

P: (800)325-7734 | F: (512)341-3931 | W: www.prlabs.com

CERTIFICATE OF ANALYSIS

Product	BD Dental Pack	Lot Number	201117-BDX3672
Item Number	BDX3672	Country of Origin	USA

TEST	SPECIFICATION	RESULTS	METHOD
Identity			
Appearance	Powder, To Match Standard	Pass	WI-QC-017
Color	Grey, To Match Standard	Pass	WI-QC-017
Odor	Characteristic to Match Standard	Pass	WI-QC-017

Purity			
Total Aerobic Microbial Count	$\leq 2 \times 10^3$ cfu/g	Pass	USP <61> or equivalent
Total Combined Yeast and Mold Count	$\leq 2 \times 10^3$ cfu/g	Pass	USP <61> or equivalent
Enterobacterial Count (Bile-Tolerant Gram Neg. Bacteria)	$\leq 2 \times 10^2$ cfu/g	Pass	02-209-01
<i>Staphylococcus aureus</i>	None detected in 10 g	Pass	USP <62> or equivalent
<i>Escherichia coli</i>	None detected in 10 g	Pass	USP <62> or equivalent
<i>Salmonella spp.</i>	None detected in 10 g	Pass	USP <62> or equivalent
<i>Klebsiella pneumoniae</i>	None detected in 10 g	Pass	02-220.6.1
<i>Streptococcus pyogenes</i>	None detected in 10 g	Pass	02-229
<i>Pseudomonas Aeruginosa</i>	None detected in 10 g	Pass	USP <62> or equivalent
Lead (Pb)	≤ 10 ppm of bioavailable lead	Pass	ICP-MS
Mercury (Hg)	≤ 1 ppm	Pass	ICP-MS



PREMIER RESEARCH LABS
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Composition			
Weight Verification	≥ 150 grams	Pass	WI-QC-007
Moisture %	$\leq 14\%$	Pass	USP <731> Or equivalent
Visual Packaging Inspection	No Gross Defects	No Gross Defects	WI-QC-007

QUALITY APPROVAL		
Prepared By / Date	Approved By / Date	Final Disposition
<i>Debra Lauer</i> 3/4/22	<i>[Signature]</i> 3/4/22	PASS

This product has been reviewed and approved by the Premier Research Labs Quality Unit. The results reported in this certificate of analysis (COA) are truthful and representative of the lot. The finished product and all raw materials used to manufacture the batch have been found to meet required specification limits in accordance with 21 CFR 111 (cGMP) regulations and the product is released.