

LYOINREADY®

LyoClear Coated Vial

Introduction

LyoIn Ready® LyoClear Coated Vial is a neutral borosilicate glass tubular coated vial. The interior is coated with a hydrophobic polydimethylsiloxane (PDMS) film, which effectively prevents drug product fogging during the lyophilization process.

Fogging refers to the phenomenon during the freeze-drying process where the liquid formulation creeps up along the vial wall, it is characterized by a persistent layer of white mist that adheres to the inner surface of the vials post-lyophilization. The presence of white “fogging” can raise concerns with respect to DP manufacturing process control and potential compromise of container closure integrity. During the drug manufacturing process, this may lead to an increased rate of product nonconformity.

Amphiphilic protein lyophilized preparations (such as monoclonal antibodies, bispecific antibodies, and antibody-drug conjugates (ADCs)) contain surfactants like PS20/PS80/Poloxamer 188, which significantly reduce solution surface tension, thereby increasing the risk of fogging. Severe fogging that reaches close to the stopper region is considered unacceptable and will lead to vial rejections in the pharmaceutical industry.

Key Feature



No Fogging
No need for excessive concern about integrity



Improved Cake elegance
Reducing Defect Rates



Improved Cake elegance
Reducing Defect Rates in Lyophilized



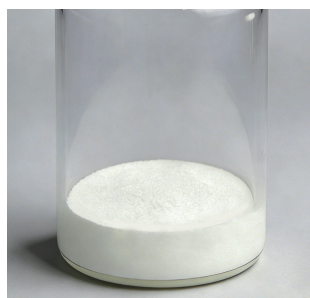
Reduce residual volume improve
dosing accuracy



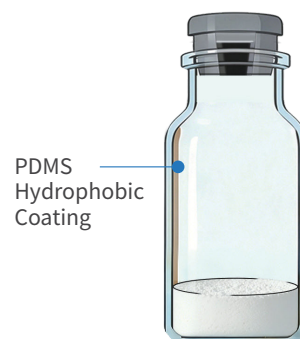
Stable after washing process
Suitable for depyrogenation



Lyophilization in standard vial

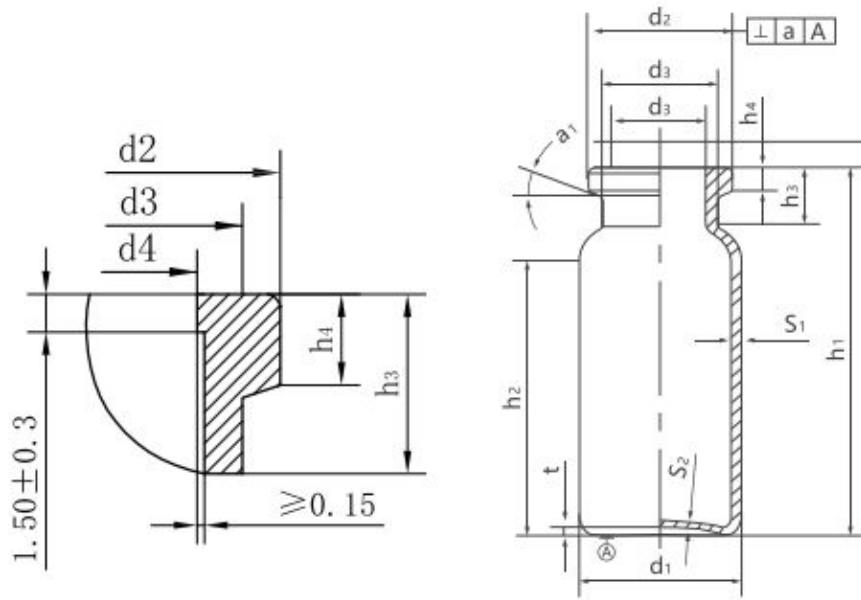


Lyophilization in LyoIn Ready® LyoClear Coated Vial



Product Specifications

Specification	Basic Dimensions (mm)			
	Body Outer Diameter(d1)	Vial Height(h1)	Finish Outer Diameter (d2)	Bore Inner Diameter(d4)
1ml	13.70	27.00	11.00	7.00
2ml	16.00	31.00	13.00	7.00
3ml	16.00	35.00	13.00	7.00
4ml	16.00	45.00	13.00	7.00
5ml	18.40	35.00	13.00	7.00
5ml	22.00	39.70	19.60	12.50
7ml	22.00	39.70	19.60	12.50
8ml	22.00	45.00	19.60	12.50
10ml	22.00	49.70	19.60	12.50
10ml	24.00	45.00	19.60	12.50
12ml	24.50	49.50	19.60	12.50
15ml	26.40	52.00	19.60	12.50
15ml	26.00	52.00	19.60	12.50
20ml	28.00	55.00	19.60	12.50
30ml	30.00	75.00	19.60	12.50
32ml	32.00	70.00	19.60	12.50
50ml	40.00	80.00	28.80	18.80
50ml	40.00	80.00	19.60	12.50



Applications

Particularly suitable for all lyophilized preparations sensitive to adsorption loss and with strict appearance requirements, including:



Monoclonal antibodies



Recombinant proteins



Antibody-drug conjugates (ADCs)



Vaccines (mRNA, viral vectors)

