Protocol: Nano-suspension formation via crystallization (Felodipine based)

Description

Preparation of 2ml sample of nanocrystals by bottoms up procedure.

Materials:

1. Felodipine (Sigma, F9677)
2. Dimethylacetamide (sigma, 38840)
3. PVP30(0.2%)and 0.25mM SLS

Equipment:

1. S220x
2. Vessel: 12x24 sample vessel P/N 520056
3. Holder: 12x24 sample holder P/N 500199
4. Chiller at 18C

Method:

1. Procure a 12X24 vessel
2. Add 99:1 ratio of the vehicle(PVP30 and SLS) and drug (felodipine in DMA) solution

   In crude terms for 2ml vials 1980ul of stabilizer solution and 20ul of Felodipine 100mM stock solution is added and subjected to AFA which the drug concentration to 1mM.

3. Load vessel into holder and position in instrument

4. Process AFA protocol:

   a. 175 PIP
   b. 20% Duty Factor
   c. 1000 Cycles per Burst
   d. 1200 second duration

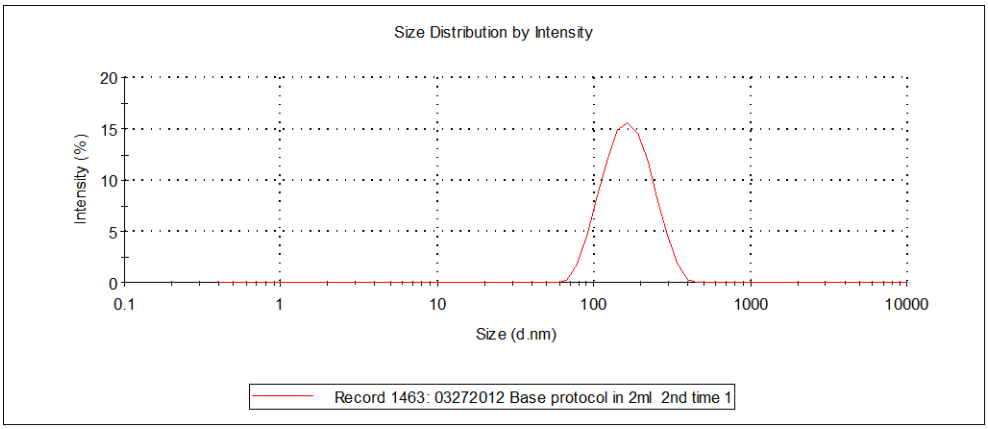
Measurement:
Malvern Zetasizer – 90 NS-90

Prepare sample:

Add 2ml of processed sample into cuvette (Malvern P/N DTS0012)
Add cuvette cap
Place in Zetasizer instrument and run the measurement

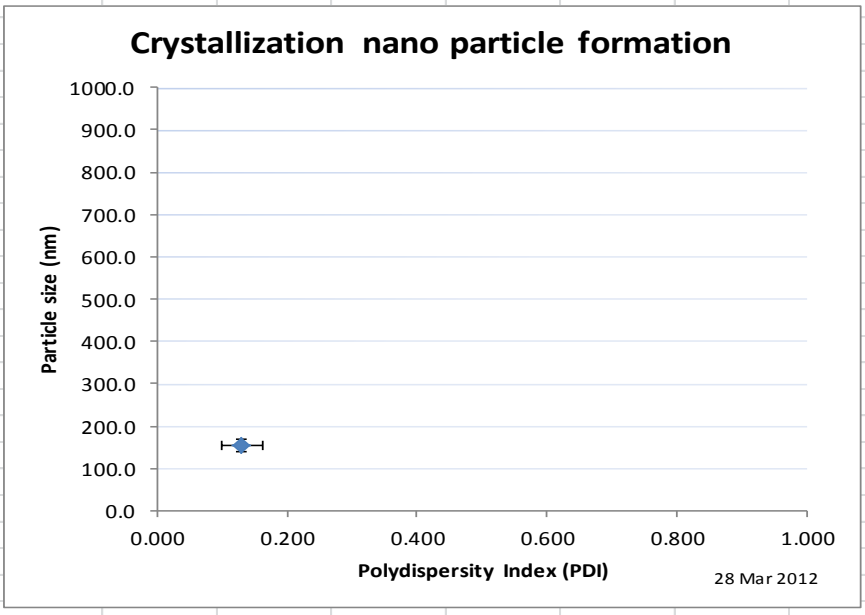
Typical output reading:

Z-Average (153.7nm) pdI (0.107)



Variation:

	Process	pdI	Z-average
	1	0.107	153.7
	2	0.099	135.7
	3	0.136	154.6
	4	0.178	172.6
	Z-average	0.130	154.2
	SD	0.031	13.1
	CV	24%	8%



CDB, SK, 28 Mar 2012