WRS
P1-3

Formson Pharmaceutical Gujarat Pvt. Ltd.

WORKING STANDARD CERTIFICATE OF ANALYSIS PARACETAMOL BP

Q.C No.:	FP/P-1133/15	Batch No.:	FP-151133
Quantity:	1.0 g	Product Code:	P-101
Date of Manufacture:	JUL - 15	Date of Analysis:	14/12/2015
Date of Expiry;	JUN - 20	Use Before	14/12/2016

NATIONAL QUALITY CONTROL LABORATORY * P.O. Box 29726 - 00202, NAIROBI * TEL: 2726963/3544520 FAX: 2718073 RECEIVED 11 MAY 2016

Sr.No	Test	Result	Standard
01.	Description	A white crystalline powder.	White Crystals or white, crystalline powder.
02.	Identification:		
	Infrared spectroscopy	The IR Spectrum of sample is concordant with paracetamol working standard.	Spectrum of sample must be concordant with paracetamol working standard.
03.	Related Substances: (ByT.L.C)		
	Impurity J	Below Detection Limit	NMT 10 ppm
	Impurity K	4.90 ppm	NMT 50 ppm
	Impurity F	Below Detection Limit	NMT 0.05%
	Any other impurity	Not Detected	NMT 0.05%
	Total of other impurities	Not Detected	NMT 0.1%
04.	Heavy metals	<10 ppm	Not more than 10 ppm.
05.	Acidity	Not more than 0.4 ml of 0.01 M sodium hydroxide is required.	0.36 ml of 0.01 M NaOH consumed.
06.	Loss on drying (at 105^0C)	0.12%	Not more than 0.5% w/w
07.	Impurity E by thin-layer chromatography	Not more than 0.20%	Complies
08.	Related substances by HPLC Impurity A Any other impurity Total impurities	 Not more than 0.20% Not more than 0.10% Not more than 0.40%	 0.02% 0.04% 0.12%
09.	Sulphated ash	0.03%	Not more than 0.10%
10.	Assay (on dried basis)	99.00% to 101.00% w/w of $C_8H_9NO_2$.	99.96%

Conclusion: The material as above complies with the BP Specification.

	Prepared By (QC)	Checked By (QC)	Approved By (QA)
Name	[signature]	[signature]	[signature]
Designation	14/12/15	14/12/15	14/12/15

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