WRS D27-1

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		No: WS 03:P01
	WORKING STANDARD TEST PROTOCOL	Effective date: 22/01/15
Title	DILUTED POTASSIUM CLAVULANATE BP	A.R. Number:

Working standard Name:	Diluted potassium clavulanate BP	
B.No / Lot:	413141000?	Code number: WS 03
Manufacturing date:	10/14	Expiry date: 09/18
Manufacturer:	SHANDONG NEW TIME	Supplier: SHANDONG NEW TIME
Traceability of Reference standard:	EP CRS	B. No: 6.0 Validity on 05/02/15

WORKING STANDARD TEST REPORT

S. No	TEST	RESULT	LIMITS
1	Description	White powder hygroscopic	White or almost white powder, hygroscopic
2	Identification A): By HPLC B): Reaction of potassium C): Reaction of silicates	A): Complies B): Complies C): Complies	A) The principal peak in the test solution is similar in RT to the principal peak in ref solution (a). B) A yellow or orange yellow precipitate is formed immediately. C) White ring is formed around water
3	Water	1.31%	Not more than 2.5%
4	Related substances (HPLC) 1) Impurity E 2) Impurity G 3) Any unknown impurity 4) Total impurities	1) Impurity E <0.05% 2) Impurity G <0.05% 3) Unknown impurity 0.09% 4) Total impurities 0.09%	1) Impurity E: NMT 1.0% 2) Impurity G: NMT 1.0% 3) Any unknown impurity:NMT 0.2% 4) Total impurities: NMT 2.0%
5	Assay: (as is basis) 1) As potassium clavulanate 2) As Clavulanic acid	1) 49.58% 2) 41.63%	1) 45.60% w/w to 53.55 % w/w 2) Not Applicable

Remarks: The material is recommended to use as the substitute for the reference standard.

Intended use: Assay, Identification, dissolution and related substances/Chromatographic purity

Storage: Store in a cooling cabinet @ +5°c

Validity period:	No of vials prepared:	Vial Quantity:
From: 06/02/15 To: 05/02/16	12 & 30 vials	about 250mg

PREPARED BY	CHECKED BY	APPROVED BY
Sign: Date: 06/02/15	Sign: Date: 06/02/15	Sign: Date: 06/02/15

13 OCT 2015

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