Cipan

COMPANHIA INDUSTRIAL PRODUTORA DE ANTIBIÓTICOS, SA

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CERTIFICADO DE ANÁLISE
CERTIFICATE OF ANALYSIS

KalChem INTERNATIONAL
Compounding Chemicals You Can Trust

Produto *Product* Minocycline Hydrochloride Non-Sterile		Lote nº *Lot nº* 329.55H019
D. Fabricação *Man. Date* November 2022	Data Análise *Analysis Date* December 22, 2022	P. Validade *Exp. Date* October 2026
DETERMINAÇÕES - TESTS	**RESULTADOS - RESULTS**	**LIMITES - LIMITS**
C. Organolépticos *Description*	Normal (yellow crystalline powder)	USP /EP: Yellow crystalline powder.
Solubilidades *Solubility*	Normal	USP /EP: Sparingly soluble in water. Slightly soluble in ethanol. Soluble in solutions of alkaline hydroxides and carbonates. USP: Practically insoluble in chloroform and ether.
Substâncias relacionadas *Related substances*	Epiminocycline: 0.5% 7-monodemethylminocycline: 0.1% Anhydrominocycline: 0.0% Sancycline: 0.2% 7,9-diminocycline: 0.1% Hydroxymethylminocycline: 0.1% Imiminocycline: 0.1% Total of impurities: 1.2% Any other impurity unspecified: 0.01% Any Unknown Impurity: 0.03%	EP: Impurity A_ Epiminocycline: ≤ 1.2% Impurity C_ 7-monodemethylminocycline: ≤ 0.6% Impurity H_ Anhydrominocycline: ≤ 0.3% Impurity B_ Sancycline: ≤ 0.8% Impurity G_ 7,9-diminocycline: ≤ 0.5% Impurity F_ Hydroxymethylminocycline: ≤ 0.5% Impurity E_ Imiminocycline: ≤ 0.6% Total of impurities: ≤ 3.5% Any other impurity unspecified: ≤ 0.15% Any Unknown Impurity: ≤ 0.10%
Identificação *Identification*	Positive	USP :IR absorption spectrum and HPLC retention time EP : Tests A and C or B and C
Cristalinidade / *Cristallinity*	Satisfactory	USP / EP : Crystalline
Aspecto da solução *Appearance of solution*	Satisfactory (0.13)	EP : ≤ 0.23
Impurezas absorventes de luz *Light absorbing impurities*	0.01	EP : ≤ 0.06
Humidade / *Moisture*	USP: 7.0%; EP: 7.0%	USP : 4.3 - 8.0% ; EP : 5.0 - 8.0%
Cinzas sulfatadas *Residue on ignition*	USP: 0.01%; EP: 0.0%	USP : ≤ 0.15% ; EP : ≤ 0.5%
Impurezas Elementares *Elemental Impurities* [1]	Complies	USP / EP, according ICH Q3D limits for class 1, 2A, Pd and Rh
pH	4.0	USP /EP : 3.5 - 4.5
Tapped density	0.77 g/ml	≥ 0.45 g/mL
Doseamento *FE / Assay EP*	98.0% an	94.5 - 102.0% an
Doseamento USP / *Assay USP*	933 µg/mg an	890 - 950 µg/mg an
Solventes residuais *Residual solvents*	Satisfactory Acetone: <DL 16ppm Acetonitrile: <DL 41pm Methanol: <DL 41pm Toluene: <DL 1.8pm	Satisfactory: (<467> USP ; 5.4 Ph. Eur.) Acetone : ≤ 0.5% Acetonitrile : ≤ 410 ppm Methanol : ≤ 500 ppm Toluene: ≤ 50 ppm
Impurezas residuais *Residual impurities*	Ammonium chloride: 0.1% CBSA: 0.1% Epiminocycline: 0.5% Sum of other impurities: 0.8% 7-monodemethylminocycline: <QL(0.18%) Sancycline: 0.2% 7,9-diminocycline: <QL(0.20%) Anhydrominocycline: 0.1% Hydroxymethylminocycline: 0 1% Imiminocycline: 0.1% Any Unknown Impurity: 0.09%	Cipan: Ammonium chloride ≤ 0.2% Cipan: CBSA (chlorobenzenosulfonic acid) ≤ 0 2% USP : Epiminocycline ≤ 1.2% USP : Sum of other impurities ≤ 2.0% Cipan. 7-monodemethylminocycline ≤ 0.4% Cipan: Sancycline ≤ 0.7% Cipan: 7,9-diminocycline ≤ 0.3% Cipan: Anhydrominocycline ≤ 0.2% Cipan: Hydroxymethylminocycline ≤ 0.4% Cipan: Imiminocycline ≤ 0.4% Cipan: Any Unknown Impunty ≤ 0.10%
Granulometria / *Crystal size* by Gilson Airjet method	100% passed through 100 mesh (150 µm) 16% retained on 325 mesh (45 µm)	
Actividade t.q. / *Activity as is*	868 µg/mg	
Conclusões *Conclusions*	Complies with the current USP, BP and Eur. Ph.	
Observações *Comments*		

"The material meets the current pharmacopoeias USP/ BP / Eur. Ph. and the corresponding tests and results are reported on the certificates of analysis".

Director do Controlo da Qualidade ***Director of Quality Control***	03/03/2023
Director Técnico ***Qualified Person***	03/03/2023