

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231103-01

生产日期/Manufacturing Date: 2023.11.01

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311001	有效期至 Valid until	2027.10.31	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.03
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/IR, Test C 氯化物试验/Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol ≤0.5%	0.01%
	Hexane ≤0.029%	ND
	Toluene ≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.33%
硫酸灰分/Sulfated ash	≤0.1%	0.04%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
含量/Assay	99.0%~101.0%	100.1%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QAsupervisor

同峰

一化实验室负责人

QCsupervisor

徐艳

检验员

Analyst

黄新

王代



常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231104-01

生产日期/Manufacturing Date: 2023.11.02

产品名称 Product Name	盐酸氯丙嗪 $C_{17}H_{19}ClN_2S \cdot HCl$ Chlorpromazine Hydrochloride					批号 Batch	300.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311002	有效期至 Valid until	2027.11.01	数量 Quantity	300.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co., Ltd.			收到日期 Received Date	2023.11.04
检品来源 Sample From	原料药车间 API workshop	抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA	报告日期 Report Date	2023.11.22		

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freeely soluble in water、ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol ≤0.5%	0.01%
	Hexane ≤0.029%	ND
	Toluene ≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.41%
硫酸灰分/Sulfated ash	≤0.1%	0.02%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0%
		99.8%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QASupervisor

同峰

化验室负责人

QCSupervisor 徐艳

检验员

Analyst

黄淑洁 仇志

检验专用章



0.2g/100g

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No:YC231106-01

生产日期/Manufacturing Date:2023.11.03

产品名称 Product Name		盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride				批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311003	有效期至 Valid until	2027.11.02	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.06
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test	Complies
	C 氯化物试验/ Chlorides test	Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	196~197℃
有关物质 Other alkylated phenothianes	$\leq 0.5\%$	0.14%
残留溶剂 Residual solvent	Isopropyl alcohol $\leq 0.5\%$	0.01%
	Hexane $\leq 0.029\%$	ND
	Toluene $\leq 0.089\%$	ND
干燥失重/Loss on drying	$\leq 0.5\%$	0.30%
硫酸灰分/Sulfated ash	$\leq 0.1\%$	0.03%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10 cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10 cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards

签署 (盖章)

QAsupervisor

化验室负责人

QCSupervisor

检验员

Analyst

检验专用章



27/11/23

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No:YC231107-01

生产日期/Manufacturing Date:2023.11.04

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311004	有效期至 Valid until	2027.11.03	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.07
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5-4.5	3.8
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.14%
残留溶剂 Residual solvent	Isopropyl alcohol≤0.5%	0.01%
	Hexane≤0.029%	ND
	Toluene≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.26%
硫酸灰分/Sulfated ash	≤0.1%	0.02%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0% 99.7%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QAsupervisor

同峰

化验室负责人

QCSupervisor

徐艳

检验员

Analyst

黄毅

1025



2023/11/22

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No:YC231108-01

生产日期/Manufacturing Date:2023.11.06

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311005	有效期至 Valid until	2027.11.05	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.08
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.8
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol≤0.5%	0.01%
	Hexane≤0.029%	ND
	Toluene≤0.089%	0.0002%
干燥失重/Loss on drying	≤0.5%	0.36%
硫酸灰分/Sulfated ash	≤0.1%	0.02%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0% 100.2%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QAsupervisor

同峰

化验室负责人

QCSupervisor

徐艳

检验员

Analyst

黄颖洁 杨斌



2023/11/22

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231109-01

生产日期/Manufacturing Date: 2023.11.07

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311006	有效期至 Valid until	2027.11.06	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.09
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	196~197℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol ≤0.5%	0.01%
	Hexane ≤0.029%	ND
	Toluene ≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.29%
硫酸灰分/Sulfated ash	≤0.1%	0.03%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0%
		100.2%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards

签署 (盖章)

QAsupervisor

同峰

化验室负责人

QCsupervisor 练松

检验员

Analyst

黄颖佳 1424



2023/11/11

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No.:YC231110-01

生产日期/Manufacturing Date:2023.11.08

产品名称 Product Name	盐酸氯丙嗪 $C_{17}H_{19}ClN_2S \cdot HCl$ Chlorpromazine Hydrochloride					批号 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311007	有效期至 Valid until	2027.11.07	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.10
检品来源 Sample From	原料药车间 API workshop	抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA			报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test	Complies
	C 氯化物试验/ Chlorides test	Positive Reaction
酸度/Acidity (pH)	3.5~4.5	4.0
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol≤0.5%	0.01%
	Hexane≤0.029%	ND
	Toluene≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.33%
硫酸灰分/Sulfated ash	≤0.1%	0.02%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards

签署 (盖章)

QA supervisor

同峰

实验室负责人

QC supervisor 徐艳

检验员

Analyst 董颖佳 杜斌



2023/11/22
fch

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231111-01

生产日期/Manufacturing Date: 2023.11.09

产品名称 Product Name	盐酸氯丙嗪 $C_{17}H_{19}ClN_2S \cdot HCl$ Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311008	有效期至 Valid until	2027.11.08	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co., Ltd.			收到日期 Received Date	2023.11.11
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.8
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol ≤0.5%	0.01%
	Hexane ≤0.029%	ND
	Toluene ≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.25%
硫酸灰分/Sulfated ash	≤0.1%	0.05%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0% 100.3%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

化验室负责人

检验员

QAsupervisor

QCsupervisor

Analyst

周峰

徐艳

黄颖佳



2023/11/22
fca

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231113-01

生产日期/Manufacturing Date: 2023.11.10

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S·HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311009	有效期至 Valid until	2027.11.09	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.13
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/ Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/ Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/ IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.8
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	≤0.5%	0.14%
残留溶剂 Residual solvent	Isopropyl alcohol ≤0.5%	0.01%
	Hexane ≤0.029%	ND
	Toluene ≤0.089%	ND
干燥失重/Loss on drying	≤0.5%	0.18%
硫酸灰分/Sulfated ash	≤0.1%	0.05%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
含量/Assay	99.0%~101.0%	100.3%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QAsupervisor

同峰 化验室负责人

QCsupervisor

检验员

Analyst

黄颖洁 伍斌



23/11/23

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No:YC231114-01

生产日期/Manufacturing Date:2023.11.11

产品名称 Product Name	盐酸氯丙嗪 $C_{17}H_{19}ClN_2S \cdot HCl$ Chlorpromazine Hydrochloride					批号 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311010	有效期至 Valid until	2027.11.10	数量 Quantity	275.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.14
检品来源 Sample From	原料药车间 API workshop		抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA		报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water, ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/IR.Test C 氯化物试验/Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	195.5~196.5℃
有关物质 Other alkylated phenothianes	$\leq 0.5\%$	0.14%
残留溶剂 Residual solvent	Isopropyl alcohol $\leq 0.5\%$	0.01%
	Hexane $\leq 0.029\%$	ND
	Toluene $\leq 0.089\%$	ND
干燥失重/Loss on drying	$\leq 0.5\%$	0.23%
硫酸灰分/Sulfated ash	$\leq 0.1\%$	0.01%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g	<10cfu/g
	霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g	<10cfu/g
	应不得检出大肠埃希菌 Escherichia coli should not be detected	ND
	含量/Assay	99.0%~101.0%
		100.2%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards

签署 (盖章)

QAsupervisor

同峰

化验室负责人

QCSupervisor

徐艳

检验员

Analyst

黄毅浩 122



29/11

CHANGZHOU KANGPU PHARMACEUTICAL CO., LTD.

常州康普药业有限公司

ADD: 6 Jingde East Road, Qianhuang Town, Wujin District

质量检验报告

CERTIFICATE OF ANALYSIS

报告号/ Report No: YC231115-01

生产日期/Manufacturing Date: 2023.11.13

报告号/ Report No: YC231115-01

产品名称 Product Name	盐酸氯丙嗪 C ₁₇ H ₁₉ ClN ₂ S•HCl Chlorpromazine Hydrochloride					批量 Batch	275.0kg
包装 Packaging	25kg/drum	批号 Batch Number	CL2311011	有效期至 Valid until	2027.11.12	数量 Quantity	225.0kg
检验项目 Test Items	全检 Full test	生产厂家 Manufacturer	常州康普药业有限公司 Changzhoukangpu pharmaceutical Co.,Ltd.			收到日期 Received Date	2023.11.15
检品来源 Sample From	原料药车间 API workshop	抽样部门 Sampled By	由 QA 负责抽样 Sampled by QA			报告日期 Report Date	2023.11.22

检验依据: BP2022 和内控标准/ Basis for Analysis: Based on BP2022 and In house standards

检验项目/Test Items	接受标准/Specification	检验结果/Test Result
外观/Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	Almost white crystalline powder
溶解性/Solubility	易溶于水、乙醇或氯仿/Freely soluble in water、ethanol or chloroform 在乙醚或苯中几乎不溶/Almost insoluble in ether or benzene	Complies
鉴别/Identification	A 红外测试/IR.Test C 氯化物试验/ Chlorides test	Complies Positive Reaction
酸度/Acidity (pH)	3.5~4.5	3.7
熔点/Melting point	195~198℃	196~197℃
有关物质 Other alkylated phenothianes	$\leq 0.5\%$	0.15%
残留溶剂 Residual solvent	Isopropyl alcohol $\leq 0.5\%$ Hexane $\leq 0.029\%$ Toluene $\leq 0.089\%$	0.01% ND ND
干燥失重/Loss on drying	$\leq 0.5\%$	0.18%
硫酸灰分/Sulfated ash	$\leq 0.1\%$	0.03%
微生物限度 Microbiological purity	需氧菌应不得过 10^3 cfu/g Aerobic bacteria should not exceed 10^3 cfu/g 霉菌和酵母菌应不得过 10^2 cfu/g Mould and yeast should not exceed 10^2 cfu/g 应不得检出大肠埃希菌 Escherichia coli should not be detected	$<10^3$ cfu/g $<10^3$ cfu/g ND
含量/Assay	99.0%~101.0%	99.7%

结论: 本品按 BP2022 和内控标准检验, 结果符合规定。

Conclusion: The test results above BP2022 and In house standards.

签署 (盖章)

QAsupervisor

化验室负责人

QCsupervisor

检验员

Analyst

葛颖洁 11/22



27/11/23