



FINISHED PRODUCT SPECIFICATION

Product Name : PARACETAMOL IP	Code : FP01
Department : Quality Control	Document No. : SPC/FP01/08
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Effective Date :	Next Review Month :

Reference : IP-2022	
Molecular weight : 151.2	
Molecular formula : C ₈ H ₉ NO ₂	
Ref. Finished Product Test method : TM/FP01/08	

Test No.	Name of Test	Acceptance Criteria	Test Method No.
1.	Description	White Crystals or White Crystalline Powder.	TM/FP01/A
2.	Solubility	Freely soluble in Ethanol	TM/FP01/B
		Sparingly soluble in Water	
		Very slightly soluble in Dichloromethane	
3.	Identification Test A may be omitted if tests B, C, D are carried out. Test B, C, D may be omitted if test A is carried out.	(A) The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	TM/FP01/C
		(B) The absorbance at 249 nm is about 0.44	
		(C) A violet colour develops which does not turn to red.	
		(D) Gives the reaction of acetyl groups.	



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Test No.	Name of Test	Acceptance Criteria	Test Method No.
4.	Related Substances (by Liquid Chromatography) Impurity J Impurity K Impurity F Any other Impurity Total of other Impurities	Not more than 10 ppm Not more than 50 ppm Not more than 0.05% Not more than 0.05% Not more than 0.1%	TM/FP01/D
5.	Heavy Metals	Not more than 10 ppm.	TM/FP01/E
6.	Sulphated Ash	Not more than 0.1 % w/w	TM/FP01/F
7.	Loss on Drying (at 105°C)	Not more than 0.5 % w/w	TM/FP01/G
8.	Assay (On dried basis)	99.0 % to 101.0 % w/w C ₈ H ₉ NO ₂ .	TM/FP01/H