



**FINISHED PRODUCT SPECIFICATION**

<b>Product Name</b> : PARACETAMOL BP	<b>Code</b> : FP02
<b>Department</b> : Quality Control	<b>Document No.</b> : SPC/FP02/18
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<b>Effective Date</b> :	<b>Next Review Month</b> :

Reference	: BP-2023 + Inhouse	
Molecular weight	: 151.2	
Molecular formula	: C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>	
Ref. Finished Product Test Method	: TM/FP02/18	

Test No.	Name of Test	Acceptance Criteria	Test Method no.
1.	Appearance	White, or almost White, Crystalline Powder.	TM/FP02/A
2.	Solubility	Sparingly soluble in Water	TM/FP02/B
		Freely soluble in Ethanol (96%)	
		Very slightly soluble in Methylene Chloride	
3.	Identification First Identification : B Second Identification : A	(A) Result-A (Determination - A): Melting Point - 168°C to 172°C	TM/FP02/C
		Result-B: The absolute difference between the melting point mixture and the value obtained in Determination A (Result-A) is not greater than 2°C	
		(B) The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	



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Test No.	Name of Test	Acceptance Criteria	Test Method no.
4.	Related substance (by HPLC)	Related substance (Test-1) Impurity -K : Maximum 50 ppm (Test-2) Impurity -B – NMT 0.05% Impurity -C – NMT 0.05% Impurity -D – NMT 0.05% Impurity -J : Maximum 10 ppm % Un-Specified Impurity (for each Impurity) : Maximum 0.05% Total impurities : Maximum 0.1%	TM/FP02/D
5.	Loss on Drying (at 105°C)	Maximum 0.5 % w/w	TM/FP02/E
6.	Sulphated Ash	Maximum 0.1 % w/w	TM/FP02/F
7.	Assay (on dried basis)	99.0 % to 101.0 % w/w C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>	TM/FP02/G