


Penyimpanan Bahan Baku Aktif			
No. : DPB011	Revisi : 07	Berlaku : 170403	Paraf : 

1. Tujuan

Untuk memberikan panduan dalam penyimpanan bahan baku aktif sehingga dapat terjaga kualitasnya.

2. Cakupan

Daftar ini berlaku untuk penyimpanan bahan baku aktif di gudang Logistik Bahan Awal dan produksi Betalaktam.

3. Penanggung jawab


Penanggung jawab protap ini adalah Asman Pengujian Bahan Awal dan Bahan Kemasan.


4. Definisi


- 4.1. Lokasi AC = $\leq 25^{\circ}\text{C}$
- 4.2. Lokasi Non AC = $\leq 30^{\circ}\text{C}$
- 4.3. Lokasi Refrigerator = suhu $2^{\circ}\text{C} - 8^{\circ}\text{C}$


5. Daftar


No.	Nama Bahan Baku	Lokasi	Keterangan
1.	Acyclovir, <i>superfine & fine powder</i>	Non AC	
2.	Adrenaline Bitartrate, <i>crystalline powder</i>	Refrigerator	
3.	Albendazole	Non AC	
4.	Allopurinol, <i>powder</i>	Non AC	
5.	Alumunium Hydroxide, <i>Heavy & light Powder</i>	AC	
6.	Ambroxol HCl	AC	
7.	Aminophylline Anhydrous, <i>powder</i>	AC	
8.	Amitriptyline HCl, <i>powder</i>	AC	
9.	Amlodipin Besilate	AC	
10.	Ammonium Chloride	AC	
11.	Amoxicillin Trihydrate, <i>compacted</i>	AC	Betalaktam
12.	Amoxicillin Trihydrate, <i>powder</i>	AC	Betalaktam
13.	Ampicillin Sodium, <i>sterile, Lyophilized</i>	AC	Betalaktam
14.	Ampicillin Trihydrate, <i>compacted</i>	AC	Betalaktam
15.	Ampicillin Trihydrate, <i>powder</i>	AC	Betalaktam
16.	Antalgin, <i>powder</i>	Non AC	
17.	Artichoke Dry Aqueous Extract	AC	
18.	Ascorbic Acid	AC	
19.	Atropine Sulfate, <i>Crystal p.i. (untuk injeksi)</i>	Refrigerator	
20.	Atropine Sulphate, <i>microfine powder (untuk tablet)</i>	Refrigerator	
21.	Attapulgite	AC	
22.	Betacaroten 10% CWS (untuk Biovision Kapsul)	AC	
23.	Betacaroten 20% (untuk Biocaroten Kapsul)	AC	

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24.	Bilberry extract 25%	AC	
25.	Caffein Anhydrous	AC	
26.	Calcitriol	Refrigerator	
27.	Calcium Lactate pentahydrate	Non AC	
28.	Captopril	Non AC	
29.	Carbamazepine, <i>Microfine</i>	Non AC	
30.	Cefadroxil Monohydrate, <i>Compacted</i>	AC	Cefalosporin
31.	Cefadroxil Monohydrate, <i>Powder</i>	AC	Cefalosporin
32.	Cefixime, <i>Superfine</i>	AC	Cefalosporin
33.	Cefotaxime Sodium, <i>Sterile</i>	AC	Cefalosporin
34.	Ceftriaxone Sodium, <i>Sterile</i>	AC	Cefalosporin
35.	Cephalexin Monohydrate, <i>Compacted</i>	AC	Cefalosporin
36.	Cephradine, <i>compacted</i>	AC	Cefalosporin
37.	Cetirizine Dihydrochloride, <i>powder</i>	AC	
38.	Chloramphenicol	Non AC	
39.	Chloroquine Diphosphate, <i>powder</i>	Non AC	
40.	Chlorpheniramine Maleate, <i>powder</i>	AC	
41.	Chlorpromazine HCl, <i>powder</i>	AC	Lemari terkunci
42.	Chondroitin, <i>Sulphate</i>	AC	
43.	Cimetidine, <i>powder</i>	AC	
44.	Citicoline Sodium Salt	AC	
45.	Ciprofloxacin HCl Monohydrate, <i>powder</i>	AC	
46.	Clindamycin HCl	AC	
47.	Clonidine HCl, <i>powder</i>	AC	
48.	Clopidogrel Bisulphate	Refrigerator	
49.	Cocoa butter (Glass Ionomer Art)	AC	
50.	Cyanocobalamine crystal pi	AC	
51.	Dexamethasone Sodium Phosphate, crystal p.i	AC	
52.	Dexamethasone, <i>superfine powder</i>	AC	
53.	Dexchlorpheniramine maleate	AC	
54.	Dextromethorphan HBr, <i>powder</i>	AC	Lemari terkunci
55.	Diazepam, <i>fine powder BP</i> (untuk tablet)	AC	Lemari terkunci
56.	Diazepam, <i>microfine p.i</i> (untuk injeksi)	AC	Lemari terkunci
57.	Dicloxacillin Sodium, <i>crystalline powder</i>	AC	Betalaktam
58.	Diethylcarbamazine Citrate, <i>powder</i>	Non AC	
59.	Digoxin, <i>superfine</i>	AC	
60.	Diltiazem HCl, <i>powder</i>	AC	

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No. : DPB011	Revisi : 07	Berlaku : 170403	Paraf : 
61.	Disopyramide Phosphate, <i>veryfine powder BP</i>	AC	
62.	Domperidone	AC	
63.	Doxycycline Hyclate, <i>crystalline powder</i>	AC	
64.	Echinacea Dry Extract 4%	AC	
65.	Ephedrine HCl, <i>powder</i>	AC	Lemari terkunci
66.	Erythromycin Ethylsuccinate, <i>superfine powder</i>	AC	
67.	Erythromycin Stearate, <i>granule</i>	AC	
68.	Ethambutol HCl, <i>powder</i>	AC	
69.	Famotidine, USP	AC	
70.	Ferrous Sulphate Dried, <i>granule</i>	AC	
71.	Flavoxate HCl	AC	
72.	Folic Acid, <i>microfine powder</i>	AC	
73.	Fuji IX Liquid (<i>glass ionomer ART</i>)	AC	
74.	Fuji IX Powder (<i>glass ionomer ART</i>)	AC	
75.	Furosemide, <i>superfine powder</i>	AC	
76.	Gemfibrozil	AC	
77.	Gentamicin sulphate, sterile	AC	
78.	Gentamicin Sulphate, <i>superfine powder</i>	AC	
79.	Ginkgo Biloba, <i>dry extract</i>	AC	
80.	Ginseng <i>dry extract</i>	AC	
81.	Glibenclamide, <i>superfine powder</i>	Non AC	
82.	Glimepiride	AC	
83.	Glucosamin Hcl	AC	
84.	Glucose Anhydrous, <i>crystalline powder</i>	Non AC	
85.	Griseofulvin, <i>microfine</i>	Non AC	
86.	Haloperidol, <i>microfine powder</i>	AC	Lemari terkunci
87.	Hydrochlorothiazide	Non AC	
88.	Hydrocortisone Acetate, <i>superfine</i>	AC	
89.	Hydrocortisone Base , <i>micronized</i>	AC	
90.	Ibuprofen, <i>sphere crystalline powder</i>	AC	
91.	Immune System Booster	AC	
92.	Indomethacin, <i>micronized</i>	AC	
93.	Irbesartan	AC	
94.	Isoniazid	AC	
95.	Isosorbide Dinitrate, <i>diluted 25%</i>	AC	
96.	Ketorolac tromethamine	AC	
97.	Lanzoprazole pellet	AC	

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No. : DPB011	Revisi : 07	Berlaku : 170403	Paraf : 
98.	Levofloxacin, Hemihydrate	AC	
99.	Lidocaine HCl, crystal p.i	AC	
100.	Lincomycin HCl	AC	
101.	Lincomycin Hcl , Compacted	AC	
102.	Loratadine	AC	
103.	Lutein 5%	AC	
104.	Magnesium Hydroxide <i>heavy & Light powder</i>	AC	
105.	Magnesium Oxide	AC	
106.	Magnesium Sulphate	Non AC	
107.	Manganese Sulphate	AC	
108.	Mebendazole, powder	Non AC	
109.	Mefenamic Acid , <i>superfine</i> (untuk tablet)	Non AC	
110.	Meloxicam, <i>superfine</i>	AC	
111.	Methyl Prednisolon micronized	Refrigerator	
112.	Metochlopramide HCl	AC	
113.	Metronidazole, <i>powder</i>	Non AC	
114.	Metformin	AC	
115.	Mineral Mix	AC	
116.	Natural Astaxanthin 10 %	Refrigerator	
117.	N. Acetyl. L. Cystein	AC	
118.	Nifedipin, granule	AC	
119.	Nimesulide	Non AC	
120.	Ondansetron	AC	
121.	Ofloxacin	AC	
122.	Omeprazole, <i>pellet 8.5 %</i>	AC	
123.	Oseltamivir posfat	AC	
124.	Oxytetracycline HCl, <i>microfine powder</i> (untuk salep kulit)	AC	
125.	Oxytetracycline HCl, <i>micronized</i> (untuk salep mata)	AC	
126.	Papaverine HCl, <i>powder</i>	AC	
127.	Paracetamol, <i>fine powder</i> (untuk sirup)	Non AC	
128.	Paracetamol, <i>powder</i> (untuk tablet)	Non AC	
129.	Phenobarbital, <i>microfine powder</i>	AC	Lemari terkunci
130.	Piracetam	AC	
131.	Piroxicam , <i>superfine</i>	AC	
132.	Polymyxin B Sulphate	AC	
133.	Pottasium Chloride, crystalline powder	AC	
134.	Pravastatin sodium	Refrigerator	

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No. : DPB011	Revisi : 07	Berlaku : 170403	Paraf : 
135.	Prednisone, <i>superfine</i>	AC	
136.	Premix Mineral	AC	
137.	Premix vitamin	AC	
138.	Propranolol HCl, powder	AC	
139.	Propylthiouracil, <i>powder</i>	Non AC	
140.	Pseudoefedrine Hcl	AC	Lemari terkunci
141.	Pyrantel Pamoate, <i>powder</i>	AC	
142.	Pyrazinamide	Non AC	
143.	Pyridoxine HCl, <i>granule</i>	AC	
144.	Pyrimethamine, <i>superfine</i>	AC	
145.	Ranitidine HCl, <i>powder</i>	AC	
146.	Ranitidine HCl, <i>Granular (DC Grade)</i>	AC	
147.	Reserpine, <i>superfine powder</i>	AC	
148.	Red Yeast Selenium	AC	
149.	Riboflavine Phosphate	AC	
150.	Rifampicin, <i>powder</i>	AC	
151.	Ropufa / DHA	AC	
152.	Salbutamol Sulphate, <i>powder</i>	AC	
153.	Salisilamide	AC	
154.	Serenoa Repens Purified Extract	AC	
155.	Silymarin S	AC	
156.	Simethicon / Dimethicone (Dimethyl Polysiloxane) untuk Indomag tablet & suspensi	AC	
157.	Sodium Bicarbonate (untuk Biofibra)	Non AC	
158.	Sodium Chloride, <i>crystalline powder</i> (standar salt)	AC	
159.	Sodium Citrate Dihydrate, <i>crystalline powder</i> (untuk Oralit)	AC	
160.	Sodium Diclofenac	AC	
161.	Sodium Fluoride, <i>powder</i>	Non AC	
162.	Spyramycin Base	AC	
163.	Streptomycin 1.5 g, steril	AC	
164.	Succus Liquiritiae	AC	
165.	Sulfadoxine, <i>superfine powder</i>	Non AC	
166.	Sulfamethoxazole, <i>powder</i> (untuk tablet)	Non AC	
167.	Sulfamethoxazole, <i>microfine powder</i> (untuk suspensi)	Non AC	
168.	Taburia, <i>powder</i>	AC	
169.	Taburin with Fe Fumarate	AC	
170.	Thiamine Mononitrate, <i>granule</i>	AC	
171.	Thiamine mononitrate, powder	AC	

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No. : DPB011	Revisi : 07	Berlaku : 170403	Paraf : 
172.	Thiamphenicol	Non AC	
173.	Thymi Extract Herb (untuk OBH Indo Jahe)	AC	
174.	Tinctur Ipeka	AC	
175.	Tramadol HCl	AC	Lemari terkunci
176.	Trihexyphenidyl HCl, powder	AC	Lemari terkunci
177.	Trimethoprim, powder (untuk tablet)	Non AC	
178.	Valerian Dry Extract	AC	
179.	Vitamin Mineral Premix	AC	
180.	Vitamin A Acetate	AC	
181.	Vitamin E Dry Powder	AC	
182.	Vitamin Mineral Mix	AC	
183.	Zinc Bacitracin	AC	
184.	Zinc Sulfate	AC	
185.	Zeaxanthin 5 %	AC	

6 Tindak lanjut

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

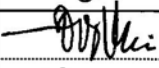

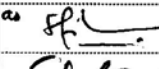

7 Catatan Perubahan


Daftar ini merupakan revisi Daftar Penyimpanan Bahan Baku Aktif No. DPB011 revisi 06 dengan penambahan Hydrocortisone base *micronized*.

8 Distribusi

- 9.1 Bidang Pengawasan Mutu
- 9.2 Bidang PPPP

9 Pengesahan

Keterangan	Jabatan	Kode Bidang	Tanda tangan	Tanggal
Disusun oleh	Supervisor Pengujian Bahan Awal	AM		170403
Diperiksa oleh	Asman Pengujian Bahan Awal dan Bahan Kemasan	AM		170403
Disetujui oleh	Manajer Pengawasan Mutu	AM		170403
	Manajer Pemastian Mutu	PM		170403

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10 Tinjauan

No.	Peninjau	Tgl. Tinjauan	Tanda tangan	Rekomendasi
1	Manajer Pengawasan Mutu			
	Manajer Pemastian Mutu			
2	Manajer Pengawasan Mutu			
	Manajer Pemastian Mutu			