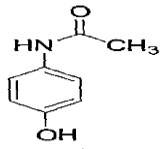
FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. NANDESARI, VADODARA.	
FINISHED PRODUCT SPECIFICATION	

Product Name	**:**	**ACETAMINOPHEN USP**	**Code**	**:**	**FP10**
Department	**:**	**Quality Control**	**Document No.**	**:**	**SPC/FP10/12**
Supersedes	**:**	**11**	**Page**	**:**	**1 of 2**
Effective Date	**:**		**Next Review Month**	**:**	

Reference	:	USP-NF 2023
Molecular Weight	:	151.16
Molecular Formula	:	$C_8H_9NO_2$
Ref. Finished Product Test method	:	TM/FP10/12



Test No.	Name of Test	Acceptance Criteria	Test Method No.
1.	Description	White, Odorless, Crystalline Powder	TM/FP10/A
2.	Solubility	Freely soluble in Ethyl Alcohol. Soluble in Boiling Water and in 1 N NaOH.	TM/FP10/B
3.	Identification		
	A. By IR	The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Acetaminophen working standard.	TM/FP10/C
	B. By HPLC	The retention time of the major peak obtained in sample solution corresponds to that obtained in the standard solution, as described in the test of assay.	TM/FP10/D
4.	Residue on ignition	Not More Than 0.1%	TM/FP10/E
5.	Loss on Drying (at 105ºC)	Not More Than 0.5%	TM/FP10/H
6.	Free 4-aminophenol (by HPLC)	Not More Than 0.005%	TM/FP10/F

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Test No.	Name of Test	Acceptance Criteria	Test Method No.
7.	Organic Impurities /Related substance (by HPLC)	Acetaminophen Related Compound B – NMT 0.05% Acetaminophen Related Compound C – NMT 0.05% Acetaminophen Related Compound D – NMT 0.05% Acetaminophen Related Compound J – NMT 0.001% Individual unspecified impurity - NMT 0.05% Total impurities – NMT 0.1%	TM/FP10/G
8.	Assay (by HPLC) (On dried basis)	98.0% - 102.0%, calculated on the dried basis.	TM/FP10/H