



**PROTOCOL FOR  
“USE BEFORE DATE” EVALUATION  
OF QC CHEMICAL AFTER INITIAL  
OPENING**

**Document Number :**

**Effective Date :**



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

### 1.0 PROTOCOL APPROVAL:

Function	Signatories	Name of Individual	Signature	Date
Prepared by				
Checked by				
Approved by				
Authorized by				



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

2.0

### TABLE OF CONTENTS

S.No.	Content	Page No.
1.0	PROTOCOL APPROVAL	2
2.0	TABLE OF CONTENT	3
3.0	OBJECTIVE	4
4.0	SCOPE	4
5.0	RESPONSIBILITIES	4
6.0	EVALUATION OF USED BEFORE DATE	5
7.0	SHELF LIFE ASSIGNING BASED ON THE FACTOR	6
8.0	DEVIATION	7
9.0	EXECUTIVE SUMMARY	8
10.0	REFERENCES	9



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

#### 3.0 OBJECTIVE:

The objective of this study is to establish time limit after opening of intact container/bottle having Chemical, Reagent and substances used for QC and Microbiology testing.

#### 4.0 SCOPE:

- 4.1 This protocol shall be applicable for the evaluation of use before date after opening of intact container containing all Chemical, Reagent and substances used in Chemical, Instrumental and microbiological testing on the basis of various parameter as per Protocol.
- 4.2 The protocol shall specify the responsibilities for the activity related to evaluation of Chemical, Reagent and substances used in the laboratory for various parameters.
- 4.3 The protocol shall establish the acceptance of used before date for each chemical used in QC and Microbiological Testing.

#### 5.0 RESPONSIBILITIES:

The team shall comprise of the following team members and their responsibilities shall be as Specified below.

	<b>Operation</b>	
	<b>Quality Assurance</b>	
	<b>Quality Control</b>	

#### Quality Assurance:

QA Officer/Executive shall monitor and ensure the physical and chemical properties of Chemical, Reagent and substances used in Chemical and microbiological testing.

The Executive QA is responsible for review included in this protocol and verification of proper scale followed to evaluate the use before date after opening of intact container containing all Chemical, Reagent and substances used in Chemical and microbiological testing .

The Head Quality Assurance is responsible for ensuring that the required documentation is available and is adequate to support the study.

The Head Quality Assurance is responsible for protocol approval for final review with subsequent approval of completed study report.



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

#### Quality Control:

QC Officer/Executive shall evaluate the physical and chemical properties of Chemical, Reagent and substances used in Chemical and microbiological testing.

The Executive QC is responsible for review of the protocol and verification of proper

Scale followed to evaluate the use before date, after opening of intact container containing all Chemical, Reagent and substances used in Chemical and microbiological testing.

#### 6.0 Evaluation of 'Used Before Date' Methodology:

Below listed Scale shall be followed for the evaluation of use before date after opening of intact container containing all Chemical, Reagent and substances used in Chemical and microbiological testing on the basis of their consumption, frequency of use, pack size, nature of Product, physical and chemical properties. This evaluation shall be done in annexure-I by multiplying the rating assigned for each parameter.

The total obtained by multiplication of various parameters rating shall be checked with the obtained criteria in section 7.0.

#### Factor A:

##### Physical characteristics:

Physical characteristics	Rating
Fine powder/Clear liquids	1
Amorphous powder/Conc.acids and bases and amine liquids	2
Crystalline substances/Readymade pH buffer, Liquids and Primary standards	3
Pellets/Fumable Liquids and Indicators	4

#### Factor B:

##### Nature of material:

Nature of material	Rating
Non-hygroscopic	1
Hygroscopic	5



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

#### Factor C:

##### Used for:

Used for	Rating
Volumetric Solution	1
Mobile phase/diluents	2
Reagents	3

#### Factor D:

##### Frequency of use:

Frequency of use	Criteria	Rating
Vary rarely	Not within 3 months	1
Rarely	Once in 3 months	2
Usually	Once in month	3
Frequently	Once in a week	4
Very frequently	Almost daily	5

#### Factor E:

##### Pack size:

Pack Size	Rating
25 -50 gm or millilitre	1
51-100 gm or millilitre	2
101-500 gm or millilitre	3
501-1000 gm or millilitre	4
More than 1000 gm or millilitre	5

#### 7.0 Shelf life assigning based on the factor:

Self life shall be assign as per Multiplication of Factor for all Chemical, Reagent and substances used in Chemical and microbiological testing.

#### Multiplication of Factor: A x B x C x D x E

Used within after opening	Multiplication of Factor
Within 6 month	1000-1500
Within 12 months	500-999
Within 24 months	100-499
Within 36 months	1-99



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

#### 8.0 DEVIATION:

S.No.	Deviation details	Justification(s) / Corrective action(s)	Remarks (Acceptable/ Not acceptable)
1.			
2.			
3.			
4.			

**Comments:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Checked By Sign \_\_\_\_\_

\_\_\_\_\_ Date

Reviewed By Sign \_\_\_\_\_

\_\_\_\_\_ Date:



**PHARMADEVILS**  
**QUALITY ASSURANCE DEPARTMENT**

**PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING**

**9.0 EXECUTIVE SUMMARY:**

\*Note: Use additional pages if required.

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

\_\_\_\_\_  
 Checked By:

\_\_\_\_\_  
 Date:

\_\_\_\_\_  
 Reviewed By:

\_\_\_\_\_  
 Date:

**10.0 REFERENCES:**

10.1 Certificate of material/chemical.

10.2 Monograph of material/chemical.





# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

### ANNEXURE I Solid Chemicals Compatibility and assigned shelf life report.

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDxE	Assigned use before
1.	Ascorbic Acid	3	1	3	3	3	81	36 Months
2.	Ammonium Carbonate	1	1	3	3	3	27	36 Months
3.	Ammonium Acetate	3	5	2	4	3	360	24 Months
4.	Ammonium Per. Sulphate	3	1	3	3	3	81	36 Months
5.	Ammonium Thiocyanate	3	1	3	3	3	81	36 Months
6.	Ammonium Ceric Sulphate	3	1	3	3	3	81	36 Months
7.	Ammonium Dihydrogen Phosphate	3	1	2	4	3	72	36 Months
8.	Ammonium Ferric Sulphate	3	1	3	3	3	81	36 Months
9.	Ammonium Chloride	3	1	3	3	3	81	36 Months
10.	Ammonium Sulphate	3	1	3	3	3	81	36 Months
11.	Ammonium Molybdate	3	1	3	3	3	81	36 Months
12.	Ammonium Oxalate Monohydrate (99%)	3	1	3	3	3	81	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDxE	Assigned use before
13.	Acetaldehyde Ammonium Trimer	3	1	3	2	3	54	36 Months
14.	Ammonium Iron Sulphate Hexahydrate	3	1	3	3	3	81	36 Months
15.	Arsenic Trioxide	1	1	1	4	3	12	36 Months
16.	Barium Chloride Dihydrate	3	1	3	3	3	81	36 Months
17.	Bismuth Sub Nitrate	3	1	3	3	3	81	36 Months
18.	Bromocresol Purple	1	1	1	3	1	3	36 Months
19.	Boric Acid	3	1	3	3	3	81	36 Months
20.	Borex	3	1	3	3	3	81	36 Months
21.	Barium Hydroxide	3	1	3	2	3	54	36 Months
22.	Calcium Carbonate	1	1	3	3	3	27	36 Months
23.	Citric Acid Anhydrous	3	5	3	4	3	540	12 Months
24.	Copper -II Sulphate	3	1	3	3	3	81	36 Months
25.	Cupric sulphate	3	1	3	3	1	27	36 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDxE	Assigned use before
26.	Cobalt-II Chloride Hexahydrate 98%	3	1	3	2	3	54	36 Months
27.	Cerium-IV sulphate	3	1	3	3	3	81	36 Months
28.	Cobalt-II Nitrate Hexahydrate	3	1	3	3	3	81	36 Months
29.	Calcium Chloride	3	1	3	3	3	81	36 Months
30.	DI-Potassium Hydrogen Phosphate Anhydrous	1	1	2	5	3	30	36 Months
31.	Dextrose	3	1	3	3	3	81	36 Months
32.	Diphenylamine	3	1	3	3	3	81	36 Months
33.	DI-Ammonium Hydrogen	3	1	3	3	3	81	36 Months
34.	Dithizone	1	1	3	1	1	3	36 Months
35.	Disodium Hydrogen Phosphate Dihydrate	3	1	3	3	3	81	36 Months
36.	D-Fructose	3	1	3	3	3	81	36 Months
37.	Di-Chloro Acetic ACID	3	1	3	3	3	81	36 Months
38.	Dextrose Anhydrous	3	1	3	3	3	81	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDxE	Assigned use before
39.	EDTA Disodium salt Dihydrate	3	1	1	3	3	27	36 Months
40.	Ethyl-4- Hydroxy Benzoate	3	1	3	1	3	27	36 Months
41.	Ferrous Sulphate Hepta Hydrate	3	1	3	3	3	81	36 Months
42.	Ferric Chloride Hexahydrate	4	1	3	3	3	108	24 Months
43.	Ferric Chloride Anhydrous	3	1	3	3	3	81	36 Months
44.	Hydroxy Napthal Blue	1	1	1	3	1	3	36 Months
45.	1-Hexane Sulphonic Acid Sodium salt	3	1	2	3	1	18	36 Months
46.	Hyamine (Benzethonium chloride)	1	1	3	2	3	18	36 Months
47.	Hydroxyl Amine Hydrochloride	3	1	3	3	3	81	36 Months
48.	Hexamine	3	1	3	3	3	81	36 Months
49.	1- Heptane Sulphonic Acid Sodium Salt	3	1	2	3	1	18	36 Months
50.	Hypoxanthin 99%	1	1	3	3	3	27	36 Months
51.	Hydrozine Sulphate	1	1	3	3	3	27	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
52.	Iodine	4	1	1	3	3	36	36 Months
53.	Indigo Carmine	1	1	1	3	1	3	36 Months
54.	Mercuric Iodide Red	1	1	1	3	1	3	36 Months
55.	Mercuric chloride	3	1	3	3	3	81	36 Months
56.	Magnesium Sulphate Tetrahydrate	1	1	3	3	3	27	36 Months
57.	Mercuric Bromide	3	1	3	3	1	27	36 Months
58.	Mercuric Acetate	3	1	3	3	3	81	36 Months
59.	M-Cresol Purple	1	1	1	3	1	3	36 Months
60.	Mercuric Sulphate	3	1	3	3	3	81	36 Months
61.	4-Methoxy Phenyl	3	1	3	3	3	81	36 Months
62.	Magnesium Oxide	1	1	3	3	3	27	36 Months
63.	Magnesium Sulphate heptahydrate	1	1	3	3	3	27	36 Months
64.	Mercuric Oxide Red	3	1	3	3	1	27	36 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDxE	Assigned use before
65.	Magnesium -II Sulphate Tetrahydrate	3	1	3	3	3	81	36 Months
66.	Ninhydrin	1	1	1	3	3	9	36 Months
67.	1-Napthnol	1	1	1	3	1	3	36 Months
68.	Nitroso -R - Salt-90%	1	1	3	3	3	27	36 Months
69.	Octan-1 sulphonic Acide Sodium salt	3	1	2	3	1	18	36 Months
70.	Oracet Blue	1	1	1	3	1	3	36 Months
71.	Potassium Dihydrogen Phosphate	3	1	2	3	3	54	36 Months
72.	Potassium Hydrogen Pellets	4	5	3	4	3	720	12 Months
73.	Picric Acid	3	1	3	3	3	81	36 Months
74.	Potassium Sodium Tartrate Tetrahydrate	3	1	3	3	3	81	36 Months
75.	P-Dimethyl Aminobenzaldehyde	3	1	3	2	3	54	36 Months
76.	1,10 Phenathraline	3	1	3	3	3	81	36 Months
77.	Potassium Bromate	3	1	3	2	3	54	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
78.	Potassium chloride	3	1	3	3	3	81	36 Months
79.	Potassium Iodide	3	1	3	3	3	81	36 Months
80.	Pyrocatechol	3	1	3	1	3	27	36 Months
81.	1-Pentane -Sulfonic Acid	3	1	2	3	1	18	36 Months
82.	Potassium Bromide	3	1	3	2	3	54	36 Months
83.	Potassium Carbonate	3	5	3	3	3	405	24 Months
84.	Potassium Nitrate	3	1	3	3	3	81	36 Months
85.	Potassium Sulphate	3	1	3	3	3	81	36 Months
86.	Phosphorus pentaoxide	3	1	3	3	1	27	36 Months
87.	Potassium Pyroantimonate	3	1	3	2	2	36	36 Months
88.	Potassium Permagnate	3	1	3	3	3	81	36 Months
89.	Potassium Chlorate	3	1	3	3	3	81	36 Months
90.	Potassium Dichromate	3	1	3	3	3	81	36 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
91.	Potassium Femicynide	3	1	3	3	3	81	36 Months
92.	Potassium Bisulphate	3	1	3	3	3	81	36 Months
93.	Resorinol	3	1	3	3	3	81	36 Months
94.	Sodium Di ethyl Carbonate	3	1	3	3	3	81	36 Months
95.	Silver Nitrate	3	1	3	3	3	81	36 Months
96.	Solo Chrome Black -T (Erioch	3	1	1	4	1	12	36 Months
97.	Stannous Chloride	3	1	3	3	3	81	36 Months
98.	Sodium Hydroxide	4	5	5	5	3	1500	06 Months
99.	Sodium Phosphate Dibasic Dodecohydrete 99%	3	1	2	4	3	72	36 Months
100.	Sucrose	3	1	3	2	3	54	36 Months
101.	Sodium Dihydrogen Phosphaphate	3	1	2	3	3	54	36 Months
102.	Starch	1	1	3	3	3	27	36 Months
103.	Sodium Fluoride	1	1	3	3	3	27	36 Months





# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
104.	Sodium Acetate	3	1	3	3	3	81	36 Months
105.	Sodium Carbonate (Anhydrous )	3	1	3	3	3	81	36 Months
106.	Sodium Ditartrate (Anhydrous )	3	1	3	3	3	81	36 Months
107.	Sodium Sulphide Flakes	4	1	3	3	3	108	24 Months
108.	Sodium Dodecyl Sulphate (SLS)	1	1	3	4	3	36	36 Months
109.	Silica Crystal Self Indication Course	3	1	3	1	1	9	36 Months
110.	Sodium Hydrogen Carbonate	3	1	3	3	3	81	36 Months
111.	Sodium Metabisulphate	3	1	3	3	3	81	36 Months
112.	Silver Diethyl Dithiocarbonate	1	1	3	3	3	27	36 Months
113.	Sodium Salicylate	3	1	3	3	3	81	36 Months
114.	Sodium Nitrate	3	1	3	3	3	81	36 Months
115.	Sodium Nicroparaside	3	1	3	2	3	54	36 Months
116.	Sodium Dihydrogen Orthophosphate Anhydrous 99%	3	5	2	5	3	450	24 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
117.	Sodium Phosphate Dibasic Anhydrous	3	1	3	4	3	108	24 Months
118.	SULPHONIC Acid	3	1	3	3	3	81	36 Months
119.	Salicyladehyde Azine	3	1	3	3	1	27	36 Months
120.	Sodium Nitrate	3	1	3	3	3	81	36 Months
121.	Thioacetamide	3	1	3	3	3	81	36 Months
122.	Thymol Blue	3	1	3	3	1	27	36 Months
123.	Tannic Acide	1	1	3	3	1	9	36 Months
124.	Titanium Dioxide	3	1	3	3	3	81	36 Months
125.	Trypsin	3	1	3	2	1	18	36 Months
126.	Trichloro Acetic Acid	3	1	2	4	3	72	36 Months
127.	Zinc Dust (Power)	4	1	1	3	3	36	36 Months
128.	Zinc Sulphate Heptahydrate	3	1	3	3	3	81	36 Months
129.	Zinc Chloride	3	1	3	3	3	81	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
130.	Lead Nitrate	3	1	3	3	3	81	36 Months
131.	Lanthanum Nitrate	3	1	3	3	3	81	36 Months
132.	Uranyl Magnesium Acetate	3	1	3	3	3	81	36 Months
133.	Xylinol Orange	3	1	1	3	3	27	36 Months
134.	Potassium Hydrogen Phosphate	4	1	3	3	3	108	24 Months
135.	4-Amino Antipyrine 99% Extra Pure	3	1	3	3	3	81	36 Months
136.	Citric acid Monohydrate	3	5	3	5	3	675	12 Months
137.	Tris Buffer ( Hydroxymethyl ) Aminomethen	3	1	2	4	3	72	36 Months
138.	Triethylamine Hydrochloride	3	1	3	3	3	81	36 Months
139.	Lead Acetate	3	1	3	3	3	81	36 Months
140.	Mercuric Oxide Yellow (Hgo)	3	1	3	3	3	81	36 Months
141.	Ceric Sulphate	3	1	3	3	3	81	36 Months
142.	Potassium Chloride	4	5	3	4	3	720	12 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics (A)	Nature (B)	Used for (C)	Frequency of use (D)	Pack size (E)	Factor AXBXCXDXE	Assigned use before
143.	DI-Sodium Hydrogen Orthophosphate	3	5	2	3	3	270	24 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

### Liquid Chemical Compatibility and assigned Shelf Life Report

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
1.	Acetone	1	1	3	4	5	60	36 Months
2.	Acetonitrile	1	1	2	5	5	50	36 Months
3.	Acetic Anhydride	1	5	3	3	3	135	24 Months
4.	Ammonia	4	1	3	5	5	300	24 Months
5.	Benzene	1	1	3	1	3	9	36 Months
6.	Bromine	4	1	3	4	3	144	24 Months
7.	Bromophenol Blue	4	1	3	5	2	120	24 Months
8.	Bromothymol Blue	4	1	3	5	2	120	24 Months
9.	Buffer Solution Ph 1.68	3	1	3	5	3	135	24 Months
10.	Buffer Solution Ph 12.45	3	1	3	5	3	135	24 Months
11.	Buffer Solution Ph 4.01	3	1	3	5	3	135	24 Months
12.	Buffer Solution Ph 6.86	3	1	3	5	3	135	24 Months
13.	Buffer Solution Ph 9.18	3	1	3	5	3	135	24 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
14.	Butan-1-ol	1	1	3	3	3	27	36 Months
15.	Benzaldehyde	1	1	3	4	3	36	36 Months
16.	Bromocresol Green	1	1	3	4	3	36	36 Months
17.	Boron Tri Fluoride	4	1	3	3	3	108	24 Months
18.	Carbon Tetrachloride	1	1	3	3	5	45	36 Months
19.	Chlorine Test Reagent	4	1	3	5	3	180	24 Months
20.	Chloroform	1	1	3	3	5	45	36 Months
21.	Conductivity Solution 100 $\mu$	3	1	3	5	3	135	24 Months
22.	Crystel Violet	4	1	3	3	3	108	24 Months
23.	Cyclohexane	1	1	3	3	3	27	36 Months
24.	Dichloromethene	1	1	3	3	5	45	36 Months
25.	Dimethyl sulfoxide	1	1	3	3	3	27	36 Months
26.	Dimethyl Yellow Indicator	4	1	3	3	3	108	24 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
27.	Diethyl Ether	1	1	3	5	5	75	36 Months
28.	Diethylamine	2	1	3	3	3	54	36 Months
29.	Di-n-Butyl Amine	2	1	3	3	4	72	36 Months
30.	Di-Butyl Phthalate	1	1	3	3	4	36	36 Months
31.	Ethyl Acetate	1	1	3	4	3	36	36 Months
32.	Ethanol	1	1	3	5	4	60	36 Months
33.	Eosine Solution	4	1	3	5	3	180	24 Months
34.	Ethylene Dichloride	1	1	3	3	3	27	36 Months
35.	Ferroine Solution	4	1	3	4	4	192	24 Months
36.	Formide	2	1	3	3	3	54	36 Months
37.	Formic Acid	2	1	3	3	3	54	36 Months
38.	Glacial Acetic Acid	2	1	3	5	5	150	24 Months
39.	Glycerol	1	1	3	3	3	27	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
40.	Glycolic Acid	2	1	3	2	3	36	36 Months
41.	HPLC Grade Water	1	1	2	4	4	32	36 Months
42.	Hydrochloric Acid	4	1	3	5	5	300	24 Months
43.	Hydrogen peroxide	4	1	3	4	3	144	24 Months
44.	Holmium Perchlorate	4	1	3	3	3	108	24 Months
45.	Hydrohuaric acid	4	1	3	5	5	300	24 Months
46.	Hydrogen Sulphide	1	1	3	3	3	27	36 Months
47.	IPA	4	1	3	3	3	108	24 Months
48.	ISO Butyl Methyl Keton	4	1	3	1	3	36	36 Months
49.	Linsed Oil	1	1	3	1	3	9	36 Months
50.	Methanol	4	1	2	5	5	200	24 Months
51.	Methyl Orange	4	1	1	4	3	48	36 Months
52.	Methyl Red	4	1	1	4	3	48	36 Months





# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
53.	Methyl Blue	4	1	1	4	3	48	36 Months
54.	Morpholine	1	1	3	3	3	27	36 Months
55.	Methyl ACETAE	1	1	3	3	3	27	36 Months
56.	N-N Dimethyl Tormamide	4	1	3	3	3	108	24 Months
57.	N-Hexane	4	1	3	3	4	144	24 Months
58.	N-Heptan	4	1	3	3	4	144	24 Months
59.	N-Peptan	4	1	3	3	3	108	24 Months
60.	N-Butyl Alcohol	4	1	3	3	3	108	24 Months
61.	N-Methyl -2 pyrrollidone	1	1	3	3	3	27	36 Months
62.	Nitric Acid	4	1	3	5	5	300	24 Months
63.	Orthophosphoric Acid	4	5	2	5	3	600	12 Months
64.	Buffer Solution 7.0	3	1	3	5	3	135	24 Months
65.	Perchloric Acid 0.1N	4	1	1	3	3	36	36 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
66.	Phenol Red	4	1	1	3	3	36	36 Months
67.	Phenolphthalin indicater	4	1	1	3	3	36	36 Months
68.	Propan -1-ol	4	1	3	3	3	108	24 Months
69.	Petroleum Ether	4	1	3	4	5	240	24 Months
70.	Pyridine	2	5	3	3	3	270	24 Months
71.	Psopylene Glycol	1	1	3	3	3	27	36 Months
72.	Rankleen Solution	1	1	3	3	3	27	36 Months
73.	Sodium Hypochloride	4	5	3	3	3	540	12 Months
74.	Sulphuric Acid	2	5	3	5	5	750	12 Months
75.	Salicyldehyde 99%	1	1	3	3	3	27	36 Months
76.	Tetrabutyl Ammonium Hydroxide	4	1	3	3	3	108	24 Months
77.	Tetrahydrofuran	4	5	2	5	5	1000	06 Months
78.	Thioglycalic Acid	1	1	3	3	3	27	24 Months



# PHARMADEVILS

## QUALITY ASSURANCE DEPARTMENT

### PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
79.	Thymophthalein	1	1	3	3	3	27	24 Months
80.	Trifluoroacetic Acid	4	5	2	4	3	480	24 Months
81.	Tetramethylammonium Hydroxide In Methanol	4	5	3	3	3	540	12 Months
82.	Titanium Tetra Chloride	1	1	3	3	3	27	24 Months
83.	Trrichloroacetic Acid	4	1	2	3	3	72	24 Months
84.	Vinyl Acetate	1	1	3	3	3	27	24 Months
85.	1-Fluoro-2Dinitro Benzene	1	1	3	3	3	27	24 Months
86.	2- Propenol	1	1	3	3	3	27	24 Months
87.	1-Methyl -2-Pyrollidone	1	1	3	3	3	27	24 Months
88.	Dried Methanol	4	5	3	5	3	900	12 Months
89.	KF Reagent	4	5	3	5	3	900	12 Months
90.	DI-N-Butyphthalate	1	1	3	3	3	27	24 Months
91.	Dichloroacetic Acide	1	1	3	3	3	27	24 Months



# PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR "USE BEFORE DATE" EVALUATION OF QC CHEMICAL AFTER INITIAL OPENING

S.No.	Name of chemical	Physical characteristics A	Nature B	Used for C	Frequency of use D	Pack Size E	Factor AxBxCxDxE	Assigned use before
92.	Triethylamine	4	5	2	4	3	480	12 Months

**Prepared By:**

(Signature/Date): \_\_\_\_\_

**Checked By:**

(Signature/Date): \_\_\_\_\_