**SNI ISO/IEC 17025 : 2008 ( ISO/IEC 17025 : 2005 )**

**SNI ISO 9001 : 2008 ( ISO 9001 : 2008 )**

**No. B-{NOMOR1}**

**{BLANKO}**

**KEMENTERIAN PERTANIAN**

**DIREKTORAT JENDERAL PETERNAKAN DAN KESEHATAN HEWAN**

**BALAI BESAR PENGUJIAN MUTU DAN SERTIFIKASI OBAT HEWAN**

**BOGOR – INDONESIA**

*MINISTRY OF AGRICULTURE*

*DIRECTORATE GENERAL OF LIVESTOCK AND ANIMAL HEALTH SERVICES*

*NATIONAL VETERINARY DRUG ASSAY LABORATORY*

*BOGOR – INDONESIA*

**SERTIFIKAT PENGUJIAN**

*CERTIFICATE OF ANALISYS*

**Nomor : {NOMOR2}**

Berdasarkan Surat Keputusan Menteri Pertanian Nomor : {NOMOR3}, Tanggal {TANGGAL1} dan Keputusan Menteri Pertanian Nomor : {NOMOR4} Tanggal {TANGGAL2}, telah dilakukan pengujian mutu terhadap obat hewan tersebut di bawah ini dan memenuhi persyaratan pengujian.

*According to Decree of The Minister of Agriculture of The Republic of Indonesia dated {TANGGAL3}, No : {NOMOR5}, and Undersigned of The Minister of Agriculture of Republic of Indonesia dated {TANGGAL4}, No : {NOMOR6}, certifies that quality control of the following veterinary drug has been carried out and met test requirements.*

Untuk kalangan terbatas / *For Limited Purpose Only*

Tidak boleh digandakan / *Must not be duplicated*

Nama Laboratorium Penguji : BBPMSOH

*Name of Assay Laboratory*

Alamat Laboratorium Penguji : Jl Raya Pembangunan Gunung Sindur, Gn. Sindur, Bogor, Jawa Barat 16340

*Address of Assay Laboratory*

Nama Pemohon : {NAMA\_PEMOHON}

*Name of Applicant*

Alamat Pemohon : {ALAMAT\_PEMOHON}

*Address of Applicant*

Nama Produsen : {NAMA\_PRODUSEN}

*Name of Producer*

Alamat Produsen : {ALAMAT\_PRODUSEN}

*Address of Producer*

Nama Dagang Obat Hewan : {NAMA\_DAGANG}

*Trade Name*

Nomor Bets : {NOMOR\_TRADING}

*Batch No ./ Lot No.*

Waktu Kadaluarsa : {KADALUARSA}

*Expired Date*

Nomor Registrasi : {NOREG}

*Registration No.*

Kemasan : {KEMASAN}

*Packaging*

Jenis Produk : {JENIS}

*Kind of Preparation*

Tanggal Penerimaan Contoh : {TANGGAL\_TERIMA\_CONTOH}

*Date of Sample Acceptance*

Acuan Prosedur Pengambilan Contoh : {ACUAN}

*Sampling Procedure Reference*

Nomor Uji : {NOMOR\_UJI}

*Assay No.*

Bogor, {TANGGAL5}

Kepala Balai Besar Pengujian Mutu dan

Sertifikasi Obat Hewan

*Director of National Veterinary Drug Assay Laboratory*

{barcode}

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| {TTD1}  {TTD2} |

Sertifikat ini berlaku selama satu kali periode pendaftaran dan hanya untuk bets sampel yang diuji

*This certificate is valid only for one period of registration and the batch of tested sample*

Lampiran : SERTIFIKAT PENGUJIAN NO : {NOMOR7}

*Annex : CERTIFICATE OF ANALYSIS*

**HASIL PENGUJIAN PRODUK BIOLOGIK**

***RESULT OF ASSAY FOR BIOLOGICAL PRODUCT***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Jenis Uji  *Kind of Test* | | | | Tanggal Uji  *Date of Test* | Acuan Metoda  *Method Reference* | Hasil  *Result* | Persyaratan Mutu  *Requirement* |
| Fisik  *Property* | Warna  *Colour* | | | {WARNA1} | {WARNA2} | {WARNA3} | {WARNA4} |
| Bau  *Odor* | | | {BAU1} | {BAU2} | {BAU3} | {BAU4} |
| Partikel Asing  *Foreign Particles* | | | {PARTIKEL\_ASING1} | {PARTIKEL\_ASING2} | {PARTIKEL\_ASING3} | {PARTIKEL\_ASING4} |
| Homogenitas  *Homogenity* | | | {HOMOGENITAS1} | {HOMOGENITAS2} | {HOMOGENITAS3} | {HOMOGENITAS4} |
| Kevakuman  *Acidity Alkalinity* | | | | {KEVAKUMAN1} | {KEVAKUMAN2} | {KEVAKUMAN3} | {KEVAKUMAN4} |
| Kelembaban  *Moisture* | | | | {KELEMBABAN1} | {KELEMBABAN2} | {KELEMBABAN3} | {KELEMBABAN4} |
| Kemurnian  *Purity* | | | | {KEMURNIAN1} | {KEMURNIAN2} | {KEMURNIAN3} | {KEMURNIAN4} |
| Sterilitas  *Sterility* | {STERIL1} | | | {STERIL2} | {STERIL3} | {STERIL4} | {STERIL5} |
| Kontaminasi :  *Contamination*  *Mycoplasma*  *Salmonella*  *Escherichia coli*  Jamur/ *Fungi*  Mikroorganisme Hidup Lain/  *Other Live Microorganism* | | | |  |  |  |  |
| {MYCROPLASMA1} | {MYCROPLASMA2} | {MYCROPLASMA3} | {MYCROPLASMA4} |
| {SALMONELLA1} | {SALMONELLA2} | {SALMONELLA3} | {SALMONELLA4} |
| {COLI1} | {COLI2} | {COLI3} | {COLI4} |
| {JAMUR1} | {JAMUR2} | {JAMUR3} | {JAMUR4} |
| {ORGANISME1} | {ORGANISME2} | {ORGANISME3} | {ORGANISME4} |
| Kandungan  Bakteri/Spora  *Bacteria or Spore Count* | | | {BAKTERI9}  {BAKTERI10}  {BAKTERI11}  {BAKTERI12} | {BAKTERI1}  {BAKTERI2}  {BAKTERI13} {BAKTERI14} | {BAKTERI3}  {BAKTERI4}  {BAKTERI15}  {BAKTERI16} | {BAKTERI5}  {BAKTERI6}  {BAKTERI17}  {BAKTERI18} | {BAKTERI7}  {BAKTERI8}  {BAKTERI19}  {BAKTERI20} |
| Kandungan Virus  *Virus Content* | | | {VIRUS25}  {VIRUS26}  {VIRUS27}  {VIRUS28}  {VIRUS29}  {VIRUS30} | {VIRUS1}  {VIRUS2}  {VIRUS3}  {VIRUS4}  {VIRUS5}  {VIRUS6} | {VIRUS7}  {VIRUS8}  {VIRUS9}  {VIRUS10}  {VIRUS11}  {VIRUS12} | {VIRUS13}  {VIRUS14}  {VIRUS15}  {VIRUS16}  {VIRUS17}  {VIRUS18} | {VIRUS19}  {VIRUS20}  {VIRUS21}  {VIRUS22}  {VIRUS23}  {VIRUS24} |
| Identitas  *Identity* | | | | {IDENTITAS1} | {IDENTITAS2} | {IDENTITAS3} | {IDENTITAS4} |
| Inaktifasi *Inactivation* | | {INAKTIF13}  {INAKTIF14}  {INAKTIF15} | | {INAKTIF1}  {INAKTIF2}  {INAKTIF3} | {INAKTIF4}  {INAKTIF5}  {INAKTIF6} | {INAKTIF7}  {INAKTIF8}  {INAKTIF9} | {INAKTIF10}  {INAKTIF11}  {INAKTIF12} |
| Toksisitas Abnormal  *Abnormal Toxicity* | | | | {TOXIC1}  {TOXIC2} | {TOXIC3}  {TOXIC4} | {TOXIC5}  {TOXIC6} | {TOXIC7}  {TOXIC8} |
| Keamanan  *Safety* | {KEAMANAN1}  {KEAMANAN2}  {KEAMANAN3}  {KEAMANAN4}  {KEAMANAN5} | | | {KEAMANAN7}  {KEAMANAN8}  {KEAMANAN9}  {KEAMANAN10}  {KEAMANAN11} | {KEAMANAN13}  {KEAMANAN14}  {KEAMANAN15}  {KEAMANAN16}  {KEAMANAN17} | {KEAMANAN19}  {KEAMANAN20}  {KEAMANAN21}  {KEAMANAN22}  {KEAMANAN23} | {KEAMANAN25}  {KEAMANAN26}  {KEAMANAN27}  {KEAMANAN28}  {KEAMANAN29} |
| Potensi  *Potency* | {POTENSI1}  {POTENSI2}  {POTENSI3}  {POTENSI4}  {POTENSI5}  {POTENSI6} | | | {POTENSI7}  {POTENSI8}  {POTENSI9}  {POTENSI10}  {POTENSI11}  {POTENSI12} | {POTENSI13}  {POTENSI14}  {POTENSI15}  {POTENSI16}  {POTENSI17}  {POTENSI18} | {POTENSI19}  {POTENSI20}  {POTENSI21}  {POTENSI22}  {POTENSI23}  {POTENSI24} | {POTENSI25}  {POTENSI26}  {POTENSI27}  {POTENSI28}  {POTENSI29}  {POTENSI30} |
| Lain-lain  *Others* | {LAIN13} | | | {LAIN1}  {LAIN2}  {LAIN3} | {LAIN4}  {LAIN5}  {LAIN6} | {LAIN7}  {LAIN8}  {LAIN9} | {LAIN10}  {LAIN11}  {LAIN12} |
| Penilaian  *Judgement* | | | | {PENILAIAN} | | | |

Bogor, {TANGGAL7}

Manager Puncak Manager Teknis

*Executive Manager Technical Manager*

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| {DEPUTI} |

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| {TTD1}  {TTD2} | {TTD3}  {TTD4} |