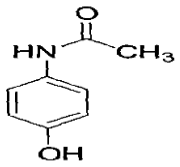
FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. NANDESARI, VADODARA.	
FINISHED PRODUCT SPECIFICATION	

Product Name	**:**	**PARACETAMOL Ph.Eur.**	**Code**	**:**	**FP04**
Department	**:**	**Quality Control**	**Document No.**	**:**	**SPC/FP04/16**
Supersedes	**:**	**15**	**Page**	**:**	**1 of 2**
Effective Date	**:**		**Next Review Month**	**:**	

Reference	:	Ph.Eur.(11th Edition) + In-house
Molecular Weight	:	151.2
Molecular formula	:	$C_8H_9NO_2$
Ref.Finished product Test method	:	TM/FP04/16



Test No.	Name of Test		Acceptance Criteria	Test Method No.
1.	Appearance		White, or almost White, Crystalline Powder.	TM/FP04/A
2.	Solubility		Sparingly soluble in Water Freely soluble in Ethanol (96%) Very slightly soluble in Methylene Chloride	TM/FP04/B
3.	Identification First Identification : B Second Identification : A	(A)	Result-A (Determination - A): Melting Point - 168°C to 172°C	TM/FP04/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	
		(B)	The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	

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

Product Name	**:**	**PARACETAMOL Ph.Eur.**	**Code**	**:**	**FP04**
Department	**:**	**Quality Control**	**Document No.**	**:**	**SPC/FP04/16**
Supersedes	**:**	**15**	**Page**	**:**	**2 of 2**
Effective Date	**:**		**Next Review Month**	**:**	

Test No.	Name of Test	Acceptance Criteria	Test Method No.
4.	Related substance (by HPLC)	Related substance (Test-1) Impurity -K : Maximum 50 ppm (Test-2) Impurity -B – NMT 0.05% Impurity -C – NMT 0.05% Impurity -D – NMT 0.05% Impurity -J : Maximum 10 ppm % Un-Specified Impurity (for each Impurity) : Maximum 0.05% Total impurities : Maximum 0.1%	TM/FP04/D
5.	Loss on Drying (at 105°C)	Maximum 0.5 % w/w	TM/FP04/E
6.	Sulphated Ash	Maximum 0.1 % w/w	TM/FP04/F
7.	Assay (on dried basis)	99.0 % to 101.0 % w/w $C_8H_9NO_2$	TM/FP04/G