

# SHANGHAI PHARM-LINK INTERNATIONAL CO., LTD.

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## PRODUCT SPECIFICATION

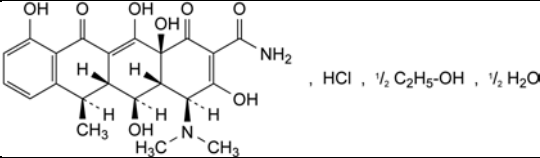
### DOXYCYCLINE HYCLATE

(Nonsterile)

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USP 40

Version No: DS04NS-USP-01

<b>Product Name</b>	DOXYCYCLINE HYCLATE		
<b>Molecular Formula</b>	$(C_{22}H_{24}N_2O_8 \cdot HCl)_2 \cdot C_2H_6O \cdot H_2O$	<b>Formula Weight</b>	1025.87
<b>Structure Formula</b>			
<b>CAS No</b>	24390-14-5		
<b>Origin</b>	Semi-synthetic		
<b>ITEMS</b>	<b>SPECIFICATIONS</b>		
<b>Appearance</b>	yellow, hygroscopic, crystalline powder.		
<b>Solubility</b>	Freely soluble in water and in methanol, sparingly soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides and carbonates.		
<b>Identification</b>			
IR absorption	The absorption bands is in accordant to that of RS.		
<b>Crystallinity</b>	Meets the requirements		
<b>pH</b>	2.0 to 3.0		
<b>Water determination</b>	1.4% to 2.8%		
<b>Organic Impurities, HPLC</b>			
4-Epidoxycyclinea (RRT0.4)	≤ 0.5%		
Methacycline(RRT0.6)	≤ 2%		
RRT0.7	≤ 2%		
Unspecified impurities	≤ 0.5%		
<b>Residual Solvents, other than ethanol.</b>			
No class I solvent used.	Compliance with ICH Q3C limits		
<b>Assay</b> ( $C_{22}H_{24}N_2O_8$ )	800-920 μg/mg		
<b>Retest Period</b>	TBD		
<b>Batch size</b>	TBD		
<b>Packing size</b>	25kg/drum		
<b>Storage</b>	Preserve in tight containers, protected from light.		

Rev.00  
Aug. 2019

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