

## METAPHARMACEUTICAL

**Product :** Minocycline Hydrochloride

**Batch no.:** 05NY01.HQ01301

**Retest Date :** July 2023

N DE LOTE:

0034121

02/11/2021

**Manufacturing Date :** July 2021

TEST	REF.	SPECIFICATION	RESULT
<b>Description:</b>	Ph. Eur. Monograph	Yellow powder	Conforms
<b>Crystallinity:</b>	USP, Monograph	The product is crystalline	Conforms
<b>Solubilities:</b>	Ph. Eur. Monograph	Sparingly soluble in water; slightly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates	Conforms
<b>Identification (by IR):</b>	Ph. Eur. Monograph	Conforms to the spectrum of the minocycline hydrochloride CRS (after drying 2 hours, at 100°C; KBr)	Conforms
<b>Chloride:</b>	Ph. Eur. Monograph	Positive to reaction a)	Conforms
<b>Appearance of solution:</b>	Ph. Eur. Monograph	A 0.1 % w/v solution in water is clear	Conforms
<b>Absorbance (at 450 nm):</b>	Ph. Eur. Monograph	Not more than 0.23 (1 cm cell, 0.1% w/v solution in water)	0.15
<b>Light-absorbing impurities:</b>	Ph. Eur. Monograph	Not more than 0.06 at 560 nm (1 % w/v solution in water)	0.03
<b>pH:</b>	Ph. Eur. Monograph	Not less than 3.5 and not more than 4.5 (1 % w/v in water)	4.0
<b>Water:</b>	Ph. Eur. Monograph	Not less than 5.0 % w/w and not more than 8.0 % w/w (200 mg)	7.5 % w/w
<b>Residue on ignition:</b>	Ph. Eur. Monograph	Not more than 0.15 % w/w (1 g; 600°C; constant weight)	0.00 % w/w
<b>Related substances (by HPLC):</b>			
Ph. Eur. Impurity A	Ph. Eur. Monograph	Not more than 1.2 % w/w	0.8 % w/w
Ph. Eur. Impurity B	Ph. Eur. Monograph	Not more than 0.8 % w/w	Less than 0.05 % w/w
Ph. Eur. Impurity C	Ph. Eur. Monograph	Not more than 0.6 % w/w	0.05 % w/w
Ph. Eur. Impurity E	Ph. Eur. Monograph	Not more than 0.6 % w/w	0.06 % w/w
Ph. Eur. Impurity F	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.37 % w/w
Ph. Eur. Impurity G	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.21 % w/w
Ph. Eur. Impurity H	Ph. Eur. Monograph	Not more than 0.3 % w/w	0.17 % w/w
Impurity with RRT 0.85	Ph. Eur. Monograph	Not more than 0.50 % w/w	0.19 % w/w
Impurity at RRT 0.88	CRLC059_034	Not more than 0.15 % w/w	0.05 % w/w
Impurity with RRT 1.13	Ph. Eur. Monograph	Not more than 0.40 % w/w	0.16 % w/w
Any unspecified impurity	Ph. Eur. Monograph	Not more than 0.10 % w/w	Less than 0.05 % w/w
<b>Total Impurities</b>	Ph. Eur. Monograph	Not more than 3.5 % w/w	2.0 % w/w
<b>Assay (by HPLC):</b>	Ph. Eur. Monograph	Not less than 94.5 % w/w and not more than 102.0 % w/w, calculated with reference to the anhydrous substance	97.7 % w/w
<b>Residual solvents (by GC):</b>			
Isopropyl alcohol	CRGC1746_004	Not more than 1000 ppm	280 ppm
Dichloromethane	CRGC1746_006	Not more than 100 ppm	Less than 64 ppm
Hexane	CRGC1746_005	Not more than 290 ppm	Less than 42 ppm
<b>Content of (by ICP):</b>			

The batch number 05NY01.HQ01301 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.

**Approved by:**

Ana Paula Lopes

22.Sep.2021 14:53:42

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:**

Tania Frazao

08.Oct.2021 14:37:03

Quality Assurance

**Reference:** 104447474, 103396358

GQSP5133.2 V\_NORMAL

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

<b>Product :</b> Minocycline Hydrochloride <b>Batch no.:</b> 05NY01.HQ01301 <b>Retest Date :</b> July 2023 <b>Manufacturing Date :</b> July 2021			
TEST	REF.	SPECIFICATION	RESULT
Palladium	AA001837_036	Not more than 10 ppm (skip testing to be performed at least every 5 batches)	Conforms
Rhodium	AA001837_037	Not more than 10 ppm (skip testing to be performed at least every 5 batches)	Conforms
<b>The batch number 05NY01.HQ01301 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.</b>		<b>Approved by:</b> <u>Ana Paula Lopes</u> 22.Sep.2021 14:53:42 Quality Control	
<b>Storage conditions :</b> Well closed and light resistant containers; store below 25°C and 60% RH			
<b>The batch was manufactured according to Good Manufacturing Practices.</b>		<b>Released by:</b> <u>Tania Frazao</u> 08.Oct.2021 14:37:03 Quality Assurance	
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