Hovione

CERTIFICATE OF ANALYSIS

Product : **Minocycline Hydrochloride**

Batch no.: 05NY01.HQ01293

Retest Date : April 2023 **Manufacturing Date :** April 2021

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 100ºC; 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)	4.0
Water:	Ph. Eur. Monograph	Not less than 5.0 % w/w and not more than 8.0 % w/w (200 mg)	7.3 % w/w
Residue on ignition:	Ph. Eur. Monograph	Not more than 0.15 % w/w (1 g; 600°C; constant weight)	0.02 % w/w
Related substances (by HPLC):			
Ph. Eur. Impurity A	Ph. Eur. Monograph	Not more than 1.2 % w/w	0.9 % w/w
Ph. Eur. Impurity B	Ph. Eur. Monograph	Not more than 0.8 % w/w	0.07 % 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	0.05 % w/w
Ph. Eur. Impurity F	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.38 % w/w
Ph. Eur. Impurity G	Ph. Eur. Monograph	Not more than 0.5 % w/w	0.29 % w/w
Ph. Eur. Impurity H	Ph. Eur. Monograph	Not more than 0.3 % w/w	0.18 % w/w
Impurity with RRT 0.85	Ph. Eur. Monograph	Not more than 0.50 % w/w	0.22 % w/w
Impurity at RRT 0.88	CRLC059_034	Not more than 0.15 % w/w	0.08 % w/w
Impurity with RRT 1.13	Ph. Eur. Monograph	Not more than 0.40 % w/w	0.20 % w/w
Any unspecified impurity	Ph. Eur. Monograph	Not more than 0.10 % w/w	0.06 % w/w
Total Impurities	Ph. Eur. Monograph	Not more than 3.5 % w/w	2.4 % 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	97.4 % w/w
Residual solvents (by GC):			
Isopropyl alcohol	CRGC1746_004	Not more than 1000 ppm	413 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
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

The batch number 05NY01.HQ01293 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.

Approved by:

Ana Paula Lopes **30.May.2021 23:14:16**

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:

Patricia Andrade **04.Jun.2021 15:10:17**

Quality Assurance

Reference: 102871173, 102159960 GQSP5133.2 V_NORMAL

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

Printed on : 10.Mar.2022 08:38:33
By: Luisa Cabrita

Manufacturing Site:
Hovione FarmaCiencia SA
Sete Casas, 2674-506 Loures, Portugal;
Tel: +351 21 982 93 85 · Fax: +351 21 982 93 88
www.hovione.com