



安丘市鲁安药业有限责任公司

ANQIU LU'AN PHARMACEUTICAL CO., LTD.

No. 35, Weixu North Road, Anqiu City, Shandong Province, 262100 China

Tel: 86-536-4386559 Fax: 86-536-4390696

E-mail: luan@luanpharm.com Http://www.luanpharm.com

Certificate of Analysis

Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240819
Batch No.	2410344	Manufacturing Date:	2024.04.06
Quantity:	3000kg	Expiry Date:	2028.04.06
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.08%
Residue on Ignition:	≤0.1%	USP <281>	0.04%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.006%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤ 0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.013%
	Total impurities: ≤0.1%		0.023%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.2%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

*. ND means not detected.

**. Skip test. It will be tested once a month.

Manufacturer: Anqiu Lu'an Pharmaceutical Co., Ltd.

DOCUMENTARY CREDIT NUMBER MI62324000181 DATE 240619





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Certificate of Analysis

Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240825
Batch No.	2410345	Manufacturing Date:	2024.04.06
Quantity:	6000kg	Expiry Date:	2028.04.06
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.08%
Residue on Ignition:	≤0.1%	USP <281>	0.04%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.008%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.012%
	Total impurities: ≤0.1%		0.024%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.4%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240840
Batch No.	2410353	Manufacturing Date:	2024.04.08
Quantity:	6000kg	Expiry Date:	2028.04.08
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.10%
Residue on Ignition:	≤0.1%	USP <281>	0.03%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.007%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.006%
	Total impurities: ≤0.1%		0.015%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.3%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Certificate of Analysis

Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240841
Batch No.	2410354	Manufacturing Date:	2024.04.08
Quantity:	6000kg	Expiry Date:	2028.04.08
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.09%
Residue on Ignition:	≤0.1%	USP <281>	0.03%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.004%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤ 0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.025%
	Total impurities: ≤0.1%		0.041%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.5%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240892
Batch No.	2410376	Manufacturing Date:	2024.04.14
Quantity:	6000kg	Expiry Date:	2028.04.14
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.09%
Residue on Ignition:	≤0.1%	USP <281>	0.04%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.005%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤ 0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.012%
	Total impurities: ≤0.1%		0.021%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.1%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240914
Batch No.	2410386	Manufacturing Date:	2024.04.17
Quantity:	6000kg	Expiry Date:	2028.04.17
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.10%
Residue on Ignition:	≤0.1%	USP <281>	0.02%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.010%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		0.001%
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.022%
	Total impurities: ≤0.1%		0.039%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	99.9%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240923
Batch No.	2410387	Manufacturing Date:	2024.04.17
Quantity:	6000kg	Expiry Date:	2028.04.17
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.08%
Residue on Ignition:	≤0.1%	USP <281>	0.03%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.012%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		ND
	Related compound J: ≤ 0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.028%
	Total impurities: ≤0.1%		0.049%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.7%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240961
Batch No.	2410408	Manufacturing Date:	2024.04.22
Quantity:	6000kg	Expiry Date:	2028.04.22
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.08%
Residue on Ignition:	≤0.1%	USP <281>	0.02%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.009%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		0.001%
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.018%
	Total impurities: ≤0.1%		0.035%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.1%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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Certificate of Analysis

Form No.: DW/BG/0200-04800

Product:	Paracetamol	COA No.:	2220240973
Batch No.	2410414	Manufacturing Date:	2024.04.24
Quantity:	5000kg	Expiry Date:	2028.04.24
Packing:	25kg/woven bag	Standard:	Current USP
Tests	Specification	Test Reference	Results
Characteristic:	Appearance: White, odorless, crystalline powder, having a slightly bitter taste.	USP monograph for Acetaminophen	Conforms
	Solubility**: Freely soluble in alcohol; soluble in boiling water and in 1N sodium hydroxide.		Conforms
Identification:	A. Infrared Absorption <197K>	USP Monograph for Acetaminophen	Conforms
	B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.		Conforms
Loss on Drying:	≤0.5%	USP <731>	0.10%
Residue on Ignition:	≤0.1%	USP <281>	0.02%
Limit of free 4-Aminophenol:	≤0.005%	USP Monograph for Acetaminophen, HPLC method	ND*
Organic Impurity:	Related compound B: ≤0.05% (N-(4-Hydroxyphenyl) propanamide)	USP Monograph for Acetaminophen, HPLC method	0.005%
	Related compound C: ≤0.05% (N-(2-Hydroxyphenyl) Acetamide)		ND
	Related compound D: ≤0.05% (N-Phenylacetamide)		0.001%
	Related compound J: ≤0.001% (p-chloroacetanilide)		ND
	Individual unspecified impurity: ≤0.05%		0.026%
	Total impurities: ≤0.1%		0.044%
Assay:	98.0-102.0% (on the dried basis)	HPLC method	100.1%
Conclusion:	It conforms to Current USP.		
QA Manager:	Analyst:	Checker:	

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