

Farmson Pharmaceutical Gujarat Pvt. Ltd. Nandesari, Vadodara



FINISHED PRODUCT SPECIFICATION

Product Name : PARACETAMOL BP	Code : FP02
Department : Quality Control	Document No. : SPC/FP02/10
Supersedes : 09	Page : 1 of 2
Effective Date : 01/01/2019	Next Review Month : DEC-2021

Reference : BP-2019	
Molecular weight : 151.2	
Molecular formula : C ₈ H ₉ NO ₂	
Ref.Finished Product Test Method : TM/FP02/10	

Test No.	Name of Test	Acceptance Criteria	Test Method no.
1.	Appearance	White, or almost White, Crystalline Powder.	TM/FP02/A
2.	Solubility	Springly 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 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	TM/FP02/C
		(B) The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	

	Prepared By	Reviewed By		Approved By
Name	Vinod Patel	Varsha Pandya	ArunKumar Singh	K.P. Singh
Designation	Executive -QC	Asst. Manager - QC	Manager -QA	GM - QA
Signature				
Date	19/11/18	19/11/18	19/11/2018	19/11/2018

Issued by QA (Sign/date) :	Copy No. :
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FQC-049/A/00

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Test No.	Name of Test	Acceptance Criteria	Test Method no.
4.	Related Substances (by Liquid Chromatography) Impurity J Impurity K Un-specified Impurity (For Each Impurity) Total Impurities	Maximum 10 ppm Maximum 50 ppm Maximum 0.05 % Maximum 0.2 %	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 ₈ H ₉ NO ₂	TM/FP02/G

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