

SHANGHAI PHARM-LINK INTERNATIONAL CO., LTD.

Room 1-8, BLD8, No.52 Hangchuan Road, Hangtoun Town, Pudong New District, Shanghai, 201316, China
Mobile: (+86)13483427292, 13813616064, E-mail: eric.qin@pharm-link.com, Http: www.pharm-link.com

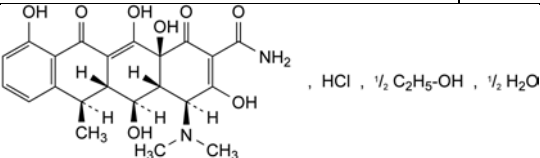
PRODUCT SPECIFICATION

DOXYCYCLINE HYCLATE

(Nonsterile)

Ph. Eur. 9.0

Version No: DS04NS-EP-01

Product Name	DOXYCYCLINE HYCLATE		
Molecular Formula	$C_{22}H_{25}ClN_2O_8 \cdot 1/2 C_2H_6O, 1/2 H_2O$	Formula Weight	512.9
Structure Formula			
CAS No	24390-14-5		
Origin	Semi-synthetic		
ITEMS	SPECIFICATIONS		
Appearance	yellow, hygroscopic, crystalline powder.		
Solubility	Freely soluble in water and in methanol, sparingly soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides and carbonates.		
Identification A. HPLC in Assay B. C. Reaction of chlorides	The principal peak in the chromatogram obtained with the TS is similar in RT and size to the principal peak in the chromatogram obtained with Ref. Sol. (a); A yellow colour develops; Positive.		
pH	2.0 to 3.0		
Absorbance (anhydrous and ethanol-free substance), at 349 nm	NMT 0.07		
Water	1.4% to 2.8%		
Sulfated ash	≤0.4%		
Related Substances, HPLC Impurity A Impurity F Impurity B Impurity C Unspecified impurities Total	≤ 2.0% ≤ 1.2% ≤ 0.5% ≤ 0.2% ≤ 0.10% ≤ 3.0%		
Ethanol, GC	4.3% to 6.0%		
Residual Solvents , other than ethanol. No class I solvent used.	Compliance with ICH Q3C limits		
Assay (anhydrous and ethanol-free substance)	95.0%~102.0% of $C_{22}H_{25}ClN_2O_8$		
Retest Period	TBD		
Batch size	TBD		
Packing size	25kg/drum		

THE INFORMATION PRESENTED HEREIN IS BELIEVED TO BE ACCURATE AND RELIABLE, BUT NO WARRANTY, EXPRESSED OR IMPLIED IS MADE REGARDING THE INFORMATION OF THE PERFORMANCE OF ANY PRODUCT. FURTHER NOTHING CONTAINED HEREIN SHALL BE TAKEN AS ANY INDUCEMENT OR RECOMMENDATION TO USE, MANUFACTURE OR SELL THAT WAY INFRINGE ANY PATENTS OR ANY OTHER PROPRIETARY RIGHTS NOW OR HEREAFTER IN EXISTENCE.

SHANGHAI PHARM-LINK INTERNATIONAL CO., LTD.

Room 1-8, BLD8, No.52 Hangchuan Road, Hangtoun Town, Pudong New District, Shanghai, 201316, China

Mobile: (+86)13483427292, 13813616064, E-mail: eric.qin@pharm-link.com, Http: www.pharm-link.com

Storage	In an airtight container, protected from light.
----------------	---

Rev .00

Aug. 2019

THE INFORMATION PRESENTED HEREIN IS BELIEVED TO BE ACCURATE AND RELIABLE, BUT NO WARRANTY, EXPRESSED OR IMPLIED IS MADE REGARDING THE INFORMATION OF THE PERFORMANCE OF ANY PRODUCT. FURTHER NOTHING CONTAINED HEREIN SHALL BE TAKEN AS ANY INDUCEMENT OR RECOMMENDATION TO USE, MANUFACTURE OR SELL THAT WAY INFRINGE ANY PATENTS OR ANY OTHER PROPRIETARY RIGHTS NOW OR HEREAFTER IN EXISTENCE.
