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Heckel Higuchi and Peppas Plots and Similarity Factors

Practical 18 - Data-analysis practical

Aim

To construct Heckel, Higuchi and Korsmeyer-Peppas plots and calculate an appropriate dissolution similarity factor.

Principle

These calculations describe different phenomena. A Heckel plot relates compaction pressure to powder-bed densification. Higuchi and Peppas relationships describe release data under their respective assumptions.

A high correlation coefficient is not sufficient proof of a physical mechanism. Data selection, geometry, model assumptions, residuals and the fitted range must be considered before interpreting a parameter.

Materials and Requirements

- Pressure and relative-density data
- Individual-unit dissolution data and sampling conditions
- Spreadsheet or suitable analysis software
- Calculation worksheet with clearly specified units

Procedure

1. For compaction data, establish the material density and calculate relative density D at each pressure. State whether the measurement is in-die or out-of-die.
2. Plot ln[1/(1-D)] against pressure over the justified approximately linear region. Record the slope, intercept and the selected range.
3. For suitable release data, plot cumulative amount released against square root of time for a Higuchi assessment.
4. For a Peppas assessment, calculate the released fraction and fit log(fraction) against log(time) over an appropriate initial range, commonly up to about 60% release when that model use is justified.
5. Review geometry and assumptions before interpreting the Peppas exponent; the same exponent has different implications for different device shapes.
6. For profile similarity, confirm that unit numbers, time points, variability and other prerequisites satisfy the applicable product guidance, then calculate f2.
7. Present the raw data, fitted parameters, residuals and limitations separately for each model.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Model	Transformed variables	Parameter	Assumption / fitted range
Heckel	ln[1/(1-D)] versus pressure	Slope K	State region and density basis
Higuchi	Released amount versus sqrt(time)	Release coefficient	State applicability

Model	Transformed variables	Parameter	Assumption / fitted range
Peppas	log(fraction) versus log(time)	Exponent n	State geometry and range
Similarity	Paired mean profiles	f2	Verify comparison prerequisites

Calculations

- Heckel: ln[1/(1-D)] = KP + A; apparent yield-pressure parameter = 1/K when the interpretation is justified
- Higuchi: Q = kH x sqrt(t)
- Peppas: Mt/Minfinity = k x t^n
- f2 = 50 log10(100 / sqrt(1 + mean((R-T)^2)))

Worked Example

Illustrative Heckel slope K = 0.010 MPa^-1 gives an apparent parameter 1/K = 100 MPa.

For release fractions 0.20 at 1 h and 0.40 at 4 h, the two-point Peppas exponent is log(0.40/0.20)/log(4/1) = 0.50. A formal fit requires more observations.

For reference means 20, 45, 70 and 85% and test means 18, 43, 68 and 83%, mean squared difference is 4; f2 = 50 log10(100/sqrt(5)) = 82.53 approximately.

This numerical similarity example does not replace verification of the applicable study-design prerequisites.

Result and Interpretation

- Give each model its own conclusion and avoid combining densification and release parameters as though they measured the same property.
- Explain the fitted range and uncertainty. Conventional f2 similarity interpretation applies only to a valid comparison design.

Precautions

- Exclude time zero from logarithmic fits and justify all other exclusions.
- Keep pressure and density definitions consistent.
- Use individual-unit information when assessing the suitability of mean profiles.
- Do not infer a release mechanism solely from the largest R-squared value.

Viva Questions and Answers

What does the Heckel analysis describe?

Densification behaviour during compaction under the specified measurement conditions.

Why limit a Peppas fit to an appropriate range?

Later release can violate the assumptions of the initial empirical relationship.

What can invalidate an f2 comparison?

Inappropriate design, excessive variability, unsuitable time points or other unmet prerequisites.

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