

CERTIFICATE OF ANALYSIS

Q.C DEPARTMENT, DATE: 27.12.2018

BATCI-TQTY. 1650 Kg. FPC/PF2/0835/18-19 EXPIRY DATE DECEMBER, 201 AR NO. FPC/PF2/0835/18-19 EXPIRY DATE NOVEMBER, 202 SAMPLED BY : V.S.V.B.NAGARAJU DATE : 15.12.2018 SIGNATURE OF CHEMIST Sr. TESTS SPECIFICATIONS RESULTS 1 Characters A) Appearance White or almost white crystalline powder. White crystalline powder. B) Solubility Sparingly soluble in water, Freely soluble in ethanol (96 %) and very slightly soluble in methylene chloride 2 Identification A) Melting Point i) Determination – A :168°C – 172°C (Sample) ii) Determination – B :168°C – 172°C (Standard and Sample mixture) iii) The absolute difference between the melting point of determination A and determination B is not greater than 2°C. B) Infrared absorption spectrup for spectrum should be concordant with that of spectrum of standard. Complies 3 Loss on drying Not more than 0.5% w/w 0.16% 4 Sulfated Ash Not more than 0.1% w/w 0.06% 5 Assay (On dried substance) Not less than 99.0% and Not more than 101.0% 6 Related Substances By HPLC A) Impurity K Not more than 10 ppm Not detected B) Impurity J Not more than 0.05 % BRT (<0.03%)	PRODUCT PARACETAMOL Ph. Eur.				
AR NO. FPC/PF2/0835/18-19 EXPIRY DATE NOVEMBER, 202 SAMPLED BY : V.S.V.B.NAGARAJU DATE : 15.12.2018 SIGNATURE OF CHEMIST Sr. No. TESTS : SPECIFICATIONS RESULTS A) Appearance White or almost white crystalline powder. B) Solubility Sparingly soluble in water, Freely soluble in ethanol (96 %) and very slightly soluble in methylene chloride 2 Identification A) Melting Point i) Determination – A :168°C – 172°C (Sample) ii) Determination – B :168°C – 172°C (Standard and Sample mixture) iii) The absolute difference between the melting point of determination A and determination B is not greater than 2 °C. B) Infrared absorption Sample spectrum should be concordant with that of spectrum of standard. Sample spectrum of standard. Complies 3 Loss on drying Not more than 0.5% w/w 0.16% 4 Sulfated Ash Not more than 0.1% w/w 0.06% 5 Assay (On dried substance) Not less than 99.0% and Not more than 10.10% 6 Related Substances By HPLC A) Impurity K Not more than 10 ppm Not detected B) Impurity J Not more than 10.05 % BRT (<0.03%)				24.12.2018	
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Soluble in ethanol (96 %) and very slightly soluble in methylene chloride		A) Appearance	White or almost white crystalline powder.	White crystalline powder	
Slightly soluble in methylene chloride		B) Solubility	Sparingly soluble in water, Freely	Complies	
Slightly soluble in methylene chloride	:		soluble in ethanol (96 %) and very		
Identification					
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5 Assay (On dried substance) Not less than 99.0% and Not more than 101.0% 6 Related Substances By HPLC A) Impurity K B) Impurity J Not more than 50 ppm Not detected Not more than 10 ppm Not detected C) Un specified impurities Not more than 0.05 % BRT (<0.03%)	3		Not more than 0.5% w/w	0.16%	
A) Impurity K B) Impurity J C) Un specified impurities Not more than 50 ppm Not detected Not more than 10 ppm Not detected BRT (<0.03%)	4	Sulfated Ash	Not more than 0.1% w/w	0.06%	
A) Impurity K Not more than 50 ppm Not detected B) Impurity J Not more than 10 ppm Not detected C) Un specified impurities Not more than 0.05 % BRT (<0.03%)	5	Assay (On dried substance)		99.7%	
B) Impurity J Not more than 10 ppm Not detected C) Un specified impurities Not more than 0.05 % BRT (<0.03%)	6	Related Substances By HPLC			
C) Un specified impurities Not more than 0.05 % BRT (<0.03%)		A) Impurity K	Not more than 50 ppm	Not detected	
		' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	Not more than 10 ppm	Not detected	
		C) Un specified impurities	Not more than 0.05 %	BRT (<0.03%)	
		D) Total impurities	Not more than 0.2 %	BRT (<0.03%)	
REMARKS: BRT - Below reporting Threshold Our CEP No. R1-CEP 2000-144-Rev 05.					
PREPARED BY QC DATE: APPROVED BY WAS Sr. MANAGER-QC/DESIGNATE DATE: 27-12-18					
ISSUED TO: M/s					
REPORT NO: 4811 (M) ISSUED ON: 27.12.2018 The above Product COMPLIES with the Specifications of Ph.Eur.9.4					

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Sri Krishna Pharmaceuticals Ltd.

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