Hovione

CERTIFICATE OF ANALYSIS

Product : Minocycline Hydrochloride
Batch no.: 05NY01.HQ01364
Retest Date : February 2025 **Manufacturing Date :** February 2023

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)	0.15
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)	7.5 % w/w
Residue on ignition:	Ph. Eur. Monograph	Not more than 0.15 % w/w (1 g; 600°C; constant weight)	0.00 % w/w
Related substances (by HPLC):			
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	0.10 % 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	0.29 % w/w
Ph. Eur. Impurity G	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.19 % w/w
Ph. Eur. Impurity H	Ph. Eur. Monograph	Not more than 0.3 % w/w	0.08 % w/w
Impurity with RRT 0.85	Ph. Eur. Monograph	Not more than 0.50 % w/w	0.16 % 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	0.11 % w/w
Any unspecified impurity	Ph. Eur. Monograph	Not more than 0.10 % w/w	Less than 0.05 % w/w
Total Impurities	Ph. Eur. Monograph	Not more than 3.5 % w/w	1.8 % w/w
Assay (by HPLC):	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
Residual solvents (by GC):			
Isopropyl alcohol	CRGC1746_004	Not more than 1000 ppm	431 ppm

The batch number 05NY01.HQ01364 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.

Approved by:
Antonio Carlos Silva 17.May.2023 17:57:03
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:
Vera Stepanyk 24.May.2023 11:43:43
Quality Assurance

Reference: 110659951, 109877184 GQSP5133.3 V_NORMAL

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

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By: João Carlos Loureiro

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CERTIFICATE OF ANALYSIS

Product : Minocycline Hydrochloride

Batch no.: 05NY01.HQ01364

Retest Date : February 2025 **Manufacturing Date :** February 2023

TEST	REF.	SPECIFICATION	RESULT
Dichloromethane	CRGC1746_006	Not more than 100 ppm	Less than 64 ppm
Hexane	CRGC1746_005	Not more than 290 ppm	Less than 42 ppm
Content of (by ICP):			
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
Content of (by HPLC-MS) N-Nitroso-7-monomethylamino-6-deoxytetracycline:	CRLC5750_001	Not more than 0.2 ppm	Conforms

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