

INFLUENCE OF SOLVENT ADMIXTURE ON EXPLOSIBILITY OF A PHARMACEUTICAL POWDER AT LABORATORY- AND INDUSTRIAL-SCALE

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Hybrid mixtures of combustible dust and flammable solvent can arise in many industrial processes when a powder undergoes transfer into a solvent, or vice versa. This transfer can increase the risk of occurrence of process incidents that propagate as a unique combination of dust explosion and solvent vapour explosion. The current research considers dispersed fuel systems of dust/solvent/air in two modes: dust alone dispersed into an environment containing a flammable gas/air atmosphere (atmospheric or ATM mode), as well as dust dispersed in an already solvent pre-wetted state into an atmosphere containing only air (pre-wetted or PW mode).

The influence of liquid and vapourized solvent (e.g., methanol at a concentration 80 % of its lower flammability limit) on explosion severity parameters of pharmaceutical-grade MCC (microcrystalline cellulose) powder has been investigated both experimentally and computationally. In the experimental work, standardized dust explosibility test equipment (Siwek 20-L explosion chamber) and American Society for Testing and Materials (ASTM) test protocols were used to determine maximum explosion pressure (P_{max}) and maximum rate of pressure rise ((dP/dt)_{max}). Simulations were accomplished by means of a comprehensive CFD (Computational Fluid Dynamics) software package called DESC (Dust Explosion Simulation Code). Laboratory- and industrial-scale scenarios of solvent admixture in atmospheric mode were simulated, with validation being provided by the aforementioned laboratory-scale experiments.

Simulations at the laboratory-scale demonstrated the significant enhancements in P_{max} and (dP/dt)_{max} brought about by solvent admixture (as was observed in the experimental work). The extent of solvent influence on explosion development was also demonstrated by the simulations conducted with an industrial-scale geometry. Here, the consequences of a credible explosion scenario during drying operations in a pharmaceutical spray dryer were successfully predicted. A thorough investigation has also been undertaken to determine whether safety measures designed for dust explosions alone (e.g., pressure panel, a passive engineering safety measure) afford adequate protection in the case of hybrid mixture explosions.

Dust explosion, explosibility, hybrid mixture, solvent admixture, pre-wetting, MCC (Microcrystalline Cellulose), CFD (Computational Fluid Dynamics), DESC (Dust Explosion Simulation Code), explosion severity, FLACS (FLame ACceleration Simulator), methanol, ethanol, isopropanol

INTRODUCTION

Hybrid mixtures consist of a flammable gas and a combustible dust and are very common in many situations that occur in the pharmaceutical industry. Explosion scenarios of hybrid mixtures have been studied with three possible approaches: (i) gaseous solvent at room temperature existing in the combustion atmosphere prior to dust dispersal, (ii) liquid solvent at room temperature requiring flashing-off for admixture to the combustion atmosphere prior to dust dispersal, and (iii) liquid solvent at room temperature admixed as a liquid with the dust prior to dust dispersal [1]. The introduction of flammable solvents in either liquid or gaseous form can significantly enhance the explosibility parameters of excipients (non-pharmaceutically active dusts) alone.

The latter two scenarios described in the paragraph above are considered in the current work to investigate the influence of liquid and vaporized solvents on explosion severity parameters of pharmaceutical-grade MCC (microcrystalline cellulose) powder, both experimentally and computationally. The influence of the co-presence of a flammable gas on the explosibility parameters of a fuel dust alone is a well-established fact as mentioned by Amyotte and Eckhoff [2]. However, due to the extent of the subject matter and its wide range of industrial applications, continued research on hybrid mixtures is still needed, as seen in recent studies [3-10]. The scope of the current work is prevention and mitigation of explosions associated with hybrid mixtures in the pharmaceutical industry during transfer of dry or solvent-laden powders into a process that may contain a flammable atmosphere [11].

CFD (Computational Fluid Dynamics) tools such as DESC (Dust Explosion Simulation Code) are capable of large-scale modeling of dust explosions; Skjold et al. [12, 13] illustrated the outcomes of dust explosion simulations using an earlier version of DESC. CFD simulation of a dust explosion is a useful approach to determine the influence of solvent admixture on the severity parameters of pharmaceutical-grade MCC powder. Moreover, it is important to assess whether control measures (e.g., pressure panels) for dust explosions alone afford adequate protection in the case of

explosions associated with hybrid mixtures. The objective in the present work is the provision of explosibility data acquired through best-practice testing methodologies using standardized apparatus and then applying the outcomes in realistic industrial applications. To accomplish this stated objective, laboratory and industrial-scale scenarios were examined computationally.

Hybrid mixtures of MCC powder admixed with methanol (M), ethanol (E) and isopropanol (IPA) were selected to be representative of common pharmaceutical excipients and solvents.

EXPERIMENTAL AND SIMULATION DETAILS

This section presents details of the experimental and simulation logistics.

Materials, Apparatus and Procedures

All materials tested were pharmaceutical-grade in terms of composition and in the case of MCC powder, particle size distribution as received from the supplier. Figure 1 shows scanning electron micrographs (SEMs) of the MCC; the particles are observed to be fibrous or flocculent in nature. Tables 1 and 2 summarize the relevant material characteristics of the dust (excipient) and solvents, respectively.

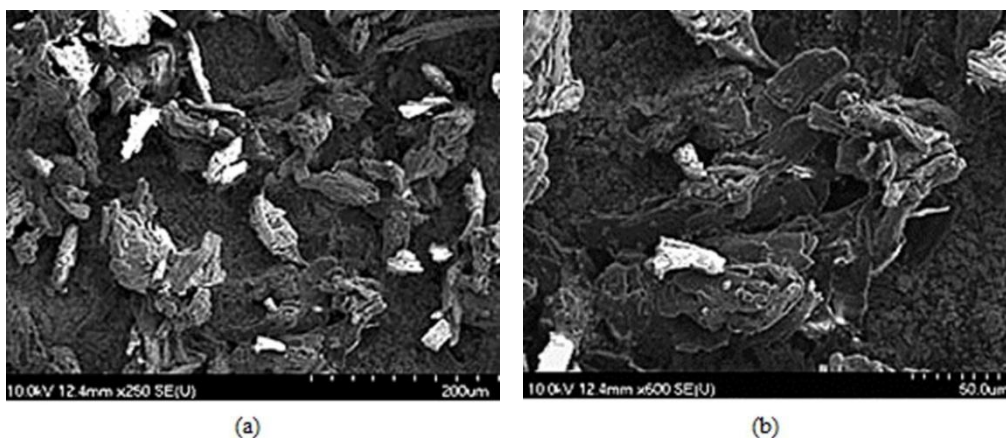


Figure 1. Scanning electron micrographs of MCC powder: (a) 250 magnification, (b) 600 magnification [14].

Table 1. Material characterization of MCC powder [14].

Characteristic	MCC
Supplier	Sigma-Aldrich
Particle Size [weight %]	90 % < 56 μm 50 % < 27 μm 10 % < 9 μm
Moisture Content [weight %]	4.5

Table 2. Material characterization of flammable solvents [14].

Characteristic	Methanol	Ethanol	Isopropanol	Reference
Formula	CH ₃ OH	C ₂ H ₅ OH	C ₃ H ₇ OH	[15]
Molecular weight	32	46	60	[15]
Lower flammability limit [volume %]	6.7	3.3	2.2	[16]
Laminar burning velocity [cm/s]	56	42	41	[17, 18]
Vapour pressure at 25 °C [mm Hg]	127	59	43	[15]
Specific heat capacity (liquid) at 25 °C [J/mol·K]	81	112	155	[19]
Boiling point at 1 atm [°C]	64.7	78.5	82.2	[15]
Heat of vapourization at boiling point and 1 atm [kJ/mol]	35.2	38.5	39.9	[15, 19]
Heat of combustion (liquid) at 25 °C and 1 atm with H ₂ O(l) product [kJ/mol]	-726.6	-1366.9	-1986.6	[15]
Specific gravity [20°C/4°C]	0.792	0.789	0.785	[15]

Explosibility parameters investigated in the experimental work include maximum explosion pressure (P_{max}), size-normalized maximum rate of pressure rise (K_{St}) and rate of pressure rise $[(dP/dt)_m]$. The relevant ASTM protocol [20] was followed using standardized dust explosibility test equipment (Siwek 20-L explosion chamber). Apparatus and procedural descriptions can be found on the manufacturer's website (www.kuhner.com). Hybrid mixture testing involved a fixed solvent concentration of 80 % of the respective lower flammability limit. For the pre-wetted (PW) tests, the required amount of liquid solvent was mixed with the amount of excipient corresponding to the concentration being tested. The pre-wetted mixture was then dispersed into the 20-L explosion chamber via the standard procedure. For the atmospheric (ATM) tests, the chamber was first evacuated to a pressure of 185 mm Hg (i.e., as low as possible close to the respective vapour pressure of the solvents given in Table 2). The required amount of liquid solvent (80 % of the respective lower flammability limit) was then injected through a septum into the 20-L chamber with a majority of the solvent flashing to vapour. From a material balance perspective, any left-over solvent would be vapourized by the shower of sparks originating from the chemical ignitors acting as the ignition source in the 20-L chamber [14].

Dust Explosion Simulation Code (DESC)

DESC 10.3 has been used in the current study. The primary step in the DESC simulation is to prepare the fuel files (e.g., MCC and MCC admixed with methanol in atmospheric condition). The fuel files are produced by Excel spreadsheets using explosibility data acquired in a 20-L Siwek chamber, along with other properties (e.g., particle density, moisture content, particle size, etc.). The fuel file is added to a predefined working directory to be read by the DESC simulator [FLACS Run Manager]. Then, the explosion geometry was built for each case study followed by setting of the scenarios. The simulations were run using the Run Manager program of the DESC simulator. Finally, results from the simulations were observed by using the post-processor Flowvis program. Skjold [21] describes how DESC uses CFD coding for the transport equations for mass, momentum, enthalpy, fuel mixture fraction, turbulent kinetic energy, and rate of dissipation of turbulent kinetic energy on a three-dimensional Cartesian grid.

RESULTS AND DISCUSSION

This section presents the experimental and simulation results according to the severity of explosion consequences (overpressure and rate of pressure rise). The experimental results were previously reported in full detail by Hossain et al. [14].

Laboratory-Scale Experiments

Figures 2 and 3 display the influence of dust concentration on explosion overpressure (P_m) and rate of pressure rise ($(dP/dt)_m$) for the pharmaceutical-grade MCC powder. (All figures in this section depict average values of P_m and $(dP/dt)_m$ at dust concentrations for which replicate testing was performed according to ASTM E-1226-10 [20]). Here, the results display the expected trend toward an increase in the measured explosibility parameters as dust concentration increases. At a concentration of 1250 g/m³, the peak values of P_m and $(dP/dt)_m$ are attained, followed by a parameter decrease or leveling-off with further increases in dust concentration.

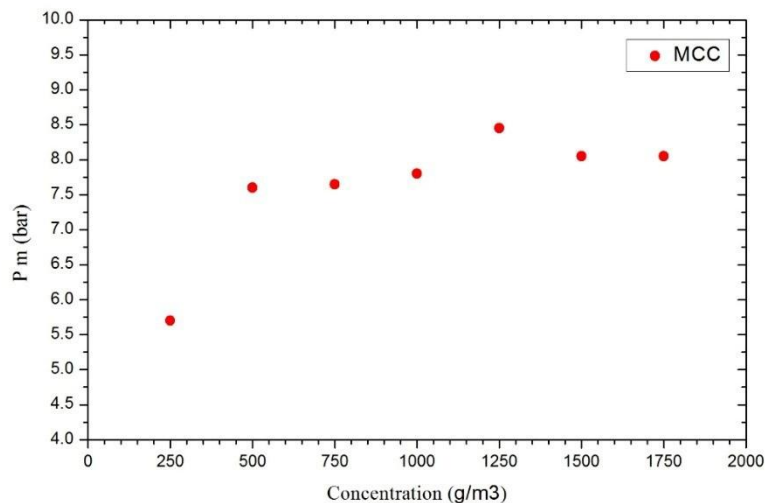


Figure 2. Influence of dust concentration on explosion overpressure of MCC powder.

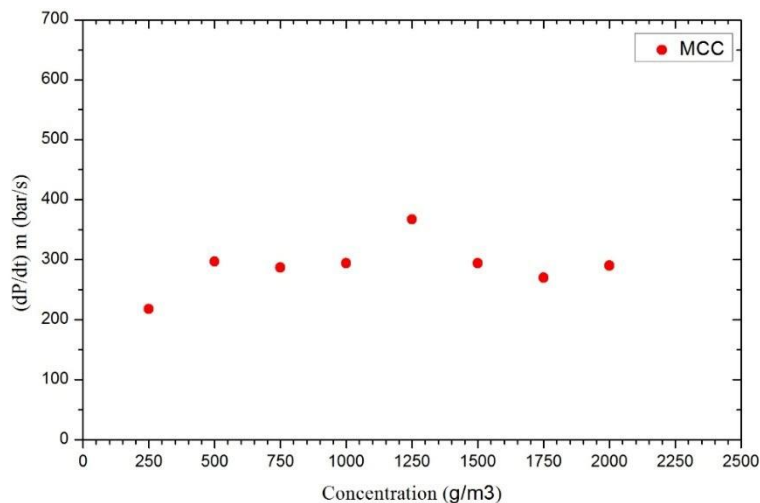


Figure 3. Influence of dust concentration on rate of pressure rise of MCC powder.

Table 3 describes the complete P_{max} and K_{St} data sets for MCC in all test conditions. Pre-wetting (PW) of MCC with solvent had a measurable impact on K_{St} . As expected, the influence was an enhancement of K_{St} ; however, P_{max} for MCC displayed a decrease of 0.6-0.8 bar(g) with solvent admixture by pre-wetting.

Table 3. P_{max} and K_{St} data for MCC and MCC admixed with solvent (standardized explosibility testing in Siwek 20-L explosion chamber).

Testing Condition	Material	P_{max} [bar(g)]	K_{St} [bar·m/s]
Baseline Excipient	MCC	8.5	103
Pre-wetted (PW)	MCC + M	7.9	144
	MCC + E	7.8	117
	MCC + IPA	7.7	116
Atmospheric (ATM)	MCC + M	7.9	168
	MCC + E	8.3	149
	MCC + IPA	8.4	172

In the current study, the magnitude of the effect on K_{St} of solvent pre-wetting for MCC was found to be distinguishable for the three solvents. This supports the concept of an empirical correlation of K_{St} with burning velocity (Table 2) for pre-wetted MCC. Such a correlation was previously shown by Amyotte et al. [5] for polyethylene admixed with various hydrocarbons. The atmospheric (ATM) test data in Table 3 indicate that K_{St} is not distinguishable for the three solvents; here, the admixed solvents have generally the same effect on K_{St} of MCC regardless of the individual solvent nature.

The method of admixture (pre-wetting or atmospheric) controls the total amount of heat produced in the combustion reaction. Generally, dry MCC powder in an atmospheric condition is capable of producing more heat than wet powder in a pre-wetted condition during a combustion reaction. These observations are somewhat speculative, and it is very likely that some other physical and thermodynamic properties (e.g., vapour pressure and specific heat capacity) of the solvents will be required to advance the phenomenological modeling of these data. These properties influence both reaction energy and reaction kinetics of the hybrid mixtures. From this discussion, it is clear that the influence of each solvent is specific to the properties of MCC and the method of admixture (pre-wetting or atmospheric). This is demonstrated by Figures 4, 5, and 6 which display rate of pressure rise data for the MCC powder admixed with methanol, ethanol, and isopropanol, respectively.

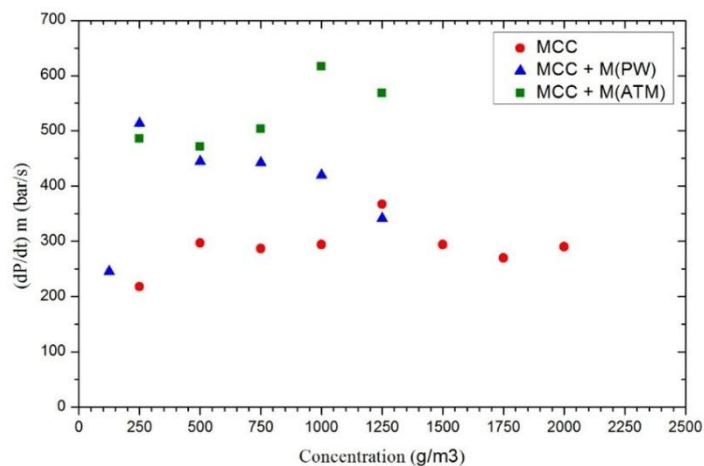


Figure 4. Influence of methanol admixture on rate of pressure rise of MCC powder.

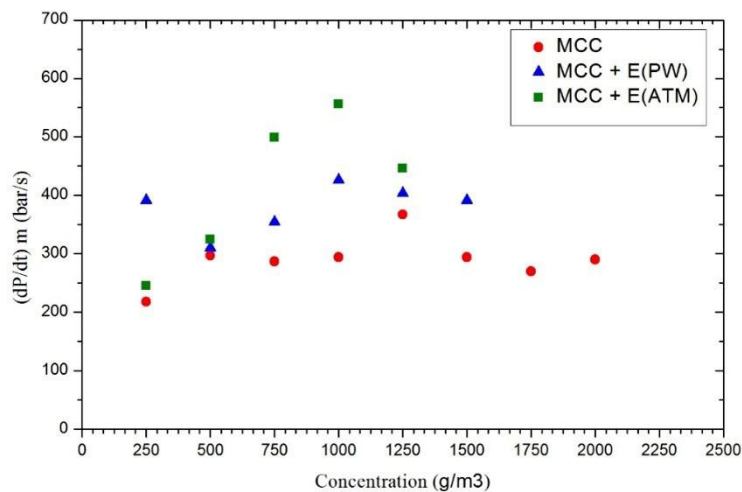


Figure 5. Influence of ethanol admixture on rate of pressure rise of MCC powder.

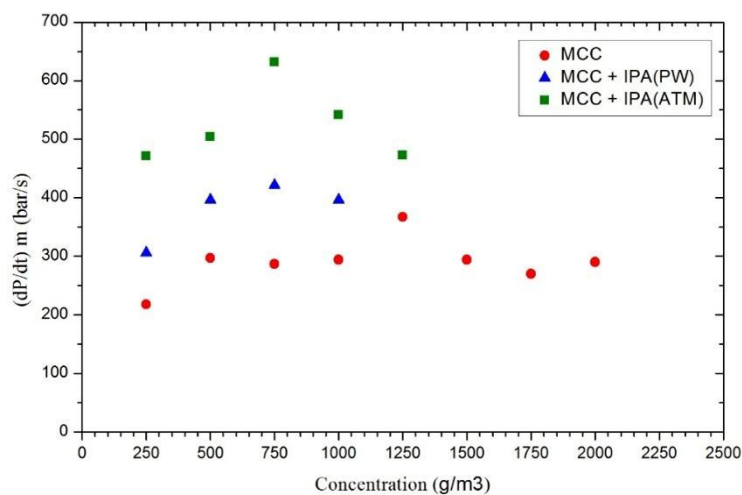


Figure 6. Influence of isopropanol admixture on rate of pressure rise of MCC powder.

Laboratory-Scale Simulation & Validation

CFD simulations of dust explosions at laboratory-scale were carried out for both MCC and hybrid mixtures of MCC and methanol. (To date, only MCC admixed with methanol in atmospheric condition has been considered in the CFD simulations; future CFD work will involve the other solvents as well as the pre-wetted condition.) The maximum explosion pressure and maximum rate of pressure rise produced during DESC simulations in a 20-L chamber were compared with the relevant experimental data for MCC and MCC admixed with methanol in atmospheric condition.

A dust concentration of 1250 g/m³ was used in all simulations. (See Figures 2 and 3.) For all cases, the error percentages between experimental and predicted data were found to be less than 4%, as shown in Table 4.

Table 4. Experimental and simulation results of MCC (excipient and hybrid mixture) explosions in 20-L chamber.

Dust	Explosibility Parameter	Experimental Results	Simulation Results	Error Percentage
MCC	P _{max} (bar(g))	8.5	8.5	0
	dP/dt (bar/s)	379	386	1.8
MCC + M (ATM)	P _{max} (bar(g))	7.9	8.2	3.8
	dP/dt (bar/s)	619	604	2.4

In addition to the 20-L chamber, DESC simulations were run for the larger-scale geometries of a 1-m³ spherical vessel and a 400-m³ silo. The results showed the same maximum explosion pressure (P_{max}) but different total explosion times (t_{exp}) for both MCC and MCC admixed with methanol in atmospheric condition, as can be seen in Table 5. These simulation results help to validate the CFD approach and support its application to large-scale, industrial geometries.

Table 5. Simulation results of MCC (excipient and hybrid mixture) explosions in 20-L chamber, 1-m³ vessel, and 400-m³ silo.

20-L Chamber			1-m ³ Vessel		400-m ³ Silo	
Material	P _{max} (bar(g))	t _{exp} (s)	P _{max} (bar(g))	t _{exp} (s)	P _{max} (bar(g))	t _{exp} (s)
MCC	8.5	0.26	8.5	0.81	8.5	3.83
MCC + M (ATM)	8.2	0.14	8.2	0.54	8.2	2.70

Industrial-Scale Simulation

A spray dryer has been considered for simulation using DESC according to the physical dimensions given by Wawrzyniak et al. [22], as representative of widely used industrial-scale pharmaceutical dryers. The dryer height is 25 m with a diameter of 5.3 m throughout the tower. The bottom part of the tower is cone-shaped with the diameter increasing from 0.5 to 5.3 m in the upper part as shown qualitatively in Figure 7. Since explosion venting is one of the most widely used protection measures, CFD simulations were carried out to test whether safety measures designed for dust explosions alone afford adequate protection in the case of hybrid mixture explosions. Ongoing research is aimed at addressing all levels in the hierarchy of controls [2].

To calculate the area of pressure panels, the Equation (1) was used according to NFPA 68 [17]:

$$A_{V0} = 1.10^{-4} \cdot (1 + 1.54 \cdot P_{stat}^{4/3}) \cdot K_{St} \cdot V^{3/4} \cdot \sqrt{\frac{P_{max}}{P_{red}} - 1} \quad (1)$$

where:

A_{V0} = total calculated area of pressure panels (m²)

P_{stat} = nominal static burst pressure of pressure panels (bar(g))

K_{St} = size-normalized maximum rate of pressure rise (bar·m/s)

V = enclosure volume (m^3)

P_{max} = maximum explosion pressure (bar(g))

P_{red} = reduced pressure after explosion venting (bar(g))

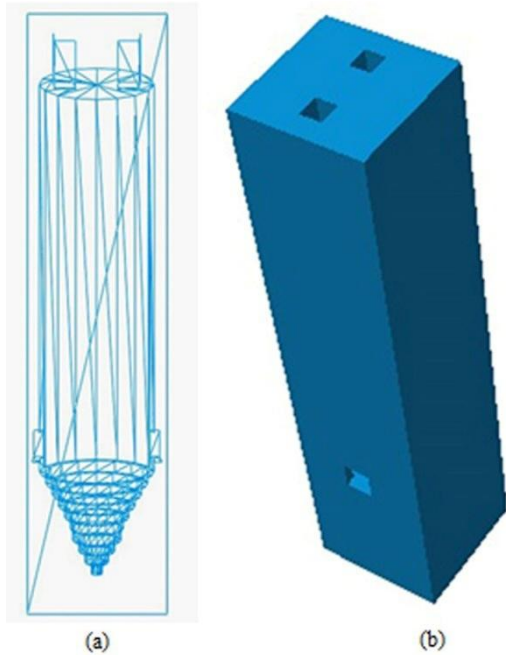


Figure 7. DESC geometry of an industrial spray dryer: (a) 2D view and (b) 3D view.

Using Equation (1), the total calculated area of the pressure panels was determined as $4.6 m^2$ for MCC and $7.2 m^2$ for MCC admixed with methanol. The pressure panels were distributed among two side walls and the top wall of the spray dryer as described in Table 6.

Table 6. Size and orientation of pressure panels in the spray dryer.

Dust	Top Wall			Side Walls			Total area of pressure panels (m^2)
	Number	Area of pressure panel (m^2)	Total area of pressure panels (m^2)	Number	Area of pressure panel (m^2)	Total area of pressure panels (m^2)	
Dryer filled with MCC	2	1.0	2.0	2	1.3	2.6	4.6
Dryer filled with MCC and M (ATM)	2	1.5	3.0	2	2.1	4.2	7.2

Simulations in the spray dryer for MCC powder and MCC admixed with methanol in atmospheric condition were configured as a closed chamber, and with pressure panels located at the top and side walls (as previously mentioned). For all pressure panels, 10 kPa (0.1 bar) was chosen as the opening pressure, which is within the acceptable range according to NFPA 68 [17].

Considering the worst-case scenario of explosions for both baseline excipient and hybrid mixture, a full spray dryer (i.e., 100 % volume) was used in calculating the size of the pressure panels. Pressure panels used in the simulations are identical in their properties (e.g., type, opening pressure, weight, etc.); the only exception is the size of the pressure panels as calculated by NFPA 68 [17] using the explosibility data determined for MCC and MCC admixed with methanol in atmospheric condition. The reduced pressure after explosion venting was set at 50 kPa (0.5 bar) as the maximum allowable pressure for spray dryers according to NFPA 68 [17] is ≤ 1.0 bar. The point of ignition was fixed on the central axis of the dryer at a height of 5.1 m from the dryer bottom due to the strong possibility of explosive atmospheres in that region.

When the chamber was configured as closed, the maximum explosion pressure in the spray dryer was determined to be similar for both MCC and MCC admixed with methanol. As expected, the total explosion time (t_{exp}) was found to be shorter in the case of the hybrid mixture as compared to the excipient alone; see Figures 8 and 9 which demonstrate the occurrence of more rapid combustion for the hybrid mixture. Reduced pressures according to NFPA 68 [17] and the CFD simulations are similar for both MCC and MCC admixed with methanol as shown in Table 7, Figure 10, and Figure 11. It has been clearly demonstrated that the reduced pressure was higher than the acceptable value when the pressure panels designed for MCC were used in the case of the dryer filled with a hybrid mixture of MCC and methanol; see Figure 12. These simulations explicitly illustrate that safety measures designed for dust explosions alone cannot provide adequate protection in the case of hybrid mixture explosions.

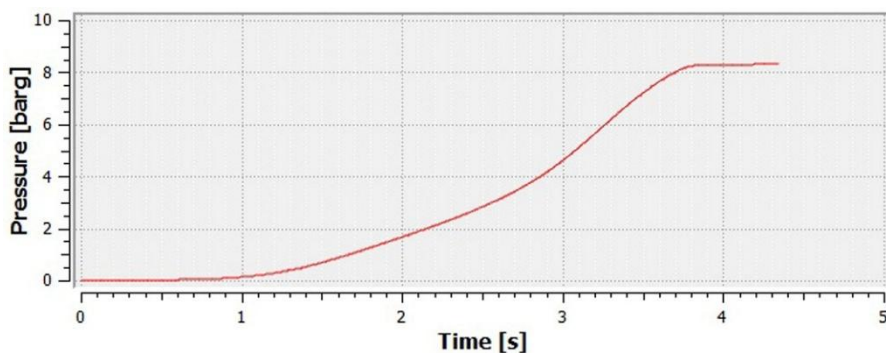


Figure 8. DESC pressure-time trace of MCC explosion in the spray dryer when the tower is closed.

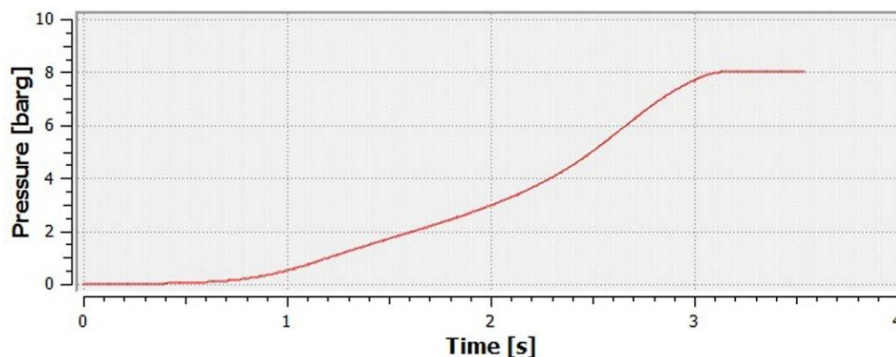


Figure 9. DESC pressure-time trace of MCC admixed with methanol explosion in the spray dryer when the tower is closed.

Table 7. Comparison between NFPA standard and DESC results of MCC explosions in the spray dryer when the chamber is configured as open with pressure panels.

Dryer filled with MCC		Dryer filled with MCC +M(ATM)
Method	Reduced/maximum pressure in bar(g)	Reduced/maximum pressure in bar(g)
NFPA 68	0.50	0.50
DESC Results	0.57	0.52

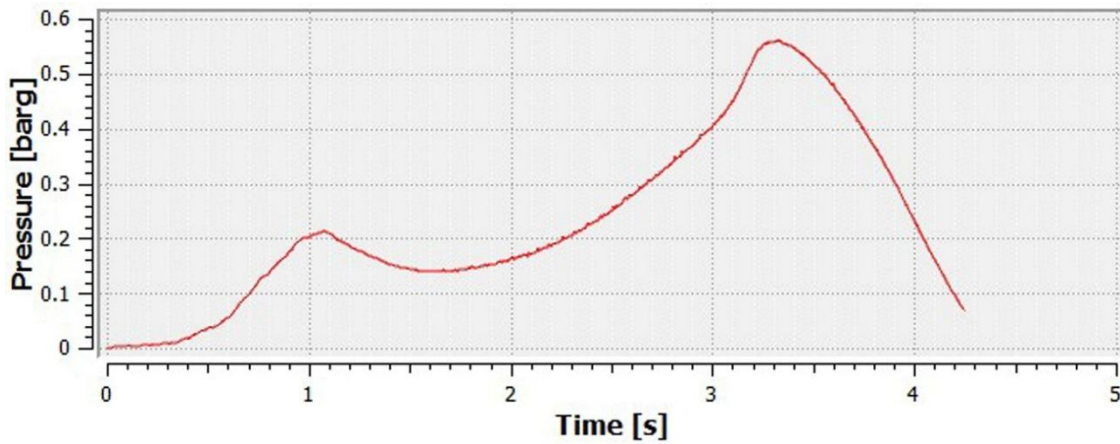


Figure 10. DESC pressure-time trace of MCC explosion in the spray dryer when the tower is open and pressure panels are used as designed for MCC.

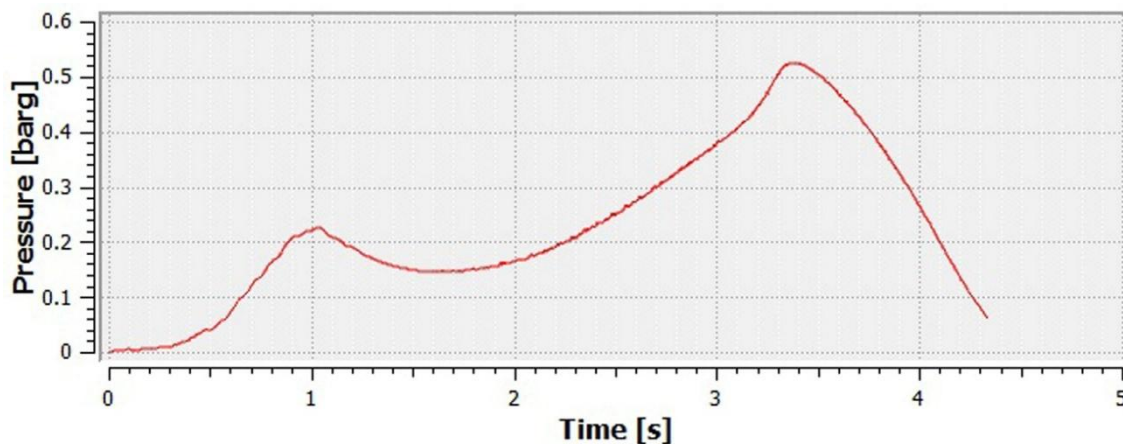


Figure 11. DESC pressure-time trace of dust explosion in the spray dryer when the tower is open (occupied by MCC admixed with methanol) and pressure panels are used as designed for MCC admixed with methanol.

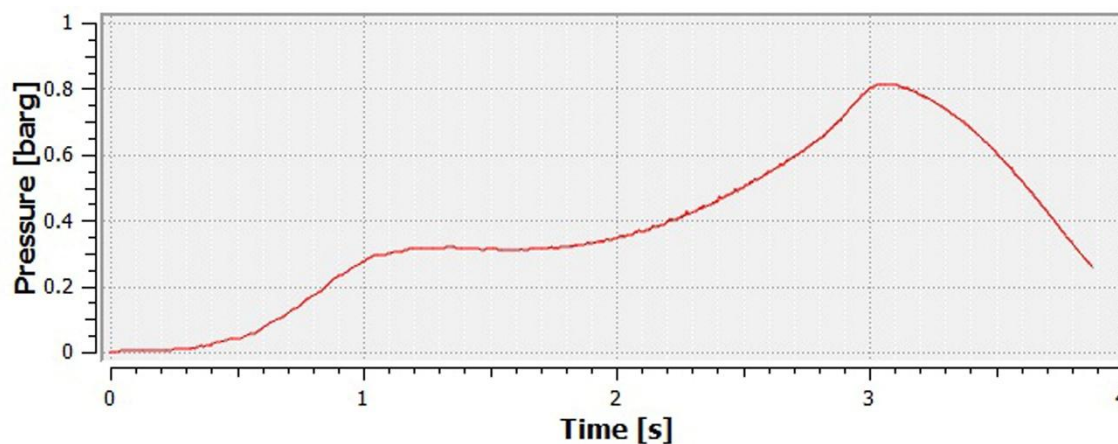


Figure 12. DESC pressure-time trace of dust explosion in the spray dryer when the tower is open (occupied by MCC admixed with methanol) and pressure panels are used as designed for MCC.

CONCLUSION

The current work provides an example of how common pharmaceutical solvents such as methanol, ethanol, and isopropanol can increase the explosion severity of microcrystalline cellulose excipient powder. The influence of solvent admixture on explosibility parameters (P_{max} and K_{St}) has been demonstrated experimentally for two modes of solvent admixture – pre-wetting of the excipient powder and direct addition to the combustion atmosphere. In addition to the laboratory-scale experiments, laboratory- and industrial-scale scenarios of solvent admixture in atmospheric mode were simulated with the accompanying experimental validation. Both experimental and simulation results demonstrated significant enhancements of the explosion severity parameters of MCC by solvent admixture. The outcomes of the current study demonstrate that safety measures designed for dust explosions alone cannot afford adequate protection in the case of hybrid mixture explosions.

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