



Data de impressão: 29/Janeiro/2021 UTC-03

Sanofi Medley Farmacêutica Ltda
R. Conde Domingos Papaiz, 413 - Vila Areião CEP: 08613-010 - Suzano - São Paulo -
Brasil
www.sanofi.com.br

CERTIFICADO DE ANALISE

PERICIAZINA (C1)

670184

Número do lote : 20RA11416

Data de fabricação : 13.DEZ.2019 Lote do Fornecedor/Ordem de processo : 20SN011
Data de validade : 30.NOV.2024 Data de reteste : 30.NOV.2024
Método Analítico : PERICIAZINA (C1) MP-0496-02
Lote de Controle : 6663911
Descrição:Pó fino
Referência:MP-0496-02
Fabricante : Katsura Chemical Co. Ltd.,4-15-19 Hibarigaoka Zama City Kanag, KANAGAWA
: Japão,

Certificado de Conformidade : Este lote foi aprovado em conformidade com as especificações.

Testes	Especificação	Resultados
ASPECTO	Pó fino a levemente granuloso, amarelo.	Pó fino a levemente granuloso, amarelo.
IDENTIFICAÇÃO: IR	O espectro da amostra é similar ao espectro do padrão	O espectro da amostra é similar ao espectro do padrão
ASPECTO DA SOLUÇÃO	Não mais opalescente que suspensão referência II.	Não mais opalescente que suspensão referência II.
PONTO DE FUSÃO	113 a 118 Celsius	117 Celsius
PERDA POR DESSECAÇÃO	<= 0.50 %	0.30 %
CINZAS SULFATADAS	<= 0.10 %	0.04 %
METAIS PESADOS	<= 0.0020 %	< 0.0020 %
SUBST. REL. RP 18688	<= 0.15 %	< 0.00 %
SUBST. REL. RP 9116	<= 0.15 %	< 0.06 %
SUBST. REL. RP 26794	<= 0.15 %	< 0.01 %
SUBST.REL. Impureza A	<= 0.10 %	< 0.00 %
SUBST. REL. IMP.TRR 0,92	<= 0.15 %	< 0.02 %
SUBST. REL.QUALQUER IMP>0,10%	Não aplicável	Conforme
SUBST.REL.-TOTAL IMPUREZAS	<= 0.35 %	0.13 %
SOLV. RES.: METANOL	<= 0.300 %	0.000 %
SOLV. RES: ACETATO DE ETILA	<= 0.500 %	0.034 %
SOLV. RES: TOLUENO	<= 0.089 %	0.000 %
DOSEAMENTO, sobre base seca	98.0 a 101.0 %	99.7 %



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Testes	Especificação	Resultados
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Certificamos que este lote foi testado de acordo com as normas vigentes de GMP e atende as especificações.

Certificat d'analyses Certificate of analysis



SANOFI CHIMIE
45 chemin de METELINE BP15
04201 SISTERON CEDEX
Téléphone: +33(0)4 92 33 32 00
Télécopie: +33(0)4 92 33 33 29

Article	: 670184	Batch number	: 20SN011
Denomination	: PROPERICIAZINE BASE		
Control number	: SIS CQ/18670		
Manufacturing date	: 13-DEC-2019		
Retest date	: 30-NOV-2024		
Monograph	: CHEM-MONO-CPA-00035 V7.0 MONO-GMID-670184-365		
Certificate version:	1		

CONTROLES/TESTS	NORMES/SPECIFICATIONS	RESULTATS/RESULTS
CARACTERES/CHARACTERS		
Aspect/ Appearance	Poudre fine à légèrement granuleuse jaune/ Fine to slightly granular yellow powder	POUDRE LEGEREMENT GRANULEUSE JAUNE SLIGHTLY GRANULAR YELLOW POWDER
IDENTIFICATION/IDENTIFICATION		
Spectre infrarouge/Infrared spectrum	Conforme/Complies	Conforme/Complies
ESSAI/TEST		
Aspect de la solution d'acétate d'éthyle (0.2g+5ml)/ Appearance of ethyl acetat solution (0.2g+5ml)	Pas supérieur à TII/ Not more than TII	<TII/<TII
Point de fusion/ Melting point	113 à 118°C/ 113 to 118°C	117 °C

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CONTROLES/TESTS	NORMES/SPECIFICATIONS	RESULTATS/RESULTS
Substances apparentées par CPL/Related substances by LC		
- RP18688/ . RP18688	Pas supérieure à 0.10 p.cent/ Not more than 0.10 p.cent	<0.05 p.cent
- RP9116/ . RP9116	Pas supérieure à 0.10 p.cent/ Not more than 0.10 p.cent	<0.06 p.cent
- RP26794/ . RP26794	Pas supérieure à 0.15 p.cent/ Not more than 0.15 p.cent	<0.05 p.cent
- impureté A (amide)/ . impurity A (amide)	Pas supérieure à 0.10 p.cent/ Not more than 0.10 p.cent	<0.05 p.cent
- impureté Trr 0.92/ . impurity Trr 0.92	Pas supérieure à 0.10 p.cent/ Not more than 0.10 p.cent	<0.05 p.cent
- chaque autre impureté/ . each other impurity	Pas supérieure à 0.10 p.cent/ Not more than 0.10 p.cent	<0.05 p.cent
- somme des impuretés/ . sum of impurities	Pas supérieure à 0.35 p.cent/ Not more than 0.35 p.cent	0.00 p.cent
Solvants résiduels par CPG Headspace/Residual solvents by Headspace GC		
- acétate d'éthyle/ . ethyl acetat	Pas supérieur à 0.500 p.cent/ Not more than 0.500 p.cent	0.047 p.cent
- méthanol/ . methanol	Pas supérieur à 0.300 p.cent/ Not more than 0.300 p.cent	<0.030 p.cent
- toluène/ . toluen	Pas supérieur à 0.089 p.cent/ Not more than 0.089 p.cent	<0.009 p.cent
Métaux lourds/ Heavy metals	Pas supérieurs à 0.0020 p.cent/ Not more than 0.0020 p.cent	<0.0020 p.cent
Perte à la dessiccation/ Loss on drying	Pas supérieure à 0.50 p.cent/ Not more than 0.50 p.cent	0.02 p.cent

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CONTROLES/TESTS	NORMES/SPECIFICATIONS	RESULTATS/RESULTS
Cendres sulfuriques/ Sulphated ash	Pas supérieures à 0.10 p.cent/ Not more than 0.10 p.cent	0.01 p.cent
DOSAGE/ASSAY		
Teneur en propériciazine base pour 100 g de substance desséchée/	98.5 à 101.0 p.cent/	100.0 p.cent
Propericiazine base calculated with reference to the dried substance	98.5 to 101.0 p.cent	

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This batch has been manufactured in compliance with the current Good Manufacturing Practice requirements and complies with the specifications of the relevant regulatory dossier.

Commentaire AQ/Observation QA: Regulatory restrictions must be considered for France, Spain, Netherlands and UK markets.

Decision

Date de décision/Decision date	16-OCT-2020 18:33:03
Responsable/Manager	GEORGES Aurore - Quality assurance deputy manager
Décision/Decision	Released with restriction

Certificat d'analyse approuvé électroniquement/Certificate of analysis approved electronically