

**COSMAS RESEARCH LAB LTD., LUDHIANA**  
**CERTIFICATE OF ANALYSIS**  
**FINISHED PRODUCT**

<b>Product Name</b>	<b>Amoburg-625</b>		
<b>Generic Name</b>	<b>Amoxicillin &amp; Potassium Clavulanate Tablets I.P. 625 mg</b>	<b>Mfg. date</b>	<b>10/2019</b>
<b>Batch No.</b>	<b>TB190441B</b>	<b>Expiry date</b>	<b>03/2021</b>
<b>A. R. No.</b>	<b>FP191899</b>	<b>Pack Size</b>	<b>10x1x6 Tablets</b>
<b>Start Date of Analysis</b>	<b>29/10/2019</b>	<b>Batch Size</b>	<b>60000 tablets</b>
<b>Date of Release</b>	<b>29/10/2019</b>	<b>Page No.</b>	<b>1 of 2</b>

S. No.	Test	Specification	Result
1.	Description	A white coloured, elongated shaped, film coated tablet.	A white coloured, elongated shaped, film coated tablet.
2.	Identification	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution corresponds to those in the chromatogram obtained with the reference solution.	Complies
3.	Average weight	1076.25 mg ± 3.0%	1082.60 mg
4.	Uniformity of weight	±5 % of Average weight	Min. -3.32% Max. +1.96%
5.	Thickness	5.90 mm ± 0.3 mm	Min. 5.83 mm Max. 5.96 mm
6.	Length	20.60 mm ± 0.2 mm	Min. 20.65 mm Max. 20.73 mm
7.	Width	9.60 mm ± 0.2 mm	Min. 9.59 mm Max. 9.71 mm
8.	Disintegration time	NMT 30 minutes	07 minute 23 second
9.	Dissolution	NLT 85% (D) of the stated amount of Amoxicillin C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>5</sub> S	Min. 91.99% Max. 101.43% Avg. 96.45%
		NLT 80% (D) of stated amount of clavulanic acid, C <sub>8</sub> H <sub>9</sub> NO <sub>5</sub>	Min. 97.74% Max. 107.84% Avg. 101.01%
10.	Uniformity of Content	Each individual content of Clavulanic Acid, C <sub>8</sub> H <sub>9</sub> NO <sub>5</sub> is 85 to 115 per cent of the average content.	Min. 98.73% Max. 101.32% Avg. 100.00%
11.	Water	NMT 10.0 % w/w	8.32%

	<b>Prepared by</b>	<b>Checked by</b>	<b>Approved by</b>
<b>Name</b>	Bikramjit Singh	Vivek Sood	Jasveer Singh
<b>Designation</b>	Officer-QC	Asst. Manager-QC	Manager-QC
<b>Signature</b>			
<b>Date</b>	29/10/2019	29/10/2019	29/10/2019

Format No.: F/QC/01/024/02/01

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12.	Assay Each film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin-500 mg	NLT 450 mg and NMT 600 mg (NLT 90.0% and NMT 120.0%)	508.36 mg (101.67%)
	Potassium Clavulanate Diluted IP eq. to Clavulanic acid-125 mg	NLT 112.5 mg and NMT 150 mg (NLT 90.0% and NMT 120.0%)	123.66 mg (98.93%)

**Remarks:** The above sample of finished product ~~complies/does not comply~~ as per specification no. QC/FPS/1051/00.

	<b>Prepared by</b>	<b>Checked by</b>	<b>Approved by</b>
<b>Name</b>	Bikramjit Singh	Vivek Sood	Jasveer Singh
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