THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diclofenac Diethylamine BP (Item No. 41021040)	**Spec. No.** : SP-AK30-D24
Reference(s): BP 2019 page I-771 to I-772	**Rev. No.** : 05
Other Requirements: GPO Specification	**Page** : 1/3

BP 2019

Test Parameters	Requirement
Description	A white to light beige, crystalline powder.
Solubility	Sparingly soluble in water and in acetone; freely soluble in ethanol (96%) and in methanol; practically insoluble in 1 M sodium hydroxide.
Melting point	It melts at about 154 °C, with decomposition.
Identification	A. Infrared Absorption.
	B. Thin-layer chromatography.
Acidity or alkalinity	6.4 - 8.4.
Clarity and colour of solution	A 5% w/v solution in methanol is clear. The absorbance of the solution measured at 440 nm is not greater than 0.05.
Related substances	In the chromatogram obtained with solution (1): the area of any secondary peak is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%); the sum of the areas of any secondary peaks is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%).
Loss on drying	Not more than 0.5 %.
Sulfated ash	Not more than 0.1 %.
Assay	99.0% - 101.0% of Diclofenac diethylamine ($C_{18}H_{22}Cl_2N_2O_2$), calculated with reference to the dried substance.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 05/02/20	Tarmin Luenwliount , 05/02/20	, 06/02/20	Vichien Ruengrongroj 07/02/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diclofenac Diethylamine BP (Item No. 41021040)	**Spec. No.** : SP-AK30-D24
Reference(s): BP 2019 page I-771 to I-772	**Rev. No.** : 05
Other Requirements: GPO Specification	**Page** : 2/3

GPO Specification

Test Parameter	Requirement
Heavy metals	Not more than 10 ppm.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 05/02/20	Teerawan Limboonsak , 05/02/20	, 06/02/20	Wichien Ruengjongroj , 07/02/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Diclofenac Diethylamine BP (Item No. 41021040)	**Spec. No.** : SP-AK30-D24
Reference(s): BP 2019 page I-771 to I-772	**Rev. No.** : 05
Other Requirements: GPO Specification	**Page** : 3/3

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Diclofenac Diethylamine BP (Item No. 41021040).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-D24.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in an airtight container. Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
02	Update ข้อกำหนด โดยอ้างอิงตาม BP 2001	30/12/03
03	Update ข้อกำหนด โดยอ้างอิงตาม BP 2009	19/10/09
04	Update ข้อกำหนด โดยอ้างอิงตาม BP 2014	24/05/16
05	Update ข้อกำหนด โดยอ้างอิงตาม BP 2019 และ GPO Specification โดยปรับหัวข้อ Heavy metals มาอยู่ใน GPO Specification เนื่องจากไม่ระบุใน monograph	15/03/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 05/02/20	Termin Lnluunt / 05/02/20	/ 06/02/20	Vichien Ruengwongroj / 07/02/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	