

Product: Minocycline Hydrochloride

Batch no.: 05NY01.HQ01207

Retest Date: March 2021 Manufacturing Date: March 2019

Description: Orystallinity: USP, Monograph V. Eur. Monograph V. Eu	TEST	REF.	SPECIFICATION		RESULT
Solubilities: Ph. Eur. Monograph Ph. Eur. Mon	Description:	Ph. Eur. Monograph	Yellow powder		Conforms
dissolves in solutions of alkali hydroides and carbonates Conforms Chloride:	Crystallinity:	USP, Monograph	The product is crystalline		Conforms
Conforms to the spectrum of the minacycline hydrochloride CRS (Solubilities:	Ph. Eur. Monograph	Sparingly soluble in water; slightly soluble in ethanol (96%). It		Conforms
Chloride: Ph. Eur. Monograph Ph.	Identification (by IR):	Ph. Eur. Monograph	Conforms to the spectrum of the	e minocycline hydrochloride CRS (Conforms
Absorbance (at 450 nm): Light-absorbing impurities: Ph. Eur. Monograph Ph: Ph. Eur. Monograph Ph. Eur. Monog	Chloride:	Ph. Eur. Monograph	, , ,	(01)	Conforms
Light-absorbing impurities: ph: ph: ph: ph: ph: ph: Eur. Monograph Not more than 0.06 at 560 nm (1 % w/v solution in water) ph: Aux Monograph Not less than 3.5 and not more than 4.5 (1 % w/v in water) ph: Eur. Monograph Not less than 3.0 s w/w and and not more than 3.0 % w/w (200 mg) ph: Eur. Monograph Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity E Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity F Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity F Ph. Eur. Monograph Not more than 0.5 % w/w Not more than 0.0 % w/w Not more	Appearance of solution:	Ph. Eur. Monograph	A 0.1 % w/v solution in water is	clear	Conforms
Mater: Water: Ph. Eur. Monograph Not more than 0.5 % w/w Not more than 0.5 %	Absorbance (at 450 nm):	Ph. Eur. Monograph	Not more than 0.23 (1 cm cell, (0.1% w/v solution in water)	0.14
Not less than 5.0 % w/w and not more than 8.0 % w/w (200 mg) Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity A Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Impurity E Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity F Ph. Eur. Monograph P	Light-absorbing impurities:	Ph. Eur. Monograph	Not more than 0.06 at 560 nm (1 % w/v solution in water)	0.02
Residue on Ignition: Rolated substances (by HPLC): Ph. Eur. Monograph Not more than 0.5 % w/w Not more than 0.15 % w/w Not more than 0.10 % w/w Not more than 100 ppm Not more than 100 ppm Less than 42 ppm Less than 44 ppm Less than 42 ppm Less	pH:	Ph. Eur. Monograph	Not less than 3.5 and not more	than 4.5 (1 % w/v in water)	4.0
Related substances (by HPLC): Ph. Eur. Impurity A Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Impurity E Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity F Ph. Eur. Monograph Not more than 0.5 % w/w 0.25 % w/w Not more than 0.5 % w/w 0.25 % w/w Not more than 0.5 % w/w Not more than 0.5 % w/w Not more than 0.5 % w/w 0.25 % w/w 0.23 % w/w 0.07 % w/w Not more than 0.15 % w/w Not more than 0.10 % w/w Not more than 10.10 % w/w Not more th	Water:	Ph. Eur. Monograph	Not less than 5.0 % w/w and no	ot more than 8.0 % w/w (200 mg)	7.2 % w/w
Ph. Eur. Impurity A Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity B Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Impurity E Ph. Eur. Monograph Not more than 0.5% w/w 0.25 % w/w 0.2	Residue on ignition:	Ph. Eur. Monograph	Not more than 0.15 % w/w (1 g;	; 600°C; constant weight)	0.00 % w/w
Ph. Eur. Impurity B Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Mo	Related substances (by HPLC):				
Ph. Eur. Impurity C Ph. Eur. Monograph Ph. Eur. Mon	Ph. Eur. Impurity A	Ph. Eur. Monograph	Not more than 1.2 % w/w		0.6 % w/w
Ph. Eur. Impurity E Ph. Eur. Monograph Not more than 0.10 % w/w Not more than 10.10 % w/w Not more than 10.00 ppm Pl. Eur. Monograph Ph. Eur. Monograph Not more than 100 ppm Pl. Eur. Monograph Not more than 0.20 % w/w Not more than 0.20 % w/w Not more than 100 ppm Pl. Eur. Monograph Not more than 0.20 % w/w Not more than 100 ppm Pl. Eur. Monograph Not more than 0.20 % w/w Not mo	Ph. Eur. Impurity B	Ph. Eur. Monograph	Not more than 0.8 % w/w		0.05 % w/w
Ph. Eur. Impurity F Ph. Eur. Monograph Not more than 0.10 % w/w Not more than 0.40 % w/w Not more than 0.10 % w/w Not more than 10.00 % w/w Not more than 10.00 % w/w Not less than 94.5 % w/w and not more than 102.0 % w/w Not more than 100 ppm Less than 64 ppm Less than 64 ppm Less than 64 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) Approved by: Cristina Alves 10.Apr.2019 20:10:26 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 The batch was manufactured according to Good Manufacturing	Ph. Eur. Impurity C	Ph. Eur. Monograph	Not more than 0.6 % w/w		0.07 % w/w
Ph. Eur. Impurity G Ph. Eur. Monograph Ph. Eur. Monograph Ph. Eur. Monograph Impurity at RRT 0.85 Impurity at RRT 0.88 Impurity at RRT 0.88 Impurity at RRT 0.88 Impurity at RRT 0.89 Impurity at RRT	Ph. Eur. Impurity E	Ph. Eur. Monograph	Not more than 0.6 % w/w		0.08 % w/w
Ph. Eur. Impurity H Impurity with RRT 0.85 Impurity with RRT 0.85 Impurity with RRT 0.88 Impurity with RRT 1.13 Any unspecified impurity Total Impurities Ph. Eur. Monograph Ph. Eur. Mo	Ph. Eur. Impurity F	Ph. Eur. Monograph	Not more than 0.5 % w/w		0.27 % w/w
Impurity with RRT 0.85 Impurity at RRT 0.88 Impurity with RRT 1.13 Any unspecified impurity Ph. Eur. Monograph Any unspecified impurity Ph. Eur. Monograph Not more than 0.10 % w/w Not more than 102.0 % w/w Ph. Eur. Monograph Not more than 102.0 % w/w Ph. Eur. Monograph Not more than 102.0 % w/w Ph. Eur. Monograph Not more than 100.0 ppm Ph. Eur. Monograph Not more than 100.0 ppm Not more than 100.0 ppm Less than 64 ppm Less than 64 ppm Less than 42 ppm Not more than 10 ppm (skip testing to be performed at least every Shatches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 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	Ph. Eur. Impurity G	Ph. Eur. Monograph	Not more than 0.5 % w/w		0.25 % w/w
Impurity at RRT 0.88 Impurity with RRT 1.13 Any unspecified impurity Total Impurities Ph. Eur. Monograph Not more than 3.1% w/w Not more than 102.0 % w/w Not more than 1000 ppm Not more than 100 ppm Less than 64 ppm Less than 64 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 Starta Alves Approved by: Cristina Alves 10.Apr.2019 20:10:26 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	Ph. Eur. Impurity H	Ph. Eur. Monograph	Not more than 0.3 % w/w		0.25 % w/w
Impurity with RRT 1.13 Any unspecified impurity Total Impurities Ph. Eur. Monograph Not more than 1000 ppm Not more than 1000 ppm Not more than 100 ppm Not more than 100 ppm Not more than 100 ppm Less than 64 ppm Less than 6	Impurity with RRT 0.85	Ph. Eur. Monograph	Not more than 0.50 % w/w		0.23 % w/w
Any unspecified impurity Total Impurities Assay (by HPLC): Residual solvents (by GC): Isopropyl alcohol Dichloromethane Hexane Content of (by ICP): Palladium AA001837_036 The batch number 05NY01.HQ01207 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione Specifications: Well closed and light resistant containers; store below 25°C and 60% RH Who the more than 0.10 % w/w Not more than 0.10 % w/w Not more than 102.0 % w/w Not more than 102.0 % w/w 2.1 % w/w 3.2 % w/w 3.3 % w/w 3.4 % w/w 3.4 % w/w 4.62 ppm 4.62 pp	Impurity at RRT 0.88	CRLC059 034	Not more than 0.15 % w/w		0.07 % w/w
Total Impurities Assay (by HPLC): Residual solvents (by GC): Isopropyl alcohol Dichloromethane Hexane Content of (by ICP): Palladium Palladium Palladium Ph. Eur. Monograph Not more than 1000 ppm Not more than 1000 ppm Not more than 100 ppm Not more than 100 ppm Not more than 10 ppm (skip testing to be performed at least every Storage been tested as above and conforms to the latest EP and Hovione Storage conditions: Well closed and light resistant containers; store below 25°C and 60% RH The batch was manufactured according to Good Manufacturing Practices Residual not more than 102.0 % w/w Not more than 1000 ppm Not more than 100 ppm Less than 442 ppm Conforms Conforms Approved by: Cristina Alves 10.Apr.2019 20:10:26 Quality Control Released by: Practices	Impurity with RRT 1.13	Ph. Eur. Monograph	Not more than 0.40 % w/w		0.16 % w/w
Assay (by HPLC): Residual solvents (by GC): Isopropyl alcohol Dichloromethane Hexane CRGC1746_004 CRGC1746_005 Not more than 100 ppm Not more than 100 ppm Not more than 100 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) Approved by: Cristina Alves 10.Apr.2019 20:10:26 Quality Control Storage conditions: Well closed and light resistant containers; store below 25°C and 60% RH Residual solvents (by GC): Not more than 100 ppm Not more than 100 ppm Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 Quality Control Released by: Practices	, ,		Not more than 0.10 % w/w		0.06 % w/w
Assay (by HPLC): Ph. Eur. Monograph Residual solvents (by GC): Isopropyl alcohol Dichloromethane Hexane CRGC1746_004 Hexane CRGC1746_005 CRGC1746_005 Not more than 100 ppm Not more than 100 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) Approved by: Cristina Alves Quality Control Storage conditions: Well closed and light resistant containers; store below 25°C and 60% RH Residual solvents (by GC): Not more than 100 ppm Not more than 100 ppm Less than 64 ppm Less than 42 ppm Conforms Approved by: Cristina Alves 10.Apr.2019 20:10:26 Quality Control Released by: Practices	Total Impurities	Ph. Eur. Monograph	Not more than 3.5 % w/w		2.1 % w/w
Isopropyl alcohol Dichloromethane Dichloromethane Hexane CRGC1746_006 CRGC1746_005 Not more than 100 ppm Not more than 290 ppm Less than 64 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) AA001837_036 Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 Quality Control Storage conditions: Well closed and light resistant containers; store below 25°C and 60% RH Released by: Practices	Assay (by HPLC):	Ph. Eur. Monograph	•	Not less than 94.5 % w/w and not more than 102.0 % w/w ,	
Dichloromethane Hexane CRGC1746_006 CRGC1746_005 Not more than 100 ppm Not more than 290 ppm Less than 64 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) AA001837_036 Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 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	Residual solvents (by GC):				
Hexane Content of (by ICP): Palladium AA001837_036 Not more than 290 ppm Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves Quality Control Storage conditions: Well closed and light resistant containers; store below 25°C and 60% RH Released by: Released by: Released by:	Isopropyl alcohol	CRGC1746_004	Not more than 1000 ppm		462 ppm
Content of (by ICP): Palladium AA001837_036 Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 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 Released by: Practices	Dichloromethane	CRGC1746_006	Not more than 100 ppm	Not more than 100 ppm	
Palladium AA001837_036 Not more than 10 ppm (skip testing to be performed at least every 5 batches) Approved by: Cristina Alves 10.Apr.2019 20:10:26 Released by: The batch was manufactured according to Good Manufacturing Practices Approved by: Cristina Alves 10.Apr.2019 20:10:26 Released by:	Hexane	CRGC1746_005	Not more than 290 ppm		Less than 42 ppm
The batch number 05NY01.HQ01207 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications. Approved by: Cristina Alves	Content of (by ICP):				
been tested as above and conforms to the latest EP and Hovione specifications. Cristina Alves 10.Apr.2019 20:10:26 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:	Palladium	AA001837_036	1		Conforms
been tested as above and conforms to the latest EP and Hovione specifications. Cristina Alves 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:	The batch number 05NV01 HOO	11207 of Minocyclina Hydr	rochlorido has	Approved by:	
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:				Crietina Alvoe	10 Apr 2019 20·10·26
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:					•
The batch was manufactured according to Good Manufacturing Practices Released by:				Quality C	ontrol
Practices	Storage conditions : We	ll closed and light resistant	t containers; store below 25°C	and 60% RH	
Practices	The batch was manufactured a	ccording to Good Manufa	cturing	Released by:	
		-	-	Jorge Valadas	16.Apr.2019 13:57:2

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By: Luisa Cabrita

Reference:





Product: **Minocycline Hydrochloride**

Batch no.: 05NY01.HQ01207

Retest Date: March 2021 Manufacturing Date: March 2019

TEST	REF.		SPECIFICATION	RESULT
Rhodium	REF. AA001837_037	Not more than 10 ppm (5 batches)	SKIP testing to be performed at least ex	
The batch number 05NY01.HQ01207 of Minocycline Hydrochloride has been tested as above and conforms to the latest EP and Hovione specifications.		Approved by: Cristina Alves	10.Apr.2019 20:10:26 uality Control	
Storage conditions : Well cl	osed and light resistant	t containers; store belov		uanty control
			Palacand hur	
The batch was manufactured according to Good Manufacturing Practices.			Released by: Jorge Valadas	16.Apr.2019 13:57:2
				lity Assurance

Printed on: 02.Apr.2020 15:17:25

By: Luisa Cabrita