



HEBEI JIHENG PHARMACEUTICAL CO., LTD.

No. 1 Wei wu Street Heng Shui Industrial Park He bei Province China 053000

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REC-BG00050-04

CERTIFICATE OF ANALYSIS

Name of Product	PARACETAMOL (ACETAMINOPHEN)		
Batch No.	012406304F	Report No.	0106304F(U)
Quantity	2580kg	Test Date	2024/07/01
Mfg. Date	2024/06/29	Report Date	2024/07/08
Quality Standard	USP43	Re-test Date	2028/06/28

Tests	Specification	Results
Appearance	White ,odorless, crystalline powder	White ,odorless, crystalline powder
Solubility	Freely soluble in alcohol; soluble in boiling water and in 1 N sodium Hydroxide	Conforms
Identification	A:Infrared Spectroscopy	Complies
	B: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies
Loss on drying	Not more than0.5%	0.10%
Residue on ignition	Not more than 0.1%	0.07%
Free 4-aminophenol	Not more than 0.005%	0.0003%
Organic impurities	Relatedcompound B(N-(4-Hydroxyphenyl) Propanamide not more than 0.05%	0.016%
	Relatedcompound C(N-(2-Hydroxyphenyl) acetamide)not more than 0.05%	ND(< LOD)
	Related compound D(N-Phenylacetamide) not more than 0.05%	ND(< LOD)
	Related compound J(p- chloroacetanilide) not more than 0.001%	ND(< LOD)
	Any unspecified impurity not more than 0.05%	0.012%
	Total impurities not more than 0.1%	0.041%
Assay(on the dried basis)	98.0~102.0%	100.1%
Residual solvent	Residual content of acetic acid is limited by the test of loss on drying not more than 0.5%	0.10%
Particle size	D50	4.344 μ m
	D90	12.946 μ m
Bacterial endotoxins	Not more than 0.15EU/mg	Less than 0.15EU/mg
Conclusion:	Complies with USP43	
Reported by:	Reviewed by:	Approved by:

- Identification : Having a slightly bitter taste

河北冀衡药业股份有限公司
HEBEI JIHENG PHARMACEUTICAL CO., LTD.

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Paracetamol	Hebei Jheng	USP43	USP47/ FI VI	Residual Solvent	Appearance : having slightly bitter taste Logan berat (FI VI) Particle size	- -	RD.02-SBA/126.04	Penyesuaian CoA dari Manufacturer Update SPBB

Diperiksa Oleh


23/10/24
Koordinator QC


23/10/24
Koordinator TS


23/10/24
Koordinator QA

Disetujui Oleh,


24/10/24
Manager QA