

TECHNICAL DATA SHEET

4643299-TDS-ENG-2024

TOCERANIB PHOSPHATE			
DESCRIPTION DCI: TOCERANIB FOSFATO		DESCRIPTION DOE:	
CAS Nº: 874819-74-6	EC Nº: 639-69-4		AEMPS CODE: 90932FO
MOL. WEIGHT: 494,46	MOL. FORMULA: C22H28FN4O6P		ARTICLE CODE: 4643299

ATTRIBUTES SHOULD BE

Appearance Orange crystalline powder

RMN Identification (1H, 13C, 15N) Complies Water <= 1 % Assay <= 97 %

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Toceranib Phosphate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.