

Procedure

To get data from Lyo Calculator, do following steps:

1. Go to <https://pharmahub.org/resources/lyocalculator> and launch the tool
2. Input required variables in folders “Vial/solution properties” and “Chamber/Resistances”
 - 2.1. Input Area of a product, Area of the vial, fill volume, the heat transfer coefficient parameters, and go to the next step. Note: some vial geometries are involved in the solver.
 - 2.2. Input resistance coefficients, solid concentration, and process parameters. Note: preset resistance coefficients for some solutions can be used.

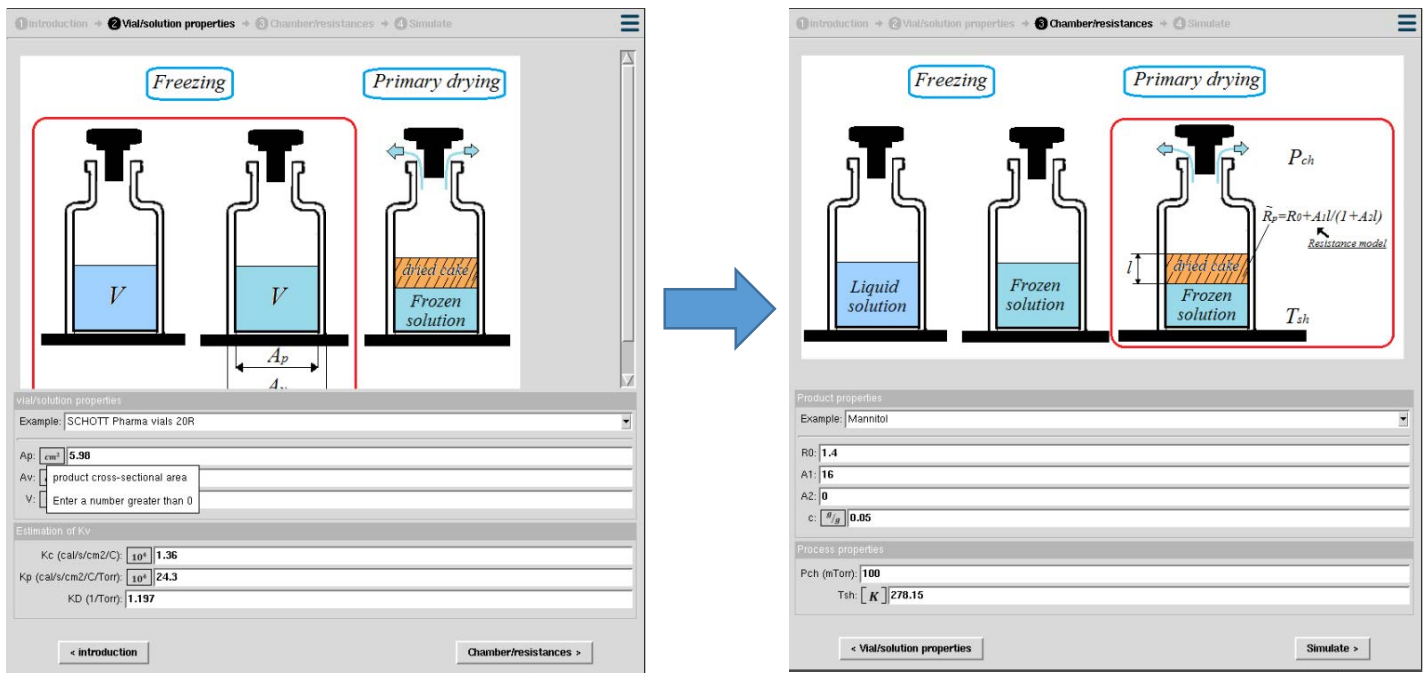


Figure 2. Input procedure (Mannitol 5%, 20R vial type)

3. Click “Simulate” button and get solution
4. Results will be presented as a set of graphs. Calculated values are product temperature, vapor pressure, sublimation rate, and percent of the dried product.

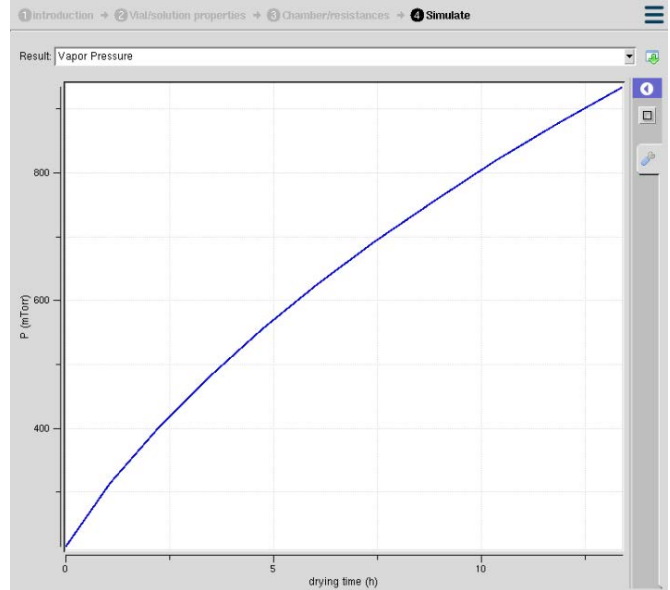
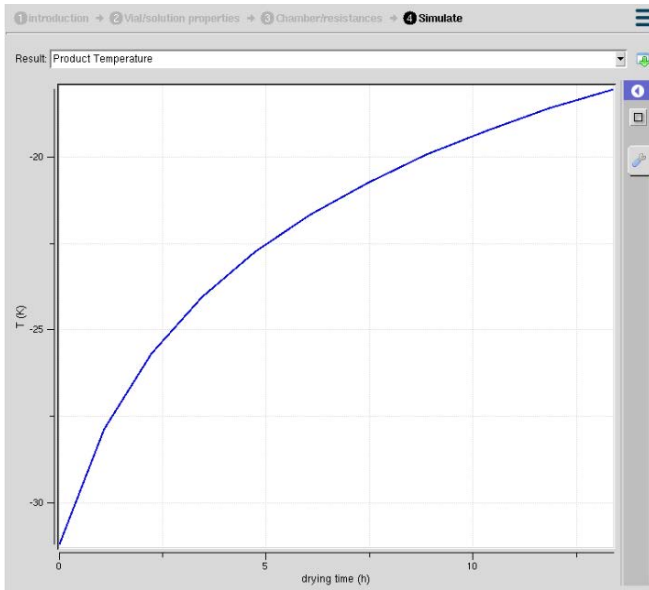


Figure 3. Product temperature and vapor pressure as functions of drying time

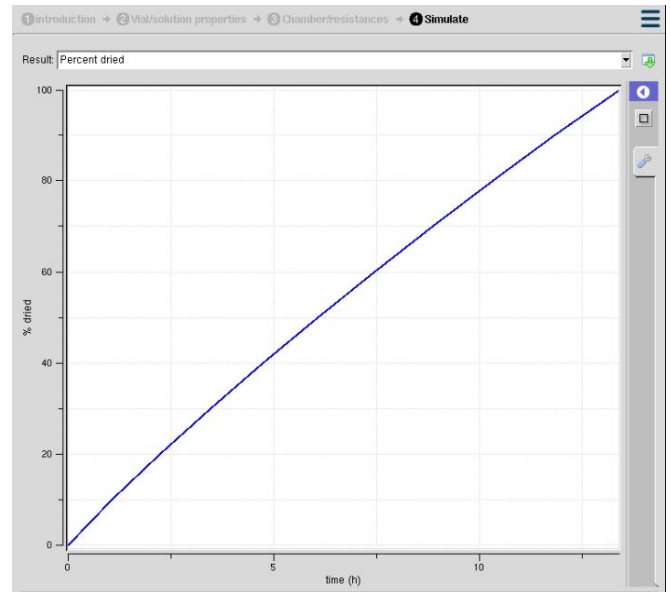
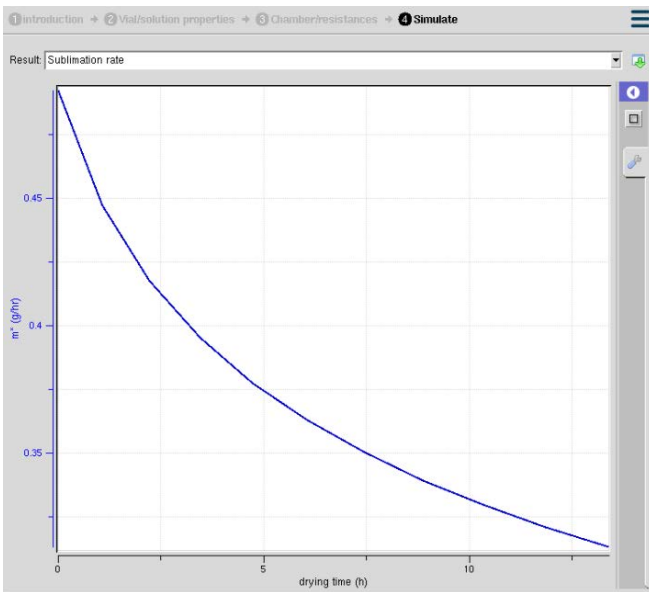


Figure 4. Sublimation rate and percent dried as functions of drying time

Useful data

Product resistance constants for different solutions:

Product type	R0	A1	A2
Aqueous	1	10	1
BSA/Sucrose	1	10	2.5
Sucrose	0.2	26	1.5
Mannitol	1.4	16	0
Povidone	1.13	5	0

Dimensions of vials for different fill volumes:

SCHOTT Pharmaceutica Vials					
Type	Fill Volume (ml)	diameter vial(cm)	diameter product(cm)	Area vial (cm ²)	Area product (cm ²)
2R	4	1.6	1.4	2.01	1.54
4R	6	1.6	1.4	2.01	1.54
6R	10	2.2	2	3.80	3.14
8R	11.5	2.2	2	3.80	3.14
10R	13.5	2.4	2.2	4.52	3.8
15R	19	2.4	2.2	4.52	3.8
20R	26	3	2.76	7.07	5.98
25R	32.5	3	2.76	7.07	5.98
30R	37.5	3	2.76	7.07	5.98

References:

1. M. J. Pikal, M. L. Roy, and Saroj Shah “Mass and Heat transfer in Vial freeze-Drying of Pharmaceuticals: Role of the Vial”, Journal of Pharmaceutical Sciences Vol. 73, No. 9, September 1984, pp 1224-1237
2. M.J. Pikal “Use of Laboratory Data in Freeze Drying Process Design: Heat and Mass Transfer Coefficients and the Computer Simulation of Freeze Drying”, Journal of Parenteral Science and Technology Vol. 39, 1985, pp 115-138
3. SCOTT Pharma Vials for freeze-drying
http://www.us.schott.com/pharmaceutical_packaging/english/download/datasheet-schott-pharma-vials-us.pdf