL	ND/400mL	N/A	N/A	N/A
4	Capsule #0 White/Purple	WRRM30350	<1000	<1000	ND	ND	N/A	ND	ND	<100
5	Capsule #0 White/ Purple	WRRM30650	<1000	<1000	N/A	ND	N/A	ND	ND	<100
6	Capsules Day #0 Hard Gelatin	WRRM30720	<1000	<1000	N/A	ND	N/A	ND	ND	<100
7	Capsule # 0 White/ White	WRRM30780	<1000	<1000	N/A	ND	N/A	ND	ND	<100
8	Night Capsules #0 Hard Gelatin	WRRM30610	<1000	<1000	ND	ND	N/A	ND	ND	<100
9	Capsule Night #0 Hard Gelatin	WRRM30730	<1000	<1000	N/A	ND	N/A	ND	ND	<100
10	Capsule # 0 Blue/ Green (Wallaby)	WRRM31250	<1000	<100	N/A	ND	N/A	ND	ND	<100
11	Capsule # 1 Turquoise/Turquoise	WRRM30630	<1000	<1000	N/A	ND	N/A	ND	ND	<100
12	Capsule # 2 Blue/ White (Halal)	WRRM30060	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
13	Capsule # 2 Blue/ White	WRRM30070	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
14	Capsule # 2 Blue/ White (Unprinted)	WRRM30071	<1000	<1000	N/A	N/A	N/A	ND	ND	<100

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15	Capsules #2 Green / Green	WRRM30820	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
16	Capsule # 2 Dark Green Opaque/ Dark Green	WRRM30310	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
17	Capsule # 2 Blue / White	WRRM30620	<1000	<1000	ND	ND	N/A	ND	ND	<100
18	Capsule #3 White/ White (Unprinted)	WRRM30401	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
19	Capsule #3 White/ White (Halal)	WRRM30410	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
20	Capsule #1 White Opaque/ White Opaque	WRRM30640	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
21	Capsule Dilantin 100mg White Opaque/Orange#3	WRRM31120	<1000	<100	ND	ND	ND	ND	ND	<100
22	Capsule Dilantin 100mg White Opaque/Orange#3	WRRM31220	<1000	<100	N/A	ND	ND	ND	ND	<100
23	Capsule No 4 White/ Turquoise	WRRM30510	<1000	<1000	ND	ND	N/A	ND	ND	<100
24	Capsule No 4 White Opaque/ White Opaque	WRRM30530	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
25	Capsule # 4 Blue/Blue (Unprinted)	WRRM30561	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
26	Capsule # 4 Blue/ White	WRRM30570	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
27	Capsule # 4 Blue/Blue (Halal)	WRRM30580	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
28	Capsule No 4 Pink Opaque/ Red Opaque	WRRM30660	<1000	<1000	N/A	ND	N/A	ND	ND	<100
29	Capsule # 4 Flesh Opaque/ Pink Opaque	WRRM30670	<1000	<1000	N/A	N/A	N/A	ND	ND	<100

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30	Capsule No 4 White/ Turquoise	WRRM30690	<1000	<1000	N/A	ND	N/A	ND	ND	<100
31	Capsule No 4 White Opaque/ White Opaque	WRRM30770	<1000	<1000	N/A	N/A	N/A	ND	ND	<100
32	Capsule Dilantin 30mg White Opaque #4 Bovine	WRRM31210	<1000	<100	N/A	ND	ND	ND	ND	<100
33	Carnauba Wax (Powder)	WRRM02250	<100	<100	ND	ND	N/A	ND	ND	<100
34	Cellulose- Microcrystalline PH 101	WRRM00980	<1000	<100	ND	ND	N/A	ND	ND	<100
35	Cellulose- Microcrystalline PH 102 (Avicel)	WRRM50040 WRRM00920	<1000	<100	ND	ND	N/A	ND	ND	<100
36	Croscarmellose Sodium	WRRM01890	<1000	<100	N/A	N/A	N/A	ND	N/A	N/A
37	Corn Flour	WRRM02141	<1000	<100	N/A	N/A	N/A	ND	ND	<100
38	Icing Sugar	WRRM08090	<1000	<100	N/A	N/A	N/A	ND	ND	<100
39	Ibuprofen 63%	WRBM54910	<1000	<100	ND	ND	N/A	ND	ND	<100
40	Kaolin Light BP	WRRM30940	<1000	<100	ND	ND	Target ND/10g Release ≤100/10g	ND	ND	Clostridium Perfringens ND/g
41	Lactose 100 Mesh	WRRM10080	<100	<100	N/A	N/A	N/A	ND	ND	<100
42	Lactose USP/BP 100 Mesh	WRRM30950	<100	<100	Target ND/10g Release <100cfu/g	ND	Target ND/10g Release <100cfu/g	ND	ND	N/A
43	Lactose Anhydrous	WRRM10050 WRRM10090	<100	<50	N/A	N/A	N/A	ND	N/A	N/A
44	Lactose Fast Flo 316	WRRM10120	<100	<50	N/A	N/A	N/A	ND	N/A	N/A

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45	Lactose Hydrous	WRRM10030	<100	<50	N/A	N/A	N/A	ND	N/A	N/A
46	Lactose Special Dense	WRRM10130	<100	<100	N/A	N/A	N/A	ND	ND	<100
47	Lanolin Anhydrous Woolfat	WRRM10090	<100	<100	ND	ND	N/A	ND	ND	<100
48	Liquid Lecithin	WRRM10140	<100	<100	ND	ND	N/A	ND	ND	<100
49	Liquid Paraffin,High Viscosity (White Pharma 68)	WRRM10281	<100	<100	ND	ND	N/A	ND	ND	N/A
50	Liquid Paraffin, Low Viscosity	WRRM10271	<100	<100	ND	ND	N/A	ND	ND	N/A
51	Magnesium Stearate	WRRM11070	<1000	<500	N/A	N/A	N/A	ND	ND	N/A
52	Magnesium Stearate	WRRM11080	<1000	<1000	N/A	N/A	N/A	ND	N/A	N/A
53	Magnesium Stearate	WRRM11180	<1000	<1000	N/A	N/A	N/A	ND	N/A	N/A
54	Magnesium Stearate	WRRM30960	<1000	<1000	N/A	N/A	N/A	ND	N/A	N/A
55	Peanut Oil	WRRM13500	<100	<100	ND	ND	N/A	ND	ND	<100
56	Silicified Microcrystalline Cellulose	WRRM01150	<100	<20	ND	ND	N/A	ND	ND	<100
57	Sodium Alginate	WRRM16440	<200	<200	ND	ND	N/A	ND	ND	N/A
58	Sodium Starch Glycollate	WRRM04800	<100	<100	ND	N/A	N/A	ND	ND	<100
59	Starch Corn	WRRM17120	<1000	<100	Target ND/10g Release <100cfu/g	ND	Target ND/10g Release <100cfu/g	ND	ND	<100
60	Starch Pregelatinised Maize	WRRM17240	<1000	<100	N/A	N/A	N/A	ND	ND	<100

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61	Starch Moisture 5%	WRRM17330	<500	<50	N/A	N/A	N/A	ND	ND	<100
62	Starch Wheat- Low Moisture	WRRM16900	<500	<50	N/A	N/A	N/A	ND	ND	<100
63	Sucrose BP	WRRM31040	<100	<100	ND	N/A	N/A	ND	ND	<100
64	Sucrose Caster	WRRM16951	<100	<100	ND	N/A	N/A	ND	ND	<100
65	Sucrose Caster	WRRM31050	<100	<100	ND	N/A	N/A	ND	ND	<100
66	Sucrose Special Powder 4.6% Starch	WRRM32060	<1000	<100	Target ND/10g Release <100cfu/g	ND	N/A	ND	ND	<100
67	Talc Purified	WRRM17510	<100	<100	ND	ND	N/A	ND	ND	N/A
68	Talc Purified BP (Sterilised)	WRRM31080	<10	<10	ND	ND	N/A	ND	ND	N/A
69	Theobroma Oil	WRRM30980	<100	<100	ND	ND	N/A	ND	ND	<100
70	Xanthan Gum	WRRM09140	<500	<500	ND	ND	<100/g	ND	ND	<100
71	Anusol Ointment	B156	<100	<100	N/A	N/A	N/A	N/A	N/A	N/A
72	Anusol Suppositories	B155	<100	<100	N/A	N/A	N/A	N/A	N/A	N/A
73	Canex Puppy Suspension	WR536565	<100	<100	ND	ND	ND	N/A	N/A	<100
74	Dilantin Infatabs	WR300210	<1000	<100	ND/g	ND/g	N/A	ND	ND	<100
75	Equiban Paste	WR536087	<100	<100	ND	ND	ND	N/A	N/A	<100

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76	Felex Paste	WR5365564	<1000	<1000	ND	ND	ND	N/A	N/A	<100
77	Felex Plus Paste	WR536563	<1000	<1000	ND	ND	ND	N/A	N/A	N/A
78	Rectinol Ointment	WR192890	<100	<100	ND	ND	ND	N/A	N/A	N/A
79	Rectinol Suppositories	WR192922	<10	<10	ND	ND	ND	N/A	N/A	N/A
80	Rectinol HC	WR0052	<10	<10	ND	ND	N/A	N/A	N/A	N/A
81	Sudafed PE Nasal	WRBM51710	<1000	<100	N/A	N/A	N/A	ND	ND	<100
82	Mastalone	WRBM69840	<100	<100	ND	ND	ND	N/A	N/A	N/A
83	Mastalone Blue	WRBM69860	<100	<100	ND	ND	ND	N/A	N/A	N/A
84	Viagra Tablets 25mg, 50mg,100mg	WR198017 WR198015 WR198011 WR198016	<1000	<100	ND/g	ND/g	N/A	ND	ND	<100
85	Vibravet Paste	WR563030	<1000	<100	ND	ND	N/A	ND	ND	<100
86	Zeldox Capsules 20mg, 40mg, 60mg, 80mg	WR192050 WR192010 WR192000 WR192020 WR192030	<1000	<100	ND/g	ND/g	N/A	ND	ND	<100
87	Zithromax 250mg 600mg	WR191160 WR191185	<1000	<100	N/A	N/A	N/A	ND	ND/g	<100
88	Zolofit 50mg 100mg	WR03041053 WR145100 WR03041103 WR145105	<1000	<100	ND/g	ND/g	N/A	ND	ND	<100

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ND = Not Detected

N/A = Not Applicable