

# **PENGUJIAN UMUM DAN KHUSUS DI UNIT UJI BAKTERIOLOGI**



**BALAI BESAR PENGUJIAN MUTU dan SERTIFIKASI OBAT HEWAN  
GUNUNG SINDUR BOGOR, 21 APRIL 2011**

# UNJT UJJ BAKTERIOLOGI



Drh. Ni Made Ria, P.hD



Drh. Tri Yulianti



Drh. Ernes



Drh. Mutia



Drh. Syaefur



Drh. Basuki



Drh. A.Maizir



Sri Arofah



Neneng



Sarji & Deden



Tasmaya



Arif Juli

# *Tugas Unit Uji Bakteriologi*

- Uji Umum (UM) : fisik, kemurnian, kevakuman, sterilitas, kontaminasi & kelembaban
- Uji Khusus (UK) : Safety, Potensi, Kandungan Bakteri

## **Sampel :**

1. Produk Farmasetik & Premik (UM)
2. Probiotik (UM & UK)
3. Vaksin Viral aktif & inaktif (UM)
4. Vaksin Bakterial aktif & inaktif (UM & UK)
5. Antigen Bakterial (UK)
6. Pengkajian Vaksin Bakterial (UM & UK)

## Jenis Uji & Lama Pengujian Umum

No	Jenis Sampel	Uji Fisik	Uji Kemurnian	Uji Kevakuman	Uji Sterilitas	Uji Kontaminasi			Uji Kelembaban	Lama Pengujian (minggu)
						Bakteri Asing	Salmonella & Mycoplasma	Jamur/kapang		
1	Antibiotika (larut air, larut lemak)				√					3
2	Obat Umum (larut air, larut lemak)				√					3
3	Vaksin Virus Inaktif	√	√		√					3
4	Vaksin Virus Aktif	√		√	√	√	√	√	√	8
5	Vaksin Bakteri Inaktif	√	√		√					3
6	Vaksin Bakteri Aktif	√	√	√	√	√	√	√	√	8
7	Probiotik	√				√		√		2

# ***Uji Sterilitas Produk Farmasetika***

- **Antibiotik**

**Sediaan injeksi : larut air & larut lemak**

**Sediaan infus : larut air & larut lemak**

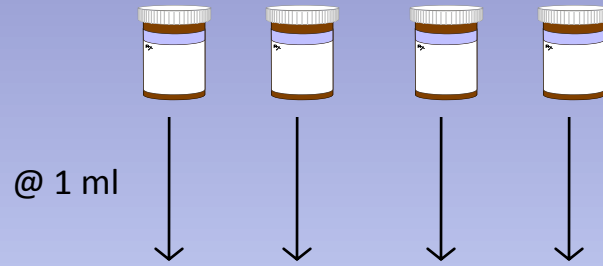
- **Obat Umum**

**Sediaan injeksi : larut air & larut lemak**

**Sediaan infus : larut air & larut lemak**

# Uji Sterilitas Antibiotik

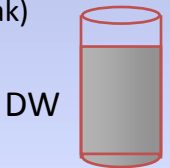
Sampel antibiotik (larut air/lemak)



1ml Sampel antibiotik (larut air/lemak) dilarutkan

9ml DW (antibiotik larut air)/ 9 ml Cotton seed oil (Antibiotik larut lemak)

Kontrol



DW

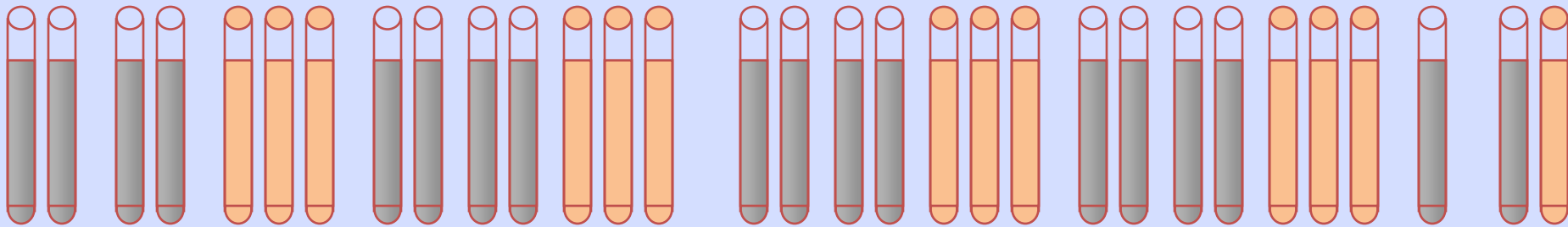
@ 1 ml

@ 1 ml

@ 1 ml

@ 1 ml

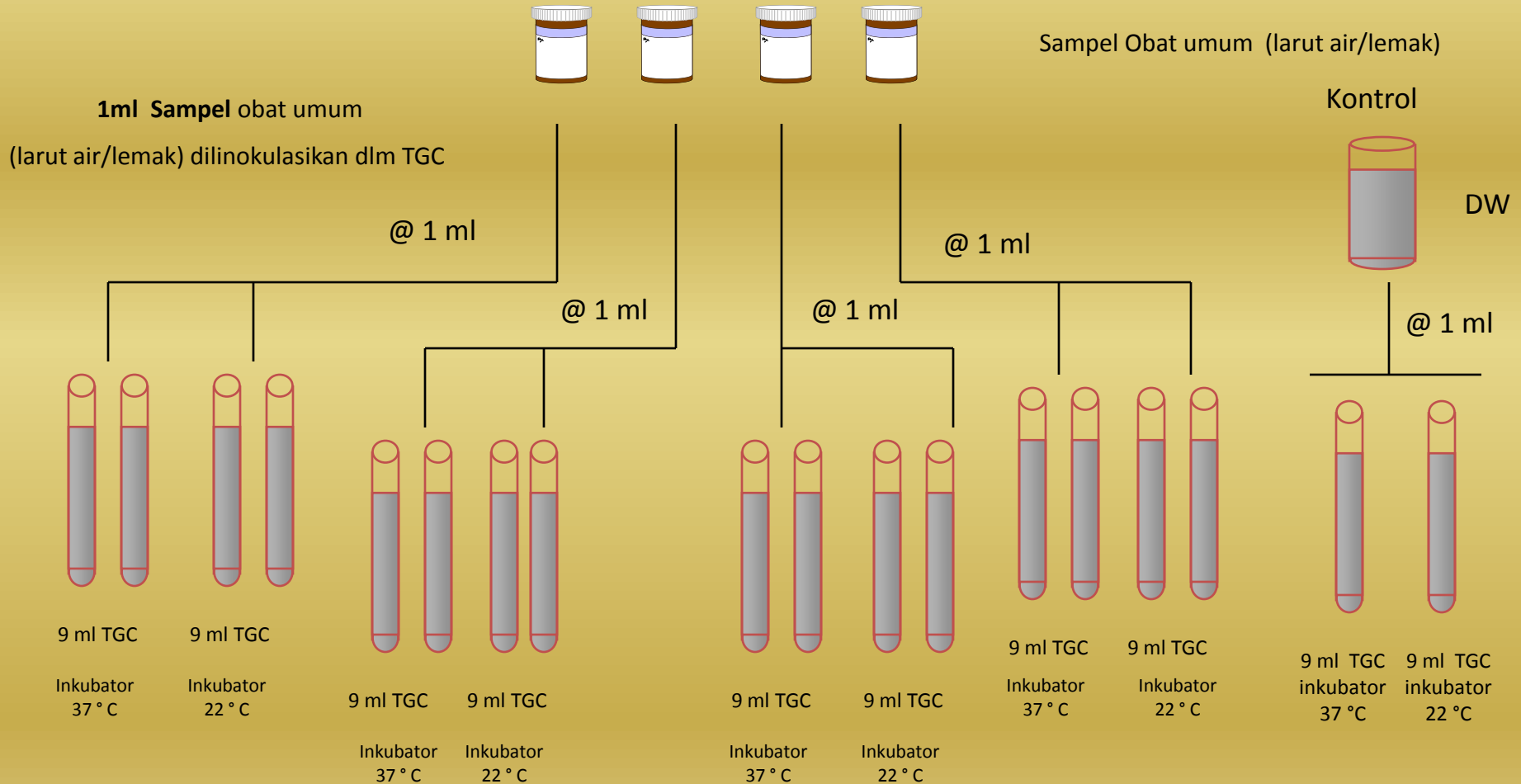
@ 1 ml



9 ml TGC Inkubator 37 °C	9 ml TGC Inkubator 22 °C	9 ml glucose peptone Inkubator 22 °C	9 ml TGC Inkubator 37 °C	9 ml TGC Inkubator 22 °C	9 ml glucose peptone Inkubator 22 °C	9 ml TGC Inkubator 37 °C	9 ml TGC Inkubator 22 °C	9 ml glucose peptone Inkubator 22 °C	9 ml TGC Inkubator 37 °C	9 ml TGC Inkubator 22 °C	9 ml glucose peptone Inkubator 22 °C	TGC Inkubator 22 °C	TGC & Glucose peptone Inkubator 22 °C
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Pengamatan Dilakukan Hari ke 3, 7 dan 14

# Uji Sterilitas Obat Umum



**Pengamatan Dilakukan Hari ke 3, 7 dan 14**

# Pengujian Probiotik

## 1. Uji Umum

Fisik : warna, kontaminasi (bakteri asing & jamur)

2. Uji Kandungan Bakteri (metode sesuai dokumen perusahaan)

3. Uji Kandungan Jamur ( metode sesuai dokumen perusahaan).

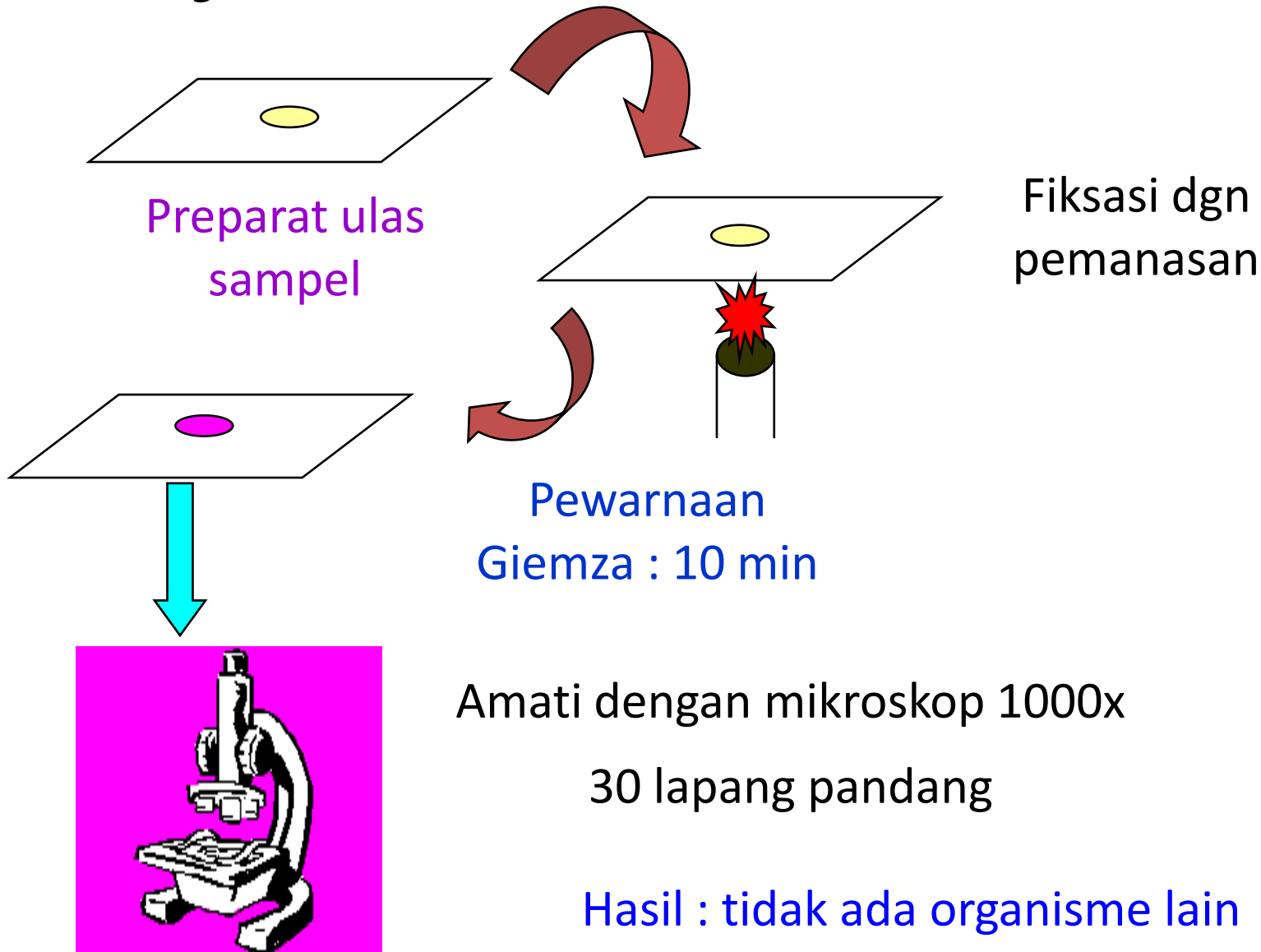


# 1. UJI FISIK



- Warna
- Homogenitas
- Volume
- Kejernihan
- Partikel Asing

# 2. Uji Kemurnian Vaksin Bakteri



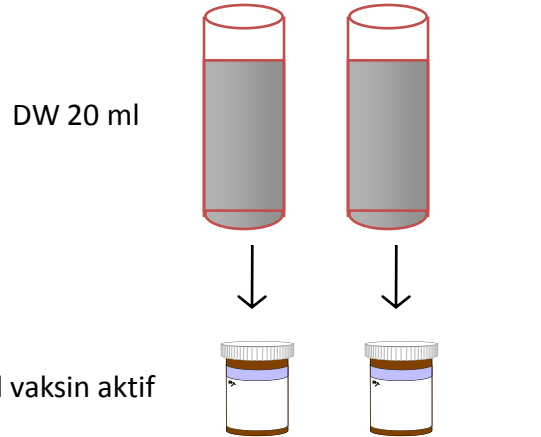
### 3. Uji Kevakuman



Sampel : Vaksin Virus aktif dan vaksin bakteri aktif dengan Menggunakan sinar UV.

# 4. Uji Sterilitas

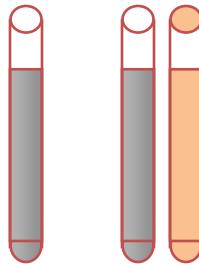
## Uji Sterilitas Vaksin Aktif



DW 20 ml



Kontrol



20 ml TGC Inkubator 37 °C

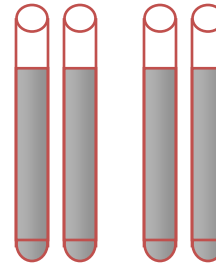
TGC & HIA Slant Inkubator 37 °C

## Uji Sterilitas Vaksin inaktif

Sampel vaksin inaktif



@ 1 ml



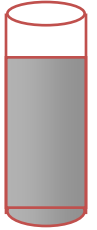
20 ml TGC Inkubator 37 °C

20 ml TGCHIA Slant Inkubator 22 °C

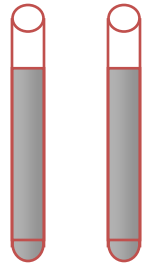
20 ml TGC Inkubator 37 °C

20 ml TGC Inkubator 22 °C

DW 20 ml

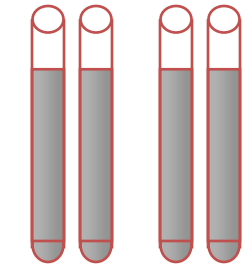


Kontrol



TGC Inkubator 37 °C

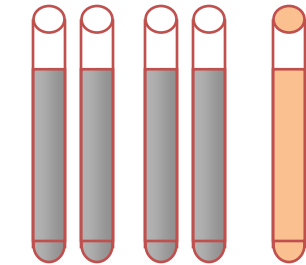
TGC inkubator 22 °C



20 ml TGC Inkubator 37 °C

20 ml TGC Inkubator 22 °C

HIA Slant Inkubator 37 °C



20 ml TGC Inkubator 37 °C

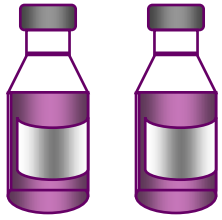
20 ml TGC Inkubator 22 °C

HIA Slant Inkubator 37 °C

Pengamatan Dilakukan hari ke 3, 7 dan 14

Pengamatan Dilakukan hari ke 3, 7 dan 14

# 5. Uji Kontaminasi



20 ML OF DW

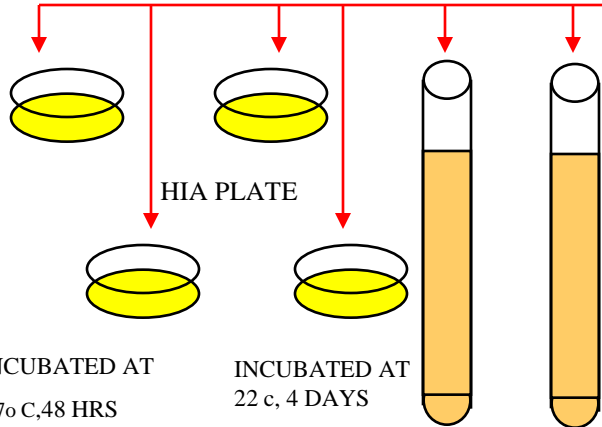
2 sampel vaksin aktif

CONTAMINATION TEST OF MISCELLANEOUS BACTERIA AND FUNGI

CONTAMINATION TEST OF Salmonella & E.coli

CONTAMINATION TEST OF MYCOPLASMA

1 ML EACH



INCUBATED AT 37°C, 48 HRS

INCUBATED AT 22°C, 4 DAYS

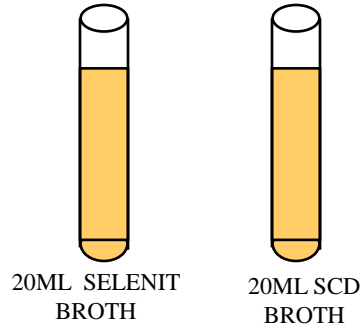
20ML/SCD BROTH

INCUBATED AT 22°C, 14 DAYS

OBSERVED IN DAY

3, 7 AND 14

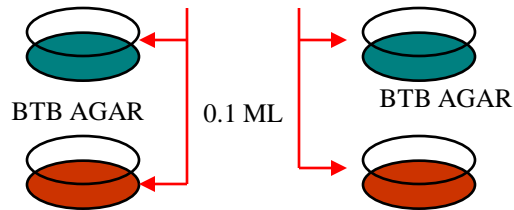
1 ml each



20ML SELENIT BROTH

20ML SCD BROTH

INCUBATED AT 37°C, 18-24 HRS



BTB AGAR

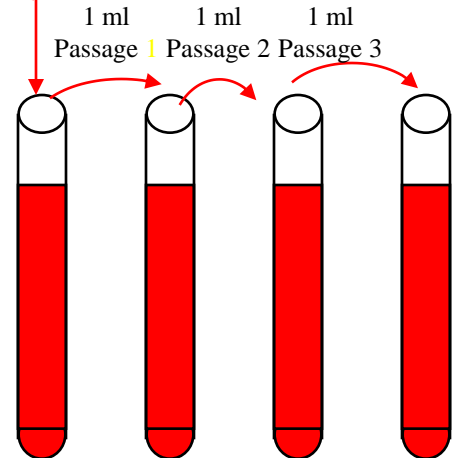
BTB AGAR

DHL AGAR

DHL AGAR

INCUBATED AT 37°C 18-24 HRS

1 ml

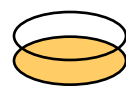


1 ml Passage 1

1 ml Passage 2

1 ml Passage 3

WEEKLY PASSAGE 10 ML OF PPLO BROTH



0,1 ML

5 ML PPLO AGAR

INCUBATED AT 37°C, CO2 5%

# Lama Pengujian Uji Khusus

No	Jenis Vaksin	Total Lama
1	Coryza Inaktif	16 minggu
2	Fowl Cholera Inaktif	22 minggu
3	Brucella abortus (aktif)	9 minggu
4	Erysipelas (inaktif)	9 minggu
5	Bacillus anthracis (aktif)	13 minggu
6	Haemorrhagic septicaemia (inaktif)	9 minggu
7	Bordetella brochoseptica (inaktif)	10 minggu
8	Leptospira (aktif)	10 minggu
9	Mycoplasma gallisepticum (inaktif)	15 minggu
10	Vaksin Ikan (Streptococcus iniae)	8 minggu
11	Salmonella enteritidis (inaktif)	23 minggu
12	Escherichia coli (inaktif)	11 minggu
13	Probiotik	6 minggu

*Terima Kasih...*

# *Pengujian Umum*

1. Uji Fisik
2. Uji Kemurnian
3. Uji Kevakuman : Vaksin virus aktif & Vaksin bakteri aktif
4. Uji sterilitas : Produk farmasetik, vaksin virus & bakteri aktif dan inaktif
5. Uji Kontaminasi : Bakteri asing, Salmonella, Mycoplasma dan jamur
6. Uji Kelembaban : vaksin virus aktif & vaksin bakteri aktif