## Transity loberty

## MEDOPHARM PRIVATE LIMITED GUDUVANCHERY

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No: WS 03:P01

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Effective date: 22/01/15

Title

WORKING STANDARD TEST PROTOCOL
DILUTED POTASSIUM CLAVULANATE BP

A.R. Number:

Working standard Name: Dilutee Pot	assem Clauslanale Bj
B.No/Lot: 4/3/4/0007	Code number: WS 03
Manufacturing date: /b//4	Expiry date: 09 /18
Manufacturer: SHANDONS NEW TIME	Supplier: SHAWBOAL NEW 71 me
Traceability of Reference standard: Epce	B. No: 6.0 Validity on 05/02/15-

	WC	RKING STANDARD TEST	REPORT
S. No	TEST	RESULT	LIMITS
1	Description	While Powder' My gras copie	White or almost white powder, hygroscopic
2 .	Identification A): By HPLC B): Reaction of potassium C): Reaction of silicates	A): lamplus  B): complus  C): (omplus	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	1.314	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) 49.58.5 2) 41.63.7.	1) 45.60% w/w to 53.55 % w/w 2) Not Applicable
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Intend	ks: The material is recommed use: Assay, Identification	ended to use as the substitute for dissolution and related substitutes welling the control of th	nnces/Chromatographic purity
Intend Storag	et use: Assay, Identification  e: Store 40 0	dissolution and related substance of the desired caling of the prepared:	ances/Chromatographic purity  Vial Quantity:
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