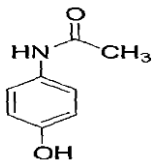
FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. NANDESARI, VADODARA.	

FINISHED PRODUCT SPECIFICATION

Product Name	**:**	**PARACETAMOL CP**	**Code**	**:**	**FP13**
Department	**:**	**Quality Control**	**Document No.**	**:**	**SPC/FP13/04**
Supersedes	**:**	**03**	**Page**	**:**	**1 of 2**
Effective Date	**:**		**Next Review Month**	**:**	

Reference	:	Chinese Pharmacopoeia -2015
Molecular weight	:	151.16
Molecular formula	:	$C_8H_9NO_2$
Ref. Finished Product Test method	:	TM/FP13/04



Test No.	Name of Test		Acceptance Criteria	Test Method No.
1.	Description		White Crystals or a Crystalline Powder, Odourless.	TM/FP13/A
2.	Solubility		Very soluble in Hot Water	TM/FP13/B
			Very soluble in Ethanol	
			Soluble in Acetone	
			Sparingly soluble in Water	
3.	Melting point		168º C-172°C	TM/FP13/C
4.	Identification Test	(I)	To the aqueous solution add ferric chloride TS; a bluish- violet color is produced.	TM/FP13/D
		(II)	To about 0.1 g add 5 ml of dilute hydrochloric acid, heat in a water bath for 40 minutes and cool. To 0.5 ml of the solution add 5 drops of sodium nitrite TS, mix well; dilute with 3 ml of water, add 2 ml of alkaline β-naphthol TS and shake: a red color is produced.	
		(III)	The Infrared absorption spectrum is concordant with the reference spectrum.	
5.	Acidity		pH 5.5 – 6.5	TM/FP13/E
6.	Clarity and color of ethanol solution		10% solution in ethanol should be clear and colorless. Any opalescence produced is not more pronounced than that of reference suspension 1. Any color produced is not more intense than of the reference solution BR_2 or OR_2.	TM/FP13/F

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Test No.	Name of Test	Acceptance Criteria	Test Method No.
7.	Chlorides	Any opalescence produced is not more intense than that of reference solution prepared by using 5 ml of sodium chloride standard solution (0.01%).	TM/FP13/G
8.	Sulfates	Any opalescence produced is not more intense than that of a reference solution prepared by using 1.0 ml of potassium sulfate standard solution (0.02%).	TM/FP13/H
9.	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/FP13/I
10.	Loss on Drying (at 105°C)	Not more than 0.5 % w/w	TM/FP13/J
11.	Residue on Ignition	Not more than 0.1%	TM/FP13/K
12.	Heavy Metals	Not more than 0.001%.	TM/FP13/L
13.	Assay By UV (On dried basis)	98.0% – 102.0%	TM/FP13/M