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BEXIMCO PHARMA

BEXIMCO PHARMACEUTICALS LIMITED
(TRACK -II) - TONGI - 1711, GAZIPUR, BANGLADESH
Phone: 88-02-9810701-5, Fax: 88-029810711, E-mail: info@bpl.net, Web: www.beximcopharma.com

CERTIFICATE OF ANALYSIS
(Working Standard)

Name of the standard	:	Paracetamol BP/Ph. Eur. WS			
Mfg. Batch No.	:	PYC004	Specification No.	:	SP/RM/001-08
AR No.	:	WS1505001	Reference	:	EP CRS
Date of preparation	:	06.05.15	Ref. Lot No.	:	4.0
Use before	:	06.05.16	Prepared Quantity	:	50 x 2.0 g
Storage condition	:	Store in closed container at a temperature 2 – 8°C			

Analytical Report

Test	Specification	Observation
Appearance	A white or almost white, crystalline powder.	A white, crystalline powder.
Identification		
i. By IR spectrophotometer	i. The IR spectrum obtained with the test sample corresponds with that of the spectrum of reference standard.	i. The IR spectrum obtained with the test sample corresponds with that of the spectrum of reference standard.
ii. By melting point	ii. 168 °C – 172 °C	ii. 170 °C
Related substances (by HPLC)		
i. 4-aminophenol (Imp. K)	i. Not more than 50 ppm	i. Not detected
ii. 4-chloroacetanilide (Imp. J)	ii. Not more than 10 ppm	ii. Not detected
iii. 4-nitrophenol (Imp. F)	iii. Not more than 0.05 %	iii. Not detected
iv. Any other impurity	iv. Not more than 0.05 %	iv. Below disregard limit
v. Total of other impurities	v. Not more than 0.1 %	v. Below disregard limit
Loss on drying (determined on 1.000 g at 105°C)	Maximum 0.5 %	0.14 %

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Analytical Report

Test	Specification	Observation
Assay (as is basis) (as Paracetamol)	For record	99.6 %
Assay On dried basis (titration method)	99.0 % - 101.0 % of Paracetamol	99.8 %

We hereby certify that, the working standard has been evaluated in accordance with the requirement of the approved SOP and specification.

Prepared By	Checked By	Approved By
06.05.15	06.05.15	06.05.15
Ratan Chandra Banik	Muhammad Aminul Islam	Md. Jahangir Alam
Sr. Officer, QC	Asst. Manager, QC	Deputy Manager, QC

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