CLINICAL STUDY PROTOCOL

EFFICACY & SAFETY OF PIROXICAM PLUS COUNTERIRRITANT GEL VS DICLOFENAC GEL IN MUSKULOSCLETAL PAIN : A RANDOMIZED CLINICAL STUDY

NO. PROTOCOL : CT_CTPPXM_PRT_V001/II/2025

Clinical Research Team

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dr. Marion Cinta Kuntjoro, Sp.KFR

Supported by:

PT Taisho Pharmaceutical Indonesia TBK

2025

History of CT_CTPPXM protocol changes as follows:

Protocol Version	Description
CT_CTPPXM_PRT_V001/II/2025	This is the first protocol that reviewed by Clinical Research Team, TPI and TPI's consultant

Changes to this protocol have been reviewed and acknowledged by:		
Sponsor **PT Taisho Pharmaceutical Indonesia**		**Clinical Research Team**
Digitally signed by Dr. Ni Putu Ardini Kartasasmita DN: cn=Dr. Ni Putu Ardini Kartasasmita, o=PT Taisho Pharmaceutical Indonesia Tbk, ou=Ramad, email=Ardini.Kartasasmita@ma.taisho.co.id, c=ID Date: 2025.02.03 08:57:59 +07'00' **dr. Ardini Kartasasmita** **Medical Manager**	Digitally signed by Aryani Pratami Dewi DN: cn=Aryani Pratami Dewi, o=PT Taisho Pharmaceutical Indonesia, Tbk, ou=Regulatory Affairs and Medical , email=aryani.dewi@ma.taisho.co.id , c=ID Date: 2025.02.03 15:25:05 +07'00' **Aryani Pratami Dewi** **Head of Regulatory Affairs and Medical**	**dr. Erica Kholinne, Sp. OT (K), Ph.d** **Principal Investigator**

PROTOCOL SIGNATURE PAGE

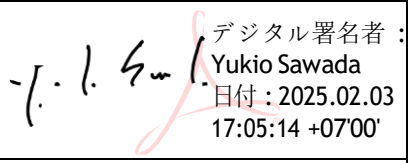
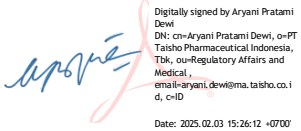
Clinical Research Team

I agree to conduct the study in accordance with this Protocol and in compliance with all applicable Health Authority requirements, Good Clinical Practice and National Laws.

Name & Position		Signature & Date of Signature
dr. Erica Kholinne, Sp.OT (K), Ph.d Principal Investigator		Signature:  Date:
dr. Astuti Pitarini, Sp.OT (K) Sub- Principal Investigator		Signature:  Date:
dr. A. Andi Kurniawan, Sp.KO SubSp. ALK (K) Sub- Principal Investigator		Signature:  Date:
dr. Wawan Budisusilo, Sp.KO Sub- Principal Investigator		Signature:  Date:
dr. Marion Cinta Kuntjoro, Sp.KFR Sub- Prinicpal Investigator		Signature:  Date:

Sponsor Acknowledgement for the Study:

We approve the design of the clinical study protocol and are willing to provide the necessary funds to carry out this clinical study.

Name & Position		Signature & Date of Signature
Yukio Sawada Director		Signature :  デジタル署名者： Yukio Sawada 日付：2025.02.03 17:05:14 +07'00' Date :
Aryani Pratami Dewi Head of Regulatory Affairs and Medical		Signature :  Digitally signed by Aryani Pratami Dewi DN: cn=Aryani Pratami Dewi, o=PT Taisho Pharmaceutical Indonesia, Tbk, ou=Regulatory Affairs and Medical , email=aryani.dewi@ma.taisho.co.id, c=ID Date: 2025.02.03 15:26:12 +07'00' Date :