WHO-GMP Approved
An ISO 9001-2008
Certified company

CIN :U24230GJ1993PTC020695

Factory : Sokhada-388 620, Ta.-Khambhat
Dist.-Anand(Guj.) INDIA
Phone:(F) (+91) 7574878021 / 22 /23 /24
E-mail : mail@baroquepharma.com
Web : www.baroquepharma.com

BAROQUE
PHARMACEUTICALS PVT. LTD.

CERTIFICATE OF ANALYSIS

MATERIAL CODE : 100006U	**A.R.NO : BPRM180114**
MATERIALNAME : AMOXICILLIN TRIHYDRATE (EXTRA DRY) PURIMOX P USP	**Date of Analysis : 11/07/2018**
BATCH NO : M595908	**MFG.DATE : JUN 2018**
QTY.RECEIVED : 750.00 KG	**EXP DATE : MAY 2023**
SAMPLE QTY. : 0.0200 KG	**SPECIFICATION :** As per USP 40
RECEIPT DATE : 07/07/2018	**SPECIFICATION NO:** SP/100006U-4
MFG.BY : DSM SINOCHEM PHARMA P.LTD	**Working standard Number :** Amoxicillin USP : WS10000618A
SUPPLIED BY : DSM SINOCHEM PHARMA P.LTD	**Supplied by :** Baroque

Sr. No.	TEST	OBSERVATION	LIMIT
1.	Description	White, practically odorless, crystalline powder	White, practically odorless, crystalline powder
2.	Solubility	Slightly soluble in water and in methanol; insoluble in benzene, in carbon tetrachloride, and in chloroform	Slightly soluble in water and in methanol; insoluble in benzene, in carbon tetrachloride, and in chloroform
3.	Identification (By IR)	The IR spectrum of sample is concordant with the IR spectrum of standard.	The IR spectrum of sample should be concordant with the IR spectrum of standard.
4.	Crystallinity*	Complies	The particles should show birefringence and extinction positions when the microscope stage is revolved.
5.	pH	4.8	Between 3.5 and 6.0
6.	Water*	12.16%	Between 11.5% and 14.5%
7.	Dimethylaniline	#	Not more than 20 ppm

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
17/07/2018	17/07/2018	17/07/2018
RIKEN PATEL	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

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SAMPLE QTY. : 0.0200 KG	**SPECIFICATION :** As per USP 40
RECEIPT DATE : 07/07/2018	**SPECIFICATION NO:** SP/100006U-4
MFG.BY : DSM SINOCHEM PHARMA P.LTD	**Working standard Number :** Amoxicillin USP : WS10000618A
SUPPLIED BY : DSM SINOCHEM PHARMA P.LTD	**Supplied by :** Baroque

Sr. No.	TEST	OBSERVATION	LIMIT
8.	Organic Impurities*		
	(A) Amoxicillin Related Compound I	Not detected	Not more than 1.0%
	(B) Amoxicillin Related Compound D At RRT 0.53	Not detected	Not more than 1.0%
	(C) Amoxicillin Related Compound D At RRT 0.68	Not detected	Not more than 1.0%
	(D) Amoxicillin Related Compound A	Not detected	Not more than 0.5%
	(E) Amoxicillin Related Compound G	Not detected	Not more than 1.0%
	(F) Amoxicillin Related Compound E At RRT 4.5	Not detected	Not more than 1.0%

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
17/07/2018	17/07/2018	17/07/2018
RIKEN PATEL	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

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MFG.BY : DSM SINOCHEM PHARMA P.LTD	**Working standard Number :** Amoxicillin USP : WS10000618A
SUPPLIED BY : DSM SINOCHEM PHARMA P.LTD	**Supplied by :** Baroque

Sr. No.	TEST	OBSERVATION	LIMIT
	(G) Amoxicillin Related Compound E At RRT 6.7	Not detected	Not more than 1.0%
	(H) Amoxicillin Related Compound M	Not detected	Not more than 1.0%
	(I) Amoxicillin Related Compound C	Not detected	Not more than 1.0%
	(J) Amoxicillin Related Compound J	Not detected	Not more than 1.0%
	(K) Amoxicillin Related Compound L	Not detected	Not more than 1.0%
	(L) Any unspecified individual impurity	0.201%	Not more than 1.0%
	(M) Total impurities	0.464%	Not more than 5.0%

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
17/07/2018	17/07/2018	17/07/2018
RIKEN PATEL	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

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SAMPLE QTY. : 0.0200 KG	**SPECIFICATION :** As per USP 40
RECEIPT DATE : 07/07/2018	**SPECIFICATION NO:** SP/100006U-4
MFG.BY : DSM SINOCHEM PHARMA P.LTD	**Working standard Number :** Amoxicillin USP : WS10000618A
SUPPLIED BY : DSM SINOCHEM PHARMA P.LTD	**Supplied by :** Baroque

Sr. No.	TEST	OBSERVATION	LIMIT
9.	Assay	991.2 µg/mg	Amoxicillin contains not less than 900 µg and not more than 1050 µg of $C_{16}H_{19}N_3O_5S$ per mg, calculated on the anhydrous basis.

* This test is performed at choksi laboratories report No: 4463/14072018/16

Dimethylaniline is not used in the manufacturing process, hence not tested.

Storage conditions: Store in dry place, between 20°C to 25°C.

REMARK: THE MATERIAL COMPLIES AS PER USP 40 SPECIFICATION.

RELEASE DATE: 17/07/2018

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
17/07/2018	17/07/2018	17/07/2018
RIKEN PATEL	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

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SINOCHEM | DSM
DSM Sinochem Pharmaceuticals

DSM Sinochem Pharmaceuticals India Private Limited
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www.dsm-sinochem.com
www.pureactives.com

CERTIFICATE OF ANALYSIS

Name of Product	:	Purimox ® Compacted Grade P
Active ingredient	:	Amoxicillin Trihydrate
Batch / Lot No.	:	M595908
Batch / Lot No. Size (Kg)	:	750
Date of manufacture	:	Jun, 2018
Date of expiry	:	May, 2023
Date of release	:	June 25, 2018

Analytical results

Parameter	Specification		Results	
Appearance	White to almost white granules	:	Complies	
Identification (IR / HPLC)	Conforms with test	:	Complies	
Solubility	Conforms with test	:	Complies if tested	
Crystallinity	Crystalline	:	Complies	
pH	3.5 to 6.0	:	4.9	
N,N-Dimethylaniline	< 20 ppm	:	Not applicable	
Water content by KF	11.5 to 14.5	:	13.0	% w/w
Sulphated ash	≤ 1.00	:	0.09	% w/w
Assay (on anhydrous)	900 to 1050 µg of C16H19N3O5S/mg	:	994.0	µg/mg
Water Activity	NMT 0.30	:	0.10	WAA
Tapped bulk density	NLT 0.70	:	0.78	g/ml
Related substances (HPLC)				
6-aminopenicillanic acid	Not more than 0.5	:	<0.05	% w/w
L-Amoxicillin	Not more than 1.0	:	<0.05	% w/w
2-(S)-piperazine-2,5-dione	Not more than 1.0	:	<0.05	% w/w
2-(R)-piperazine-2,5-dione	Not more than 1.0	:	<0.05	% w/w
Penicilloic acids of Amoxicillin	Not more than 1.0	:	0.07	% w/w
p-hydroxy phenyl glycine	Not more than 1.0	:	<0.05	% w/w
Amoxicillin dimer (open)	Not more than 1.0	:	<0.05	% w/w
Amoxicillin dimer (closed)	Not more than 1.0	:	0.16	% w/w
Amoxicillin trimer (closed)	Not more than 1.0	:	<0.05	% w/w
Amoxicillin trimer (open)	Not more than 1.0	:	<0.05	% w/w
p-hydroxy phenyl glycyl amoxicillin	Not more than 1.0	:	<0.05	% w/w
Penilloic acids of amoxicillin	Not more than 1.0	:	<0.05	% w/w
Amoxicillin -6-APA amide	Not more than 1.0	:	<0.05	% w/w
Any unspecified impurity	Not more than 1.0	:	0.05	% w/w
Total Impurities	Not more than 5.0	:	0.28	% w/w

Remarks: -

Pharmacopoeia quality: Complies with the current editions of USP

Manufactured according to ICH Q7 GMP for APIs

N, N – Dimethylaniline is not used in the manufacturing process of this substance or present in any of the raw materials.

Solubility checked at regular interval

Date of issue: June 29, 2018

Approved / ~~Not Approved~~

29/06/2018

(Authorised Signatory)

Quality Assurance Department

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CERTIFICATE OF ANALYSIS

MATERIAL CODE : 100206B	**A.R.NO : BPRM180134**
MATERIALNAME : POTASSIUM CLAVULANATE DILUTED (1:1) BP	**Date of Analysis :** 31/07/2018
BATCH NO : 4121805006	**MFG.DATE :** MAY 2018
QTY.RECEIVED : 990.7800 KG	**EXP DATE :** APR 2022
SAMPLE QTY. : 0.0200 KG	**SPECIFICATION :** As per BP2017
RECEIPT DATE : 28/07/2018	**SPECIFICATION NO:** SP/100206B-4
MFG.BY : SHANDONG NEW TIME	**Working standard Number :** WS100206B18A
SUPPLIED BY : LONGCHEM INTERNATIONAL TRADING COMPANY LINITED	

Sr. No.	TEST	OBSERVATION	LIMIT
1.	Description	Almost white powder, hygroscopic	White or almost white powder, hygroscopic
2.	Identification (A) By HPLC test	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).	The principal peak in the chromatogram obtained with the test solution should be similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).
	(B) Reaction (b) of potassium	A orange-yellow precipitate is formed	A yellow or orange-yellow precipitate should be form.
	(C) Reaction of cellulose	The solution becomes violet-blue	The solution should become violet- blue
3.	pH	5.89	4.8 to 8.0

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
R.A. Makwana 11/08/2018	11/08/2018	11/08/2018
RAKESH MAKWANA	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

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CERTIFICATE OF ANALYSIS

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BATCH NO : 4121805006	**MFG.DATE :** MAY 2018
QTY.RECEIVED : 990.7800 KG	**EXP DATE :** APR 2022
SAMPLE QTY. : 0.0200 KG	**SPECIFICATION :** As per BP2017
RECEIPT DATE : 28/07/2018	**SPECIFICATION NO:** SP/100206B-4
MFG.BY : SHANDONG NEW TIME	**Working standard Number :** WS100206B18A
SUPPLIED BY : LONGCHEM INTERNATIONAL TRADING COMPANY LINITED	

Sr. No.	TEST	OBSERVATION	LIMIT
4.	Polymeric impurities and other impurities absorbing at 278 nm	Complies	The absorbance of solution determined at 278 nm is not greater than 0.40.
5.	Related substances*		
	(i) Impurities E	Complies	Not more than 1.0%
	(ii) Impurities G	Complies	Not more than 1.0%
	(iii) Any other impurity	Complies	Not more than 0.2%
	(iV) Total impurity	Complies	Not more than 2.0%
6.	Water	0.99%	Not more than 2.5%
7.	Assay	101.3%	Potassium clavulanate diluted contains not less than 91.2% and not more than 107.1% of stated amount

Storage conditions: Store In an airtight container, protect from light. At a temperature of 2 °C to 8 °C

* This test is performed at choksi laboratories report No: GL/B/180801010

REMARK: THE MATERIAL COMPLIES AS PER BP2017 SPECIFICATION.

RELEASE DATE: 11/08/2018

PREPARED BY / DATE	CHECKED BY / DATE	APPROVED BY / DATE
R.A. Makwana 11/08/2018	11/08/2018	11/08/2018
RAKESH MAKWANA	HARDIK PATEL	VINOD PATEL
Q.C. OFFICER	Q.C. EXECUTIVE	Q.C. MANAGER

SHANDONG NEW TIMES PHARMACEUTICAL CO., LTD.
No.1, North Outer Ring Road, Tengzhou County, Shandong Province, China
Tel: +86-539-5030608,8308258 Fax: +86-539-5030900,8331269

Certificate of Analysis

Product name	POTASSIUM CLAVULANATE DILUTED WITH MICROCRYSTALLINE CELLULOSE (1:1) IP		
Batch No.	4121805006	Batch size	991.080kg
Manufacturing date	May.12, 2018	Package	10KGA/ drum
Test date	May.14, 2018	Expiry date	Apr., 2023

Test	Specification	Result
Appearance	White or almost white powder, hygroscopic	Almost white powder, hygroscopic
Identification	(1) HPLC: positive	Positive
	(2) Reaction (b) of potassium: positive	Positive
	(3) Reaction of cellulose: positive	Positive
pH	4.8～8.0	5.8
Light absorption	NMT 0.40 at 278 nm	0.031
Water	NMT 2.5 %	0.48%
Related substances	Impurity E: NMT 1.0%	0.0083%
	Impurity G: NMT 1.0%	0.0015%
	Any other single impurity (major): NMT 0.10%	<0.05%
	Total impurities: NMT 2.0%	0.0098%
Assay (HPLC)	91.2% ～ 107.1% (as content of potassium clavulanate stated on the label)	101.4%
	CLAV.ACID(as is)38.3%～45.0%	42.6%
	CLAV. POT. (as is)45.6%～53.5%	50.7%
Conclusion	Conforms to the requirements of EP/IP.	

QC Manager:

Reporter: