



FINISHED PRODUCT SPECIFICATION

Product Name : ACETAMINOPHEN JP	Code : FP11
Department : Quality Control	Document No. : SPC/ FP11/05
Supersedes : 04	Page : 1 of 2
Effective Date :	Next Review Month :

Reference : JP-XVIII	
Molecular Weight : 151.16	
Molecular Formula : C ₈ H ₉ NO ₂	
Ref. Finished Product Test method : TM/FP11/05	

Test No.	Name of Test	Acceptance Criteria	Test Method No.
1.	Description	White Crystals or Crystalline Powder	TM/FP11/A
2.	Solubility	Freely soluble in methanol & ethanol (95%)	TM/FP11/B
		Sparingly soluble in Water	
		Very slightly Soluble in diethyl ether	
		Soluble in 1 N NaOH	
3.	Identification	The Infrared absorption spectrum of Acetaminophen being examined must be concordant with the IR spectrum obtained from Acetaminophen working standard.	TM/FP11/C
4.	Melting Point	Between 169° and 172°C	TM/FP11/D
5.	Purity		
5.1	Chloride	Not more than 0.014%	TM/FP11/E
5.2	Sulfate	Not more than 0.019%	TM/FP11/F
5.3	Heavy metals	Not more than 10 ppm	TM/FP11/G



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Test No.	Name of Test	Acceptance Criteria	Test Method No.
5.4	Arsenic	Not more than 2 ppm	TM/FP11/H
5.5	Related substances	The total area of all peaks other than the peak area of acetaminophen from the sample solution should not be larger than the peak area of acetaminophen from the standard solution.	TM/FP11/I
6.	Loss on drying	Not more than 0.3%	TM/FP11/J
7.	Residue on ignition	Not more than 0.1%	TM/FP11/K
8.	Assay (On dried basis)	Not less than 98.0% of C ₈ H ₉ NO ₂	TM/FP11/L