



Certificate of Analysis

Name of Product	: Paracetamol BP	Mfg. Date	: AUG – 24
Product Code	: P-201	Exp. Date	: JUL – 29
Batch No.	: FP-243034	Batch Size	: 4000 Kg
A.R. No.	: FP2/FG/2403399	Date of Analysis:	07/08/2024

Sr. No.	Tests	Specification	Result
1	Description	White or almost white crystalline powder	White crystalline powder.
2	Solubility	Sparingly Soluble in water Freely Soluble in 96% Ethanol Very Slightly Soluble in Methylene chloride	Complies Complies Complies
3	Identification (First Identification)		
	B. Infrared Spectroscopy	The Infrared absorption spectrum of the substance being examined must be concordant with the IR spectrum obtained from paracetamol working standard	Complies
	Identification (Second Identification)		
	A. Melting Point		
	Result- A	168 °C to 172 °C	170.1°C
	Result- B	The absolute difference between the melting point of the mixture and the value obtained in the determination is not greater than 2 °C.	0.3°C
4	Related Substances: (By Liquid Chromatography) (Ph. Eur. in-house)		
	Test-1: Related Substances:		
	Impurity K	Maximum 50 ppm	1.9 ppm
	Test-2: Related Substances:		
	Impurity B	NMT 0.05%	0.0049%
	Impurity C	NMT 0.05%	Not Detected
	Impurity D	NMT 0.05%	Not Detected
	Impurity J	Max. 10 ppm	Not Detected
	Unspecified impurities (For each impurity)	NMT 0.05%	0.0066%
	Total impurities	Max. 0.1%	0.016%
5	Loss on drying (at 105°C)	NMT 0.5% w/w	0.15%
6	Sulphated ash	NMT 0.1% w/w	0.03%
7	Assay (on dried basis)	99.0% to 101.0% w/w of C ₈ H ₉ NO ₂	99.8%
Additional In-house test:			
8	Bulk Density (Tapped)	0.60-0.70 g/ml	0.667 g/ml
9	Particle Size Distribution		
	Retained on 40 Mesh	NMT 5.0%	0.60%
	Retained on 100 Mesh	NLT 10.0%	11.07%