

Penyimpanan Bahan Baku Penolong			
No. : DPB012	Revisi : 05	Berlaku : 170117	Paraf : <i>g</i>


- 1 **Tujuan**
Untuk memberikan panduan dalam penyimpanan bahan baku penolong sehingga dapat terjaga kualitasnya.
- 2 **Cakupan**
Daftar ini berlaku untuk penyimpanan bahan baku penolong di gudang Logistik Bahan Awal dan Bidang Litbang.
- 3 **Penanggung Jawab**
Penanggung jawab protap ini adalah Asman Pengujian Bahan Awal dan Bahan Kemasan.
- 4 **Definisi**
 - 4.1 AC = $\leq 25\text{ }^{\circ}\text{C}$.
 - 4.2 Non AC = $\leq 30\text{ }^{\circ}\text{C}$

5 **Daftar**

No	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
1	Acetic Acid Glacial p.a / extra pure		AC	
2	Alcohol Absolute p.a / extra pure			Solvent
3	Alkohol 96 %			Solvent
4	Ammonium Dihydrogen Phosphate p.a / Crystal extra pure		AC	
5	Amylum Maydis		Non AC	
6	Apple Green Soluble Color		AC	
7	Aqua p.i 20 ml		Non AC	
8	Aspartame		Non AC	
9	Banana Flavor, liquid		AC	
10	Benzalkonium Chloride		AC	
11	Benzoic Acid p.a		Non AC	
12	Benzyl Alcohol p.a / extra pure			Solvent
13	Beverage Cloud, powder		AC	
14	Boric Acid p.a / Crystal extra pure		AC	
15	Briliant Blue Alulake	Lynlake blue FD&C Blue No. 1 Alulake	AC	
16	Brown HT (CI 20285) Soluble Color	Dalfcol Brown HT Eurocert Brown HT	AC	
17	Butter Scoth Flavor	Odoriferous MTX of Essential oils Frutarom	AC	
18	Butylated Hydroxytoluena		Non AC	
19	Cire de lanol		AC	
20	Certolake Green Mixture III		AC	
21	Cetyl Pyridinium Chloride, monohydrate		AC	
22	Cetyl Alkohol		AC	


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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
23	Citric Acid Monohydrate p.a / Crystal extra pure		AC	
24	Colloidal Silicon Dioxide	Cab-o-sil Aerosil 200 HDK N 20 Aerosil	Non AC	
25	Cross Carmelose Sodium	Primellose	Non AC	
26	Crosspovidone	Kollidon Cl Polyplasdon XL	AC	
27	Dextrates Hydrated	Emdex	AC	
28	Dibasic Calcium Phosphate	Emcompress Dicafos	Non AC	
29	Dibasic Sodium Phosphate Dihydrate p.a		AC	
30	Disodium Edetate	Titriplex III	AC	
31	Disodium Tetraborate Decahydrate (Sodium Borate / Borax) p.a / extra pure		AC	
32	DW light green 2174 soluble color		AC	
33	Easpray yellow GMIEID02C		AC	
34	Easpray white GMIEID PB 01 A-1073		AC	
35	Empty Gelatin Capsule No. 0 Deep red (c) - White (b)		AC	
36	Empty Gelatin Capsule No. 0 Scarlet (c) - White (b)		AC	
37	Empty Gelatin Capsule No. 0, M. Orange Op (c) - M. Orange Op (b)		AC	
38	Empty Gelatin Capsule No. 0, Dark Green Op (c) - Ivory Op (b)		AC	
39	Empty Gelatin Capsule No.0, Purple Op (c) - Purple Op (b)		AC	
40	Empty Gelatin Capsule No. 0, Black TR (c) - Standard Pink Op (b)		AC	
41	Empty Gelatin Capsule No. 1 Yellow op 41.735 (c / b)		AC	
42	Empty Gelatin Capsule No. 2 Buff Op. 37.7131 - White Op. 44.700 (b)		AC	
43	Empty Gelatin Capsule No. 0, Deep Scarlet Op (c) - Deep Scarlet Op (b)		AC	
44	Empty Gelatin Capsule No. 0, Apple Green (c) - Yellow Op (b)		AC	
45	Empty Gelatin Capsule No. 0, Dark Blue (c) - Powder Blue (b)		AC	
46	Empty Gelatin Capsule No. 1 Purple Op. 51711(c) - purple Op. 51711 (b)		AC	
47	Empty Gelatin Capsule No. 1 Black TR (c) - Purple Op. (b)		AC	


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48	Empty Gelatin Capsule No. 1 Caramel Op (c) – Caramel Op (b)		AC	
49	Empty Gelatin Capsule No. 1 Scarlet Op (c)- Scarlet Op (b)		AC	
50	Empty Gelatin Capsule No. 1, Apple Green (c) - White Op (b)		AC	
51	Empty Gelatin Capsule No. 1, Aqua Blue Op (c) - Ivory Op (b)		AC	
52	Empty Gelatin Capsule No. 1, Black TR (c) - Dark Green Op (b)		AC	
53	Empty Gelatin Capsule No. 1, Black TR (c) - Rich Yellow Op (b)		AC	
54	Empty Gelatin Capsule No. 1, Black TR AC - Sw Orange Op (b)		AC	
55	Empty Gelatin Capsule No. 1, Coral red Op AC - coral red Op (b)		AC	
56	Empty Gelatin Capsule No. 1, Scarlet Op 32.743(c) - Scarlet Op 32.743(b)		AC	
57	Empty Gelatin Capsule No. 1, Green Apple Op (c) - Green Apple Op (b)		AC	
58	Empty Gelatin Capsule No. 1, Scarlet Op 32.717AC - Scarlet Op 32.717(b)		AC	
59	Empty Gelatin Capsule No. 1, D. Green Op 539(c) - D. Green Op 539 (b)		AC	
60	Empty Gelatin Capsule No. 2 LT. Blue Op AC - White Op (b)		AC	
61	Empty Gelatin Capsule No. 2 Yellow Op AC - Yellow Op (b)		AC	
62	Empty Gelatin Capsule No. 2, Deep Red Op AC - Dull Yellow Op (b)		AC	
63	Empty Gelatin Capsule No. 2, Scarlet Op AC - Blue Op (b)		AC	
64	Empty Gelatin Capsule No. 2, Scarlet Op AC - Scarlet Op (b)		AC	
65	Empty Gelatin Capsule No. 2, Black TR AC - Ocean Blue Op (b)		AC	
66	Empty Gelatin Capsule No. 2, M. Orange Op AC - White Op (b)		AC	
67	Empty Gelatin Capsule No. 2, Dark Green Op AC - Dark Green Op (b)		AC	
68	Empty Gelatin Capsule No. 2, Dark Green Op AC - White Op (b)		AC	
69	Empty Gelatin Capsule No. 2, Orange Op AC - Orange Op (b)		AC	


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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
70	Empty Gelatin Capsule No. 2, Black TR (c) - Amethys Op (b)		AC	
71	Empty Gelatin Capsule No. 2, Dark Blue Op (c) - Dark Blue Op (b)		AC	
72	Empty Gelatin Capsule No. 2, Dark Green AC - Apple Green (b)		AC	
73	Empty Gelatin Capsule No. 2, Powder Blue AC - Powder Blue (b)		AC	
74	Empty Gelatin Capsule No. 2, Maroon (c) - Maroon (b)		AC	
75	Empty Gelatin Capsule No. 3 M. Dark Green AC - G. Buff (b)		AC	
76	Empty Gelatin Capsule No. 3, Ivory Op (c) - Ivory Op (b)		AC	
77	Empty Gelatin Capsule No. 3, Ocean Blue Op AC - Ocean Blue Op (b)		AC	
78	Empty Gelatin Capsule No. 3, Rich Yellow Op AC - Rich Yellow Op (b)		AC	
79	Erythrocin (CI 15985) Soluble Color	Dalfcol erythrocin Eurocert erythrocin	AC	
80	Erythrocin Alulake	Lynlake erythrocin Certolake / Eurolake erythrocin	AC	
81	Ethyl Cellulosa	Ethocel 20 premium	Non AC	
82	Ethyl Maltol FCC 4 (untuk Biofibr)		AC	
83	Fragrance Eau Fleuri AD7855	Odoriferous oil	AC	
84	Fragrance Madame for Cream SE5887		AC	
85	Glycerin		Non AC	
86	Glyceryl Behenate	Compritol 888 ATO	AC	
87	Grape Concord 52.929C, liq. Flavor		AC	
88	HPMC - Phtalate HP 55		Non AC	
89	HPMC 615	Pharmacoat 615	Non AC	
90	HPMC 645	Pharmacoat 645	Non AC	
91	Hydrochloride Acid 36 % p.a		AC	
92	Hypophosphoric Acid 50% p.a		AC	
93	Hydroxypropyl methylcellulose 2910 (methocel E 15) Hypromellose		AC	
94	Indigo Carmine Alulake (325015)	Certolake indigo Carmine	AC	
95	Kollicoat MAE 30 DP		AC	
96	Isopropanol			Solvent
97	Lactose Mesh 200		Non AC	

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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
98	Lactose Mesh 80		Non AC	
99	Lanolin Anhydrous	Adeps Lanae	AC	
100	Lemon Flavor 51.416, liquid		AC	
101	Low-substituted Hydroxypropyl Cellulose (L-HPC)		Non AC	
102	Lubriwax		AC	
103	Lutrol F127 Micronized		AC	
104	Magnesium Aluminometasilicate	Neusilin UFL 2	AC	
105	Magnesium Stearate, Heavy Powder		Non AC	
106	Maltodextrin		AC	
107	Manitol		Non AC	
108	Melon Flavour, powder		AC	
109	Menthol, Crystal		AC	
110	Methanol			Solvent
111	Methyl cellulose	Methocel E 15 LV Premium	Non AC	
112	Methyl Paraben	Nipagin	Non AC	
113	Methylen Chloride			Solvent
114	Monobasic Sodium Phosphate Dihydrate, extra pure	Sodium dihidrogen phosphate dihydrate	AC	
115	Microcrystalline Cellulose PH 101	Avicel PH 101 Vivapur PH 101 Comprecel	Non AC	
116	Microcrystalline Cellulose PH 102	Avicel PH 102 Vivapur PH 102 Cyclocel	Non AC	
117	Microcrystalline Hydroxyapatite (MCHA)		AC	
118	Opadry AMB 80W66720 Brown (untuk RHZE)		AC	
119	Opadry Brown OY-9249 (untuk Rifampicin 450 & 600 mg)		AC	
120	Opadry Yellow OY-GM-22900		AC	
121	Opadry Brown pink OY-9461 (untuk Amitriptylin 25 mg)		AC	
122	Opadry II Brown 85G86674 (untuk amitriptylline 25mg)		AC	
123	Opadry II Brown 85G56861 (untuk Rifampicin 600mg)		AC	
124	Opadry Green OY-C-21011 (untuk Ranitidine 200 mg)		AC	
125	Opadry Grenn AMB 80W51493 (untuk Ranitide 150mg)		AC	

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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
126	Opadry Orange OY-23010 (untuk Chlorpromazine 25 dan 100mg)		AC	
127	Opadry Pink OY-24807 (untuk Nifedipin 10 mg)		AC	
128	Opadry II Pink 85G54002 (untuk FDC 2. Rifanh)		AC	
129	Opadry II Red 85G55015 (untuk Ferro Folat 200,25 mg)		AC	
130	Opadry TM - Purple		AC	
131	Opadry White – OYC7000A		AC	
132	Opadry White OY-B-AMB-28920 (untuk Urispas 200 mg)		AC	
133	Opadry White II 85 F 28751		AC	
134	Opadry II Yellow 85652561 (untuk asam mefenamat 500mg)		AC	
135	Orange Durarome		AC	
136	Orange Flavor, powder	Essens orange 51941 AP0551	AC	
137	Orange Red Alulake		AC	
138	Orange Red Soluble Color		AC	
139	Paraffin Liquidum	Vestan AC360B	Non AC	
140	Peach Flavor FL 2020, liquid		AC	
141	Peppermint Oil		AC	
142	Phenol		AC	
143	Phenyl Mercury Nitrate		AC	
144	Pigmen Orange C508		AC	
145	Pigmen Yellow C350		AC	
146	Pineapple Flavor F502163/C, liquid		AC	
147	Polyethylen Glycol 4000		AC	
148	Polyethylen Glycol 6000, powder		AC	
149	Polyoxyethylene Glycol Palmitostearate	Tefose 1500	AC	
150	Polysorbate 80	Tween 80 Rheodol TWD 120	AC	
151	Polyvinyl Pyrolidone	Kollidone K30 Kollidone K25 Plasdone K29 / 32	Non AC	
152	Poncheau 4 R Alulake	Lynlake Poncheau 315021 Certolake Poncheau 4R	AC	
153	Potasium Iodide p.a / extra pure		AC	

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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan
154	Potassium Dihydrogen phosphat extra pure		AC	
155	Propyl Paraben	Nipasol	Non AC	
156	Propylen Glycol (untuk produk steril)		Non AC	
157	Propylen Glycol (untuk sirup)		Non AC	
158	Raspberry Flavor SU969C, liquid		AC	
159	Raspberry Flavor, powder		AC	
160	Raspberry Red Soluble Color	Eurocert raspberry red	AC	
161	Silicon Oil KF96 / 350 cp		Non AC	
162	Simethicone / Dimethicone untuk sirup kering	Dimethyl Polysiloxane Medical antifoam AF30%	AC	
163	Sodium Alginat, micronized		AC	
164	Sodium Benzoat (untuk produk steril)		AC	
165	Sodium Benzoat (untuk produk non steril)		Non AC	
166	Sodium Bicarbonat		Non AC	
167	Sodium Carboxy Methyl Cellulose	Celogen FSH Sodium CMC	AC	
168	Sodium Chloride p.a / extra pure low in endotoxin / extra pure		AC	
169	Sodium Citrate Dihydrate		AC	
170	Sodium Citrate Dihydrate p.a/extra pure		AC	
171	Sodium Hydroxide p.a		AC	
172	Sodium Lauryl Sulphate	Texapone OC powder	Non AC	
173	Sodium Metabisulfite, p.a	Sodium disulfite	AC	
174	Sodium Saccharin		AC	
175	Sodium Starch Glycolate	Primojel Explosol Explotab	Non AC	
176	Sodium Sulfite p.a		AC	
177	Sodium Siklamat		AC	
178	Sorbitol Liquid 70 % (Sorbitol Solution)	Neosorb Indosorb TS 7	Non AC	
179	Sorbitol Powder		Non AC	
180	Starch 1500		Non AC	
181	Starch Soluble GR		Non AC	
182	Stearic Acid		Non AC	
183	Strawberry Flavor 52.311, powder		AC	
184	Sucrose		Non AC	

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No.	Nama Bahan Baku	Sinonim	Lokasi	Keterangan	
185	Sunset Yellow FCF Alulake		AC		
186	Sunset Yellow Soluble Color	Dalfcol SY FCF Eurocert SY	AC		
187	Talc		Non AC		
188	Tartaric Acid p.a / Crystal extra pure		AC		
189	Tartrazine (CI 19140) Soluble Color	Dalfcol tartrazine Eurocert tartrazine	AC		
190	Tartrazine Alulake	Lynlake tartrazine Eurolake tartrazine	AC		
191	Thiomersal		AC		
192	Titanium Dioxide		Non AC		
193	Vaselin Album	White Petrolatum	Non AC		
194	Vaselin Flavum	Yellow Petrolatum	Non AC		
195	Vanilla flavour W2 / V2 (NA) / PCA 9061212		AC		
196	Violet Liquid		AC		
197	Vitacel A 300		Non AC		
198	Xantham Gum	Rhodigel Easy	AC		

6 Tindak lanjut

Jika kondisi penyimpanan bahan tidak bisa mengikuti ketentuan ini maka bidang PPPP mengajukan usulan perubahan disertai kajian resiko

7 Daftar Pustaka


PT. Indofarma Tbk.

8 Catatan Perubahan

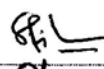

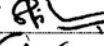

Daftar ini merupakan revisi Daftar Penyimpanan Bahan Baku Penolong No. DPB012 revisi 04 dengan perubahan pada daftar penyimpanan

9 Distribusi

- 9.1 Bidang Pengawasan Mutu
- 9.2 Bidang PPPP (Logistik Bahan Awal)
- 9.3 Bidang Litbang
- 9.4 Bidang Produksi II (Betalaktam)

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11 Pengesahan

Keterangan	Jabatan	Kode Bidang	Tanda tangan	Tanggal
Disusun oleh	Asman Pengujian Bahan Awal dan Bahan Kemasan	AM		17 01 13
Diperiksa oleh	Asman IPC dan Pengujian Produk	AM		17 01 13
Disetujui oleh	Manajer Pengawasan Mutu	AM	an. 	17 01 13
	Manajer Pemastian Mutu	PM 2		17 01 16