

Product : Minocycline Hydrochloride Batch no.: 05NY01.HQ01421 Retest Date : April 2026 → <i>Hex estabilidade 36m!</i> Manufacturing Date : April 2024 <i>04/2027 VP</i>			
TEST	REF.	SPECIFICATION	RESULT
Description:	Ph. Eur. Monograph	Yellow powder	Conforms ✓
Crystallinity:	USP, Monograph	The product is crystalline	Conforms ✓
Solubilities:	Ph. Eur. Monograph	Sparingly soluble in water; slightly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates	Conforms ✓
Identification (by IR): ✓	Ph. Eur. Monograph	Conforms to the spectrum of the minocycline hydrochloride CRS (after drying 2 hours, at 100°C; KBr)	Conforms ✓
Chloride: ✓	Ph. Eur. Monograph	Positive to reaction a)	Conforms ✓
Appearance of solution: ✓	Ph. Eur. Monograph	A 0.1 % w/v solution in water is clear	Conforms ✓
Absorbance (at 450 nm):	Ph. Eur. Monograph	Not more than 0.23 (1 cm cell, 0.1% w/v solution in water)	0.14
Light-absorbing impurities: ✓	Ph. Eur. Monograph	Not more than 0.06 at 560 nm (1 % w/v solution in water)	0.03
pH: ✓	Ph. Eur. Monograph	Not less than 3.5 and not more than 4.5 (1 % w/v in water)	3.9 ✓
Water: ✓	Ph. Eur. Monograph	Not less than 5.0 % w/w and not more than 8.0 % w/w (200 mg)	7.4 % w/w ✓
Residue on ignition: ✓	Ph. Eur. Monograph	Not more than 0.15 % w/w (1 g; 600°C; constant weight)	0.01 % w/w
Related substances (by HPLC):	Ph. Eur. Monograph	Not more than 1.2 % w/w	0.8 % w/w
Ph. Eur. Impurity A	Ph. Eur. Monograph	Not more than 0.8 % w/w	0.07 % w/w
Ph. Eur. Impurity B	Ph. Eur. Monograph	Not more than 0.6 % w/w	0.06 % w/w
Ph. Eur. Impurity C	Ph. Eur. Monograph	Not more than 0.6 % w/w	0.08 % w/w
Ph. Eur. Impurity E	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.42 % w/w
Ph. Eur. Impurity F	Ph. Eur. Monograph		
The batch number 05NY01.HQ01421 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.		Approved by: Rita Pereira 29.May.2024 14:59:04 Quality Control	
Storage conditions : Well closed and light resistant containers; store below 25°C and 60% RH			
The batch was manufactured according to Good Manufacturing Practices.		Released by: Ana Fragoso 29.Jul.2024 15:32:52 Quality Assurance	
Reference: 142452098, 137280299		GQSP5133.4 V_NORMAL	

This document has been signed electronically in compliance with 21CFR Part 11.