



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

CLORIDRATO CLORPROMAZINA (C1) - SISTERON

553327

Número do lote : **20RA12368**

Data de fabricação : 17.OUT.2020 Lote do Fornecedor/Ordem de processo : ASNE004
 Data de validade : 16.OUT.2025 Data de reteste : 16.OUT.2025
 Método Analítico : CLORIDRATO DE CLORPROMAZINA MP-0406-03
 Lote de Controle : 6671024
 Descrição: Pó cristalino branco
 Referência: MP-0406-03
 Fabricante : SANOFI CHIMIE, 45 R 45, CHEMIN DE METELINE, SISTERON CEDEX 01 FRANCE
 : França, 04 92333200
 Certificado de Conformidade : Este lote foi aprovado em conformidade com as especificações.

| Testes | Especificação | Resultados |
|------------------------------|---|---|
| ASPECTO | Pó cristalino branco ou quase branco | Pó cristalino branco ou quase branco |
| IDENTIFICAÇÃO: IR | O espectro da amostra é similar ao espectro do padrão | O espectro da amostra é similar ao espectro do padrão |
| IDENTIFICAÇÃO: CLORETOS | A solução amostra responde ao teste de cloretos | A solução amostra responde ao teste de cloretos |
| pH (25 °C) | 3.5 a 4.5 | 4.2 |
| S.R.: IMPUREZA A | <= 0.15 % | < 0.05 % |
| S.R.: IMPUREZA B | <= 0.3 % | < 0.1 % |
| S.R.: IMPUREZA C | <= 0.3 % | < 0.1 % |
| S.R.: IMPUREZA D | <= 0.3 % | < 0.1 % |
| S.R.: IMPUREZA E | <= 0.15 % | < 0.05 % |
| S.R.: IMP. IND. DESCONHECIDA | <= 0.10 % | < 0.05 % |
| S.R.: TOTAL DE IMPUREZAS | <= 1.0 % | 0.0 % |
| IMPUREZA F | <= 0.15 % | < 0.15 % |
| METAIS PESADOS | <= 10 ppm | < 10 ppm |
| PERDA POR DESSECAÇÃO | <= 0.5 % | 0.0 % |
| CINZAS SULFATADAS | <= 0.1 % | 0.0 % |
| DOSEAMENTO, substância seca | 99.0 a 101.0 % | 100.3 % |
| SOLVENTES RESIDUAIS: ACETONA | <= 0.5 % | < 0.5 % |



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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 : 553327 Batch number : ASNE004
Denomination : CHLORPROMAZINE CHLORHYDRATE
Control number : SIS CQ/18897 ✓
Manufacturing date : 17-OCT-2020 ✓
Retest date : 16-OCT-2025 ✓
Monograph : CHEM-MONO-PE-00034 V7.0
Certificate version: 4

| CONTROLES/TESTS | NORMES/SPECIFICATIONS | RESULTATS/RESULTS |
|--|--|--|
| CARACTERES/CHARACTERS | | |
| Aspect | Poudre cristalline blanche ou sensiblement blanche/ | POUDRE CRISTALLINE SENSIBLEMENT BLANCHE |
| Appearance | White or almost white crystalline powder | ALMOST WHITE CRYSTALLINE POWDER |
| IDENTIFICATION/IDENTIFICATION | | |
| Spectre infrarouge/Infrared spectrum | Conforme/Complies | Conforme/Complies |
| Reaction des chlorures/ Reaction of chlorides | Conforme/Complies | Conforme/Complies |
| ESSAI/TESTS | | |
| pH de la solution aqueuse à 10 p.cent/ pH of 10 p.cent aqueous solution | 3.5 à 4.5 p.cent/ 3.5 to 4.5 p.cent | 4.2 |
| Impureté F/ Impurity F | Pas supérieure à 0.15 p.cent/ Not more than 0.15 p.cent | < 0.15 p.cent |

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| CONTROLES/TESTS | NORMES/SPECIFICATIONS | RESULTATS/RESULTS |
|-----------------|-----------------------|-------------------|
|-----------------|-----------------------|-------------------|

| | | |
|--|-------------------------------|--------------|
| Substances apparentées par CPL/Related substances by LC | | |
| - Impureté A(chlorpromazine sulfoxyde)/ | Pas supérieure à 0.15 p.cent/ | <0.05 p.cent |
| . Impurity A(chlorpromazine sulfoxyde) | Not more than 0.15 p.cent | |
| - Impureté B(chaine aminée doublée)/ | Pas supérieure à 0.3 p.cent/ | <0.05 p.cent |
| . Impurity B(double amined chain) | Not more than 0.3 p.cent | |
| - Impureté C(promazine)/ | Pas supérieure à 0.3 p.cent/ | <0.05 p.cent |
| . Impurity C(promazine) | Not more than 0.3 p.cent | |
| - Impureté D(chlorpromazine desméthylée)/ | Pas supérieure à 0.3 p.cent/ | <0.05 p.cent |
| . Impurity D(desmethylchlorpromazine) | Not more than 0.3 p.cent | |
| - Impureté E(2-chloro phénothiazine)/ | Pas supérieure à 0.15 p.cent/ | <0.05 p.cent |
| . impurity E(2-chloro phénothiazine) | Not more than 0.15 p.cent | |
| - Chaque autre impureté/ | Pas supérieure à 0.10 p.cent/ | <0.05 p.cent |
| . Each other impurity | Not more than 0.10 p.cent | |
| - Somme des impuretés/ | Pas supérieure à 1.0 p.cent/ | 0.00 p.cent |
| . Sum of impurities | Not more than 1.0 p.cent | |
| Perte à la dessiccation/ | Pas supérieure à 0.5 p.cent/ | 0.0 p.cent |
| Loss on drying | Not more than 0.5 p.cent | |
| Cendres sulfuriques/ | Pas supérieures à 0.1 p.cent/ | 0.0 p.cent |
| Sulphated ash | Not more than 0.1 p.cent | |

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| | | | |
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| CONTROLES/TESTS | NORMES/SPECIFICATIONS | RESULTATS/RESULTS |
|---|-----------------------|-------------------|
| DOSAGE/ASSAY | | |
| Teneur en chlorhydrate de chlorpromazine pour 100 g de substance desséchée/ | 99.0 à 101.0 p.cent/ | 100.3 p.cent |
| Chlorpromazine hydrochloride calculated with reference to the dried substance | 99.0 to 101.0 p.cent | |

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

| Decision | |
|--------------------------------|---|
| Date de décision/Decision date | 13-NOV-2020 11:01:39 |
| Responsable/Manager | BOUCHET Sébastien- Quality assurance deputy manager |
| Décision/Decision | Accepté/Released |

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