

SOLUBILITY ENHANCEMENT OF CURCUMIN BY SOLID DISPERSION: FORMULATION, CHARACTERISATION AND IN VITRO DISSOLUTION EVALUATION

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ABSTRACT

Curcumin has considerable pharmaceutical interest but its poor aqueous solubility and slow dissolution restrict formulation performance. The present study compared curcumin solid dispersions prepared with an equal-proportion carrier system of polyethylene glycol 6000 (PEG 6000) and polyvinylpyrrolidone K30 (PVP K30). Physical mixtures (PM1–PM3) and solid dispersions were prepared at drug:total carrier ratios of 1:1, 1:2 and 1:3 by kneading (F1–F3), solvent evaporation (F4–F6) and melting (F7–F9). The products were evaluated for practical yield, drug content, apparent saturation solubility in phosphate buffer pH 6.8 and in vitro dissolution using USP apparatus II. The selected batch was characterised by Fourier-transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD), scanning electron microscopy (SEM) and a 30-day short-term stability study. Apparent saturation solubility increased from 7.70 ± 0.15 $\mu\text{g/mL}$ for pure curcumin to 84.40 ± 0.58 $\mu\text{g/mL}$ for F6, corresponding to a 996.10% increase. F6 showed a practical yield of $94.42 \pm 0.69\%$, drug content of $96.66 \pm 0.62\%$ and 96.25% dissolution at 120 minutes compared with 33.68% for pure curcumin. FTIR retained the principal drug and carrier bands without a new prominent covalent functional group. The disappearance of the distinct curcumin melting endotherm in DSC, marked attenuation of curcumin reflections in PXRD and altered surface morphology in SEM indicated substantial reduction of the crystalline contribution, although residual PXRD peaks supported partial rather than complete amorphisation. F6 retained drug content and dissolution performance with only minor numerical changes over 30 days. The solvent evaporation method at a 1:3 drug:total carrier ratio produced the most favourable combined performance and represents a practical approach for enhancing the apparent solubility and dissolution of curcumin.

Keywords: curcumin; solid dispersion; PEG 6000; PVP K30; solvent evaporation; dissolution enhancement

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INTRODUCTION

Curcumin is the principal yellow-orange polyphenolic constituent of *Curcuma longa* and has been investigated for antioxidant, anti-inflammatory, antimicrobial and other biological activities. Its pharmaceutical development is nevertheless constrained by a hydrophobic molecular structure, poor wetting, very low aqueous solubility, slow dissolution and limited intestinal availability. Chemical instability in neutral and alkaline aqueous environments and extensive presystemic metabolism further reduce the exposure of unchanged curcumin after oral administration.^{1–3}

Solid dispersion technology distributes a poorly water-soluble drug within a hydrophilic carrier or carrier combination. Dissolution enhancement may arise from improved wetting, reduced aggregation, finer drug distribution, reduced crystalline order and maintenance of drug–polymer interactions. The final performance depends on the carrier chemistry, drug loading and preparation method because the same components can produce different degrees of molecular mixing, residual crystallinity and physical stability.^{4–9}

PEG 6000 is a water-soluble semicrystalline carrier with a low melting range and can improve

wetting and dispersion of hydrophobic drugs. PVP K30 is an amorphous, hygroscopic polymer capable of providing a less ordered matrix and interacting non-covalently with compatible drug molecules. Curcumin dispersions prepared with PEG- or PVP-based systems have shown improved solubility and dissolution, while FTIR, DSC and PXRD studies have demonstrated that carrier selection and processing can substantially alter the detectable crystalline contribution of the drug.^{10–15}

The present work was designed to compare three accessible preparation methods—kneading, solvent evaporation and melting—using the same PEG 6000–PVP K30 carrier system and identical drug: total carrier ratios. The objectives were to identify the formulation with the most favourable combined practical yield, drug content, apparent saturation solubility and dissolution profile, and to characterise the solid-state and morphological changes associated with the selected batch.

MATERIALS AND METHODS

Materials

Curcumin, PEG 6000, PVP K30 and Tween 80 were obtained from Loba Chemie Pvt. Ltd., Mumbai, India. Methanol, ethanol, hydrochloric acid, sodium hydroxide and reagents used for preparation of phosphate buffer pH 6.8 were of analytical grade and were obtained from S. D. Fine-Chem Ltd., Mumbai, India. Distilled water was

prepared in-house. All materials were used without further purification.

Preformulation and UV-visible spectrophotometric analysis

Curcumin was examined for colour, odour, appearance, powder characteristics and visible foreign matter. The melting point was determined by the capillary method in triplicate. Preliminary solubility was assessed in distilled water, 0.1 N hydrochloric acid, phosphate buffer pH 6.8, ethanol, methanol and acetone. For quantitative analysis, a curcumin solution in ethanol was scanned from 200 to 600 nm and the analytical wavelength was fixed at 425.8 nm. Calibration curves were prepared over 2–12 µg/mL in ethanol for drug-content analysis and in phosphate buffer pH 6.8 for apparent saturation-solubility and dissolution studies. Both calibration relationships were linear over the selected range ($R^2 > 0.999$).^{16,17}

Formulation design

Curcumin was maintained at 500 mg in every formulation. PEG 6000 and PVP K30 were used in equal proportions and the total carrier quantity was varied to provide drug:total carrier ratios of 1:1, 1:2 and 1:3. Physical mixtures were coded PM1–PM3; kneaded dispersions F1–F3; solvent-evaporated dispersions F4–F6; and melting-method dispersions F7–F9 (Table 1).^{10,11}

Table 1: Composition of physical mixtures and curcumin solid-dispersion batches

Preparation method	Batch	Drug: total carrier ratio	Curcumin (mg)	PEG 6000 (mg)	PVP K30 (mg)
Physical mixture	PM1	1:1	500	250	250
Physical mixture	PM2	1:2	500	500	500
Physical mixture	PM3	1:3	500	750	750
Kneading	F1	1:1	500	250	250
Kneading	F2	1:2	500	500	500
Kneading	F3	1:3	500	750	750
Solvent evaporation	F4	1:1	500	250	250
Solvent evaporation	F5	1:2	500	500	500
Solvent evaporation	F6	1:3	500	750	750
Melting	F7	1:1	500	250	250
Melting	F8	1:2	500	500	500
Melting	F9	1:3	500	750	750

PEG 6000 and PVP K30 together constitute the total carrier quantity.

Preparation of physical mixtures and solid dispersions

Physical mixtures were prepared by geometric dilution of curcumin with the carrier blend, followed by gentle trituration and passage through sieve no. 60. Kneaded batches were prepared by adding ethanol:water (1:1 v/v) dropwise to the drug-carrier blend, kneading for 30 minutes, drying the wet mass at $40 \pm 2^\circ\text{C}$, powdering and sieving. For solvent evaporation, curcumin was dissolved in ethanol, PEG 6000 and PVP K30 were incorporated with continuous stirring, and the solvent was removed on a water bath at $40 \pm 2^\circ\text{C}$. The recovered mass was dried at $40 \pm 2^\circ\text{C}$, powdered and sieved. For the melting method, PEG 6000 was melted at $60 \pm 2^\circ\text{C}$, PVP K30 and curcumin were incorporated with continuous mixing, and the uniform mass was cooled, solidified, powdered and passed through sieve no. 60. All batches were stored in labelled amber-coloured containers in a desiccator.^{10,11}

Evaluation of formulations

Physical appearance was recorded for colour, powder nature, texture and lump formation. Practical yield was calculated as the recovered dry weight divided by the theoretical total formulation weight $\times 100$. For drug-content determination, powder equivalent to 10 mg curcumin was extracted with ethanol, filtered, diluted and analysed at 425.8 nm. Apparent saturation solubility was determined by adding excess sample to 10 mL phosphate buffer pH 6.8, shaking at 100 rpm and $37 \pm 0.5^\circ\text{C}$ for 24 hours, separating undissolved material and analysing the filtrate at 425.8 nm.

In vitro dissolution was conducted using USP apparatus II with 900 mL phosphate buffer pH 6.8 at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. Powder equivalent to 10 mg curcumin was added directly to the vessel. Samples of 5 mL were withdrawn at 5, 10, 15, 30, 45, 60, 90 and 120 minutes and replaced with equal volumes of fresh medium. The cumulative percentage dissolved was corrected for sample replacement.¹⁷

Selection and characterisation of the optimised batch

The batch selected from the combined evaluation results was compared with pure curcumin, PEG 6000, PVP K30 and the corresponding physical mixture. FTIR spectra were recorded over $4000\text{--}400\text{ cm}^{-1}$. DSC samples (approximately 3–5 mg) were heated from 30 to 300°C at $10^\circ\text{C}/\text{min}$ in sealed aluminium pans. PXRD patterns were recorded over $5\text{--}80^\circ 2\theta$. SEM images were obtained after mounting the dried powders on carbon adhesive tape and gold coating. The solid-state results were interpreted collectively because the loss of a DSC endotherm alone does not establish complete amorphisation.^{12–15}

Short-term stability study

Selected batch F6 was packed in a tightly closed amber-coloured glass container and stored in a desiccator at room temperature (approximately

25°C) for 30 days. Relative humidity was not controlled or recorded. Samples were evaluated at day 0, day 15 and day 30 for physical appearance, drug content and dissolution. This study was exploratory and was not designed as an ICH-compliant stability programme.^{19–21}

Data presentation

Analytical determinations were carried out in triplicate unless otherwise stated. Results are presented as mean $\pm$ standard deviation where replicate dispersion values were available. Comparisons among batches were descriptive; no claim of statistical significance was made.

RESULTS AND DISCUSSION

Preformulation and analytical findings

Curcumin was a yellow-orange, dry crystalline powder with a faint characteristic odour and no visible foreign matter. It was practically insoluble in distilled water and 0.1 N hydrochloric acid, very slightly soluble in phosphate buffer pH 6.8 and soluble in ethanol, methanol and acetone. The observed melting range was $181\text{--}183^\circ\text{C}$. The UV spectrum showed a maximum at 425.8 nm, and the calibration responses in ethanol and phosphate buffer pH 6.8 were suitable for quantitative comparison of the prepared samples.

Curcumin showed maximum absorbance at 425.8 nm. Calibration curves prepared in ethanol and phosphate buffer pH 6.8 were linear over the concentration range $2\text{--}12\text{ }\mu\text{g/mL}$, with regression equations $A = 0.0756C + 0.0049$ ($R^2 = 0.9992$) and $A = 0.0694C + 0.0047$ ($R^2 = 0.9998$), respectively. These calibration plots were used for the estimation of drug content, apparent saturation solubility and in vitro dissolution samples.

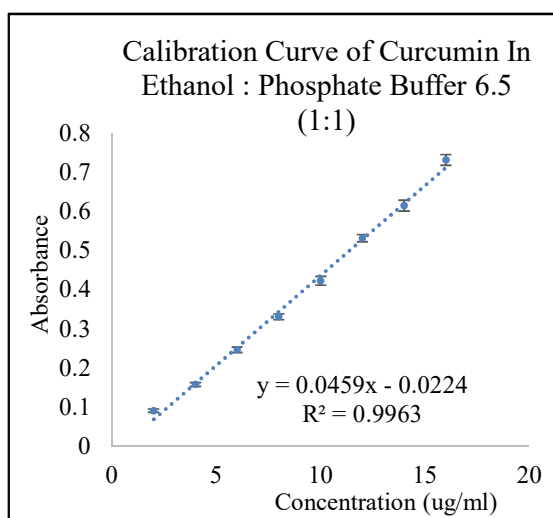
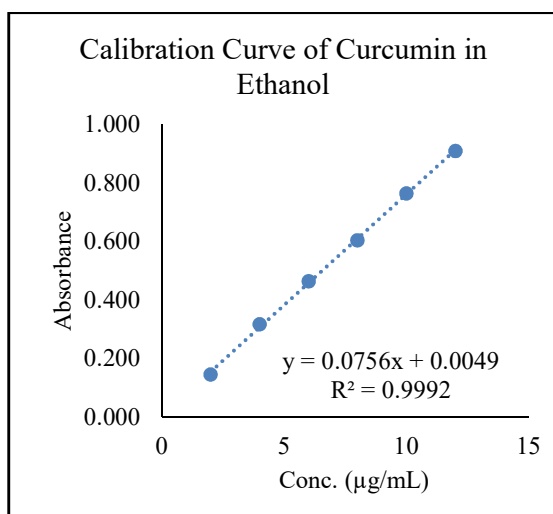


Figure 1A: Calibration curves of curcumin in (A) ethanol and (B) phosphate buffer pH 6.8 over the concentration range 2–12 µg/mL.

Physical appearance, practical yield and drug content

Increasing the carrier proportion changed the powder colour from yellow to pale yellow. The

kneaded batches showed a dried powder texture and F1–F2 contained a few soft aggregates. Solvent-evaporated batches, particularly F5 and F6, were comparatively uniform and less gritty. Melting-method batches were slightly waxy because of the PEG-rich matrix. No hard lumps remained after sieving (Figure 1).

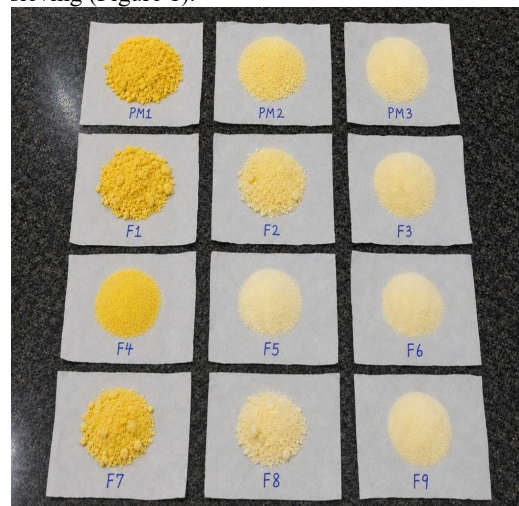


Figure 1: Physical appearance of physical mixtures PM1–PM3 and curcumin solid dispersions F1–F9 prepared by kneading, solvent evaporation and melting methods.

Practical yield ranged from $86.41 \pm 0.65\%$ to $94.64 \pm 0.36\%$. Recovery was lowest for F1 and highest for F9, while F6 gave $94.42 \pm 0.69\%$. The comparatively lower recovery of kneaded batches was consistent with adhesion of the wet mass to the mortar, pestle and drying surface. Drug content ranged from $91.62 \pm 0.61\%$ to $96.66 \pm 0.62\%$. F6 showed the highest mean drug content, indicating substantial retention and uniform extractability of curcumin after solvent evaporation (Table 2).

Table 2: Comparative performance of pure curcumin, physical mixtures and solid-dispersion batches

Sample	Practical yield (%)	Drug content (%)	Apparent saturation solubility (µg/mL)	Increase over pure curcumin (%)	Dissolved at 120 min (%)
Pure curcumin	—	—	7.70 ± 0.15	0.00	33.68
PM1	—	91.62 ± 0.61	15.07 ± 0.23	95.71	46.48
PM2	—	92.96 ± 1.01	20.61 ± 0.93	167.66	58.67
PM3	—	94.25 ± 0.15	26.61 ± 1.45	245.58	67.87
F1	86.41 ± 0.65	92.83 ± 0.46	32.80 ± 1.38	325.97	73.68
F2	89.14 ± 0.61	94.61 ± 1.01	45.92 ± 0.55	496.36	82.17
F3	90.99 ± 0.29	95.41 ± 0.51	56.49 ± 1.46	633.64	87.98

Sample	Practical yield (%)	Drug content (%)	Apparent saturation solubility (µg/mL)	Increase over pure curcumin (%)	Dissolved at 120 min (%)
F4	89.19 ± 0.77	94.07 ± 0.54	48.70 ± 1.71	532.47	88.75
F5	91.73 ± 0.11	96.26 ± 1.08	67.68 ± 0.30	778.96	92.69
F6	94.42 ± 0.69	96.66 ± 0.62	84.40 ± 0.58	996.10	96.25
F7	91.61 ± 0.52	93.32 ± 0.81	41.11 ± 1.04	433.90	85.51
F8	93.15 ± 0.24	95.41 ± 0.67	63.79 ± 0.08	728.44	91.37
F9	94.64 ± 0.36	96.03 ± 0.35	76.32 ± 1.17	891.17	95.15

Values for practical yield, drug content and apparent saturation solubility are mean ± standard deviation (n = 3). Dissolution values are mean cumulative percentage dissolved (n = 3).

Apparent saturation solubility

Pure curcumin showed an apparent saturation solubility of 7.70 ± 0.15 µg/mL in phosphate buffer pH 6.8. Physical mixing alone improved the value progressively to 26.61 ± 1.45 µg/mL for PM3, which can be attributed mainly to carrier-assisted wetting and dispersion. Every solid-dispersion batch showed a higher value than the corresponding physical mixture. Within each method, solubility increased as the carrier ratio increased from 1:1 to 1:3. F6 gave the highest value, 84.40 ± 0.58 µg/mL, representing a 996.10% increase over pure curcumin. F9 was second at 76.32 ± 1.17 µg/mL. These findings show that both carrier concentration and processing history governed the measured aqueous performance (Figure 2).^{4,6,10–15}

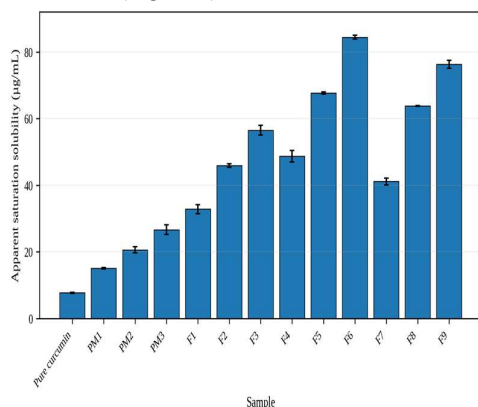


Figure 2: Apparent saturation solubility of pure curcumin, physical mixtures and solid-dispersion batches in phosphate buffer pH 6.8. Values are mean ± standard deviation (n = 3).

In vitro dissolution and selection of F6

Pure curcumin dissolved slowly and incompletely, reaching 33.68% at 120 minutes. Physical mixtures improved dissolution to 46.48%, 58.67% and 67.87% for PM1, PM2 and PM3, respectively. The kneaded dispersions reached 73.68–87.98%, solvent-evaporated dispersions

88.75–96.25% and melting-method dispersions 85.51–95.15% at 120 minutes. At every corresponding carrier ratio, the solvent-evaporated batch showed a numerically higher endpoint than the kneaded and melting batches. F6 produced the highest overall dissolution of 96.25%, followed closely by F9 at 95.15% (Figure 3).

The dissolution ranking was consistent with the apparent saturation-solubility results. Higher carrier levels increased the hydrophilic environment around the drug and reduced aggregation, while solvent evaporation provided intimate distribution of curcumin within the PEG 6000–PVP K30 matrix before removal of the volatile phase. F6 was selected because it combined a high practical yield, the highest drug content and apparent saturation solubility, and the highest 120-minute dissolution.^{4–8,10–15}

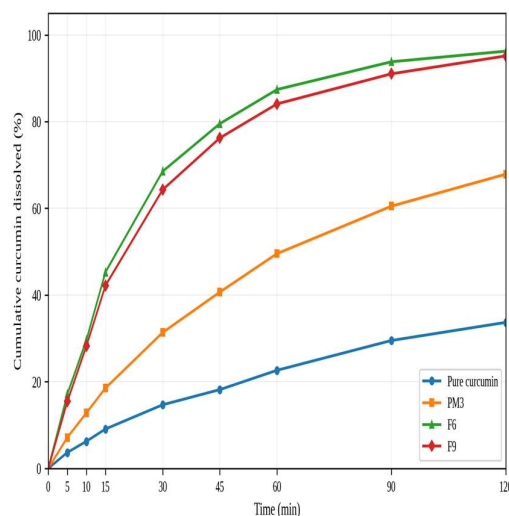


Figure 3: Comparative in vitro dissolution profiles of pure curcumin, PM3, F6 and F9 in phosphate buffer pH 6.8. Values represent mean cumulative percentage dissolved (n = 3).

FTIR analysis

Pure curcumin showed characteristic bands at 3510, 1627, 1602, 1508 and 1274 cm⁻¹. PEG 6000 showed prominent bands at 2887 and 1110 cm⁻¹, while PVP K30 showed bands at 1655 and 1288

cm⁻¹. PM3 retained the principal drug and carrier bands. In F6, the O–H region appeared as a broad band near 3426 cm⁻¹, the curcumin-related conjugated C=O/C=C region was observed near 1622 cm⁻¹ with reduced intensity and broadening, and the PEG-related C–O–C band remained near 1112 cm⁻¹. The changes may reflect band overlap and non-covalent drug–carrier interactions, but small shifts alone do not identify a specific interaction. No new prominent band was observed, indicating retention of the principal chemical functionalities (Figure 4).^{12–14}

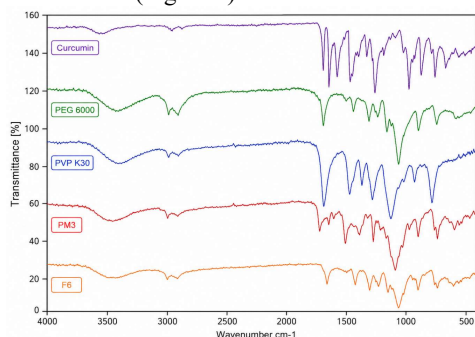


Figure 4: Comparative FTIR spectra of pure curcumin, PEG 6000, PVP K30, physical mixture PM3 and selected solid-dispersion batch F6.

DSC analysis

Pure curcumin showed a sharp melting endotherm at 179.2°C. PEG 6000 melted at 61.4°C, while the broad PVP K30 event around 83.6°C was consistent with loss of absorbed or bound moisture. PM3 retained the PEG-related event at 60.8°C and showed a weak curcumin-related endotherm at 176.8°C. F6 showed a broad carrier-related event at 58.9°C, while a distinct curcumin melting endotherm near 179°C was not detected. This finding indicated a marked reduction in the thermally detectable crystalline drug contribution; however, possible dissolution of curcumin in molten PEG during the DSC scan prevented interpretation of DSC as independent proof of complete amorphisation (Figure 5).^{12–15}

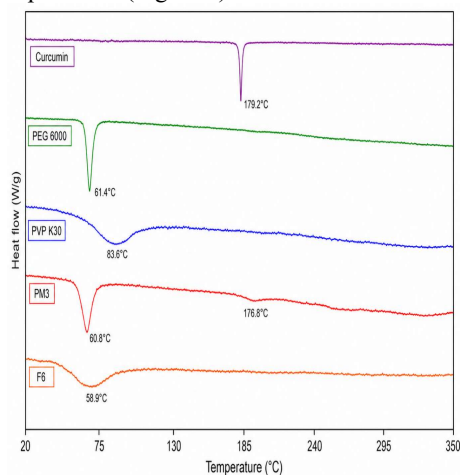


Figure 5: DSC thermograms of pure curcumin, PEG 6000, PVP K30, physical mixture PM3 and selected solid-dispersion batch F6.

PXRD analysis

Pure curcumin showed sharp reflections at approximately 8.9°, 12.2°, 14.5°, 17.2°, 23.2°, 24.6° and 25.5° 2θ, confirming a substantial crystalline contribution. PM3 retained the principal curcumin reflections with lower prominence, largely because of carrier dilution and peak overlap. F6 exhibited a predominantly diffuse pattern with low-prominence residual peaks near 8.8°, 12.2°, 17.1°, 23.1° and 24.5° 2θ. The residual reflections demonstrate that some crystalline material remained; therefore, the selected batch is more accurately described as partially amorphised or markedly reduced in crystalline order rather than completely amorphous (Figure 6).^{10,12–15}

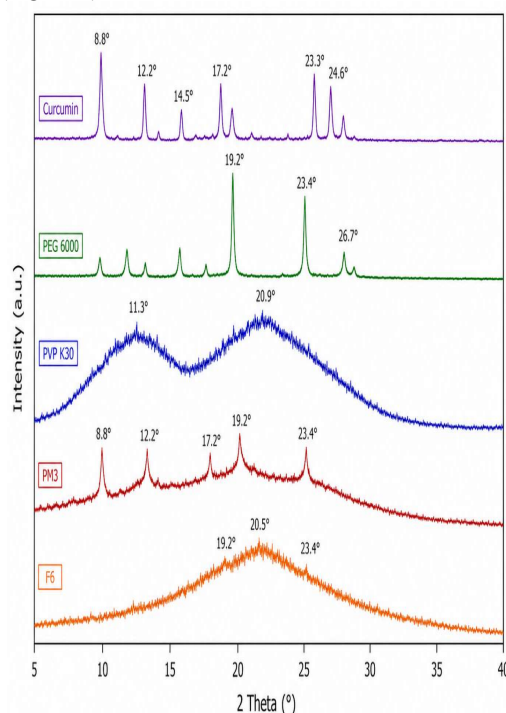


Figure 6: PXRD diffractograms of pure curcumin, PEG 6000, PVP K30, physical mixture PM3 and selected solid-dispersion batch F6.

SEM analysis

Pure curcumin showed irregular particles with comparatively sharp edges and uneven surfaces. PM3 displayed a heterogeneous mixture with distinct particle boundaries, consistent with simple physical blending. In contrast, F6 showed an irregular, comparatively fused carrier-dominant surface with less distinct particle boundaries. The altered morphology supported the occurrence of substantial physical restructuring during solvent evaporation and drying, although SEM alone cannot establish molecular dispersion or amorphisation (Figure 7).^{10,12–15,18}

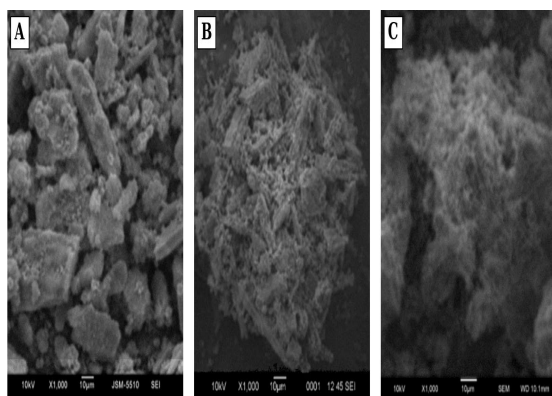


Figure 7: SEM photomicrographs of (A) pure curcumin, (B) physical mixture PM3 and (C) selected solid-dispersion batch F6 at the indicated instrument magnification and scale.

Short-term stability

F6 remained pale yellow throughout the 30-day observation period. The powder remained dry and free from hard lumps at day 15; a few soft aggregates were observed at day 30 and dispersed with gentle handling. Drug content decreased numerically from $96.86 \pm 0.37\%$ to $96.13 \pm 0.27\%$, and the 120-minute dissolution value decreased from $95.53 \pm 0.35\%$ to $94.69 \pm 0.32\%$ (Table 3). The complete profiles showed only small numerical differences (Figure 8). The soft aggregation may have reflected limited moisture uptake by the hydrophilic carriers, although moisture content and relative humidity were not measured. These findings support short-term retention of performance under the tested laboratory conditions but do not establish long-term or ICH-compliant stability.^{19–21}

Table 3: Short-term stability results of selected solid-dispersion batch F6

Storage period	Physical appearance	Drug content (%)	Dissolved at 120 min (%)
Day 0	Pale-yellow, dry powder	96.86 ± 0.37	95.53 ± 0.35
Day 15	Pale-yellow, dry powder; no hard lumps	96.26 ± 0.24	95.00 ± 0.20
Day 30	Pale-yellow powder with few soft aggregates	96.13 ± 0.27	94.69 ± 0.32

Drug-content and dissolution values are mean $\pm$ standard deviation (n = 3).

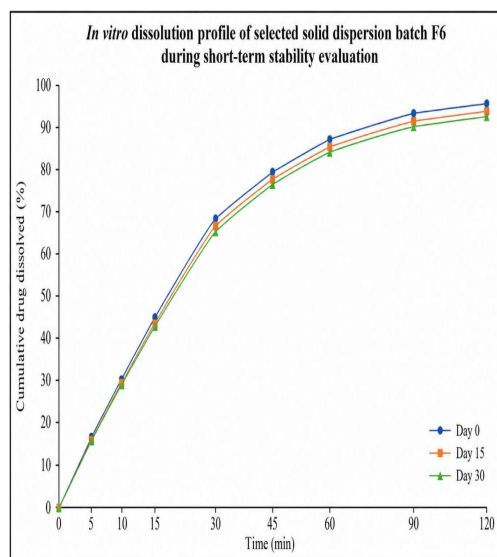


Figure 8: In vitro dissolution profiles of F6 during short-term stability evaluation at day 0, day 15 and day 30.

CONCLUSION

Curcumin solid dispersions were successfully prepared with PEG 6000 and PVP K30 by kneading, solvent evaporation and melting methods. Increasing the carrier proportion improved apparent saturation solubility and dissolution within each method. F6, prepared by solvent evaporation at a 1:3 drug:total carrier ratio, showed the most favourable combined performance, with a practical yield of $94.42 \pm 0.69\%$, drug content of $96.66 \pm 0.62\%$, apparent saturation solubility of $84.40 \pm 0.58 \mu\text{g/mL}$ and 96.25% dissolution at 120 minutes. FTIR retained the principal chemical functionalities, while DSC, PXRD and SEM collectively indicated extensive physical restructuring and a marked reduction, but not complete elimination, of curcumin crystallinity. The formulation retained drug content and dissolution with only minor numerical changes during 30 days of laboratory storage. The PEG 6000–PVP K30 carrier system prepared by solvent evaporation therefore offers a simple and practical approach for enhancing the aqueous performance of curcumin. Further development should include residual-solvent testing, moisture assessment, ICH stability studies, dosage-form conversion and in vivo evaluation.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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