

SERTIFIKAT PELULUSAN
CERTIFICATE OF RELEASE
No. : PP.01.05.02d.11.111.03.12.21.347

Nama sediaan	Vaksin Jerap Td	vial / 10 dosis	diproduksi
The following lots of	Adsorbed Td Vaccine	vial / 10 doses	produced by

PT. Bio Farma, Bandung, Indonesia	memenuhi syarat
	meet all National Requirements,

Farmakope Indonesia V, 2014 dan Persyaratan WHO untuk Vaksin Jerap Td.
Indonesian Pharmacopoeia V, 2014; Recommendations to assure the quality, safety and efficacy of diphtheria vaccines (adsorbed), WHO Expert Committee on Biological Standardization, Sixty-third report, Geneva, World Health Organization, 2014, Annex 4 (WHO Technical Report Series, No. 980); Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed), WHO Expert Committee on Biological Standardization, Sixty-third report, Geneva, World Health Organization, 2014, Annex 5 (WHO Technical Report Series, No. 980); and Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines, WHO/IVB/11.11, Geneva, World Health Organization, 2013.

No. Bets Batch No.	No. Kode Code Number	Tgl. Kedaluwarsa Expiration Date	Jumlah vial Number of vials
0411321	12/V-Td/IM/PPPOMN/XII/2021	October 2024	83,263
0411421	13/V-Td/IM/PPPOMN/XII/2021	October 2024	83,467

Sertifikat ini didasarkan pada evaluasi protokol pabrik.
This certificate is based on examination of the manufacturing protocols.

Jakarta, 27 December 2021

**PUSAT PENGEMBANGAN PENGUJIAN
OBAT DAN MAKANAN NASIONAL**

E. Ika Prawahju A.
Kepala Balai Pengujian Produk Biologi

SERTIFIKAT PELULUSAN
CERTIFICATE OF RELEASE
No. PP.01.01.02d.11.111.03.10.21.237

Nama sediaan The following lot of	Vaksin TT TT Vaccine	vial / 10 dosis vial / 10 doses	diproduksi produced by
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PT. Bio Farma, Bandung, Indonesia	memenuhi syarat meets all National Requirements,
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Farmakope Indonesia V, 2014 dan Persyaratan WHO untuk Vaksin TT Jerap.
Indonesian Pharmacopoeia V, 2014; Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed), WHO *Expert Committee on Biological Standardization*, Sixty-third report, Geneva, World Health Organization, 2014, Annex 5 (WHO Technical Report Series, No. 980); and Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines, WHO/IVB/11.11, Geneva, World Health Organization, 2013.

No. Bets Batch No.	No. Kode Code Number	Tgl. Kedaluwarsa Expiration Date	Jumlah vial Number of vials
0200121	01/V-TT/IM/PPPOMN/X/2021	June 2024	83,458

Sertifikat ini didasarkan pada evaluasi protokol pabrik.
This certificate is based on examination of the manufacturing protocols.

Jakarta, 8 October 2021

**PUSAT PENGEMBANGAN PENGUJIAN
OBAT DAN MAKANAN NASIONAL**

E. Ika Prawahju A.
Kepala Balai Pengujian Produk Biologi

SERTIFIKAT PELULUSAN
CERTIFICATE OF RELEASE

No. : PP.01.05.02d.11.111.03.11.21.293

Nama sediaan dosis	Vaksin Pentabio 5 dosis diproduksi	Vial / 5	
The following lot of	5 Doses Pentabio Vaccine	Vial / 5 doses	produced
by			

PT. Bio Farma, Bandung, Indonesia memenuhi syarat

meets all National Requirements,

Farmakope Indonesia V, 2014; Persyaratan WHO untuk Vaksin DTP, Hepatitis B, dan *Haemophilus influenzae* tipe B.

Indonesian Pharmacopoeia V, 2014; WHO Technical Report Series Fifty Sixth Report, Geneva, 2007; Part A of Recommendations to Assure the Quality, Safety and Efficacy of Recombinant Hepatitis B Vaccines, Annex 4, WHO Technical Report Series 978, Sixty First Report, Geneva, 2013; Part A of the Recommendations for the Production and Control of *H. influenzae* type B Conjugate Vaccines, Annex 1, WHO Technical Report Series, No. 897, Geneva, 2000 and Manual of Laboratory Methods for Testing of Vaccines Used in the WHO Expanded Programme on Immunization, WHO/VSQ/ 97.04, Geneva, 1997.

No. Bets	No. Kode	Tgl. Kedaluwarsa	Jumlah vial
Batch No.	Code Number	Expiration Date	Number of vials
5041821	13/V-Pentabio 5/IM/PPPOMN/XI/2021	July 2023	161,246

Sertifikat ini didasarkan pada evaluasi protokol pabrik.

This certificate is based on examination of the manufacturing protocols.

Jakarta, 17 November 2021

**PUSAT PENGEMBANGAN
PENGUJIAN
OBAT DAN MAKANAN NASIONAL**

E. Ika Prawahju A.
**Kepala Balai Pengujian Produk
Biologi**

SERTIFIKAT PELULUSAN
CERTIFICATE OF RELEASE
No : PP.01.01.02d.83.837.03.02.21.018

Nama sediaan Vaksin DTP Vial / 10 dosis diproduksi
The following lot of DTP Vaccine Vial / 10 doses produced by

PT. Bio Farma, Bandung, Indonesia
syarat

memenuhi

**meets all National
Requirements,**

Farmakope Indonesia V, 2014; Persyaratan WHO untuk Vaksin DTP.
Indonesian Pharmacopoeia V, 2014; Recommendations to assure the quality, safety, and efficacy of tetanus vaccines (adsorbed), WHO Expert Committee on Biological Standardization. Sixty- third Report. Geneva, World Health Organization, 2014, Annex 5 (WHO Technical Report Series, No. 980); Part A of the Recommendations for Whole-Cell Pertussis Vaccine, Annex 6, WHO Technical Report Series 941, Fifty Sixth Report, Geneva, 2007 and Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines, WHO/IVB/11.11, Geneva, World Health Organization, 2013.

No. Bets	No. Kode	Tgl. Kedaluwarsa	Jumlah vial
Batch No.	Code Number	Expiration Date	Number of vials
0001220	01/V-DTP/IM/PPPOMN/II/2021	October 2022	74,935

Sertifikat ini didasarkan pada evaluasi protokol pabrik.

This certificate is based on examination of the manufacturing protocol.

Jakarta, 22 February 2021

**PUSAT PENGEMBANGAN PENGUJIAN
OBAT DAN MAKANAN NASIONAL**

E. Ika Prawahju A.
Kepala Balai Pengujian Produk Biologi

SERTIFIKAT PELULUSAN
CERTIFICATE OF RELEASE
No. : PP.01.01.02d.83.837.03.03.21.035

Nama sediaan The following lot of by	Vaksin Bio TT Bio TT Vaccine	ampul / 1 dosis ampoule / 1 dose	diproduksi produced
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PT. Bio Farma, Bandung, Indonesia

memenuhi syarat
meets all National Requirements,

Farmakope Indonesia V, 2014 dan Persyaratan WHO untuk Vaksin Jerap TT.
Indonesian Pharmacopoeia V, 2014; Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed), WHO Expert Committee on Biological Standardization, Sixty-third report, Geneva, World Health Organization, 2014, Annex 5 (WHO Technical Report Series, No. 980); and Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines, WHO/IVB/11.11, Geneva, World Health Organization, 2013.

No. Bets Batch No.	No. Kode Code Number	Tgl. Kedaluwarsa Expiration Date	Jumlah ampul Number of ampoules
0283320	01/V-Bio TT/IM/PPPOMN/III/2021	December 2023	74,250

Sertifikat ini didasarkan pada evaluasi protokol pabrik.
This certificate is based on examination of the manufacturing protocols.

Jakarta, 19 March 2021

**PUSAT PENGEMBANGAN PENGUJIAN
OBAT DAN MAKANAN NASIONAL**

E. Ika Prawahju A.
Kepala Balai Pengujian Produk Biologi