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Formulation and evaluation of diclofenac powder

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Abstract

- Diclofenac potassium powder for oral solution (Voltfast, Catafast, Cambia; hereafter referred to as diclofenac potassium powder) is a non-steroidal anti inflammatory drug (NSAID), and is indicated for the acute treatment of migraine. This article reviews the pharmacological properties of diclofenac potassium powder and its efficacy and tolerability in patients with acute migraine also evaluation and study the effect of addition different type of polymer on it . Diclofenac potassium powder was clinically efficacious and generally well tolerated in placebo-controlled trials in patients with this indication

Introduction:-

- Powders are intimate mixtures of dry, finely divided drugs and/or chemicals that may be intended for internal (Oral Powders) or external (Topical Powders) use. Because of their greater specific surface area, powders disperse and dissolve more readily than compacted dosage forms. Children and those adults who experience difficulty in swallowing tablets or capsules may find powders more acceptable..(1). Drugs that are too bulky to be formed into tablets or capsules of convenient size may be administered as powders. Immediately prior to use, oral powders are mixed in a beverage or apple sauce. Often, stability problems encountered in liquid dosage forms are avoided in powdered dosage forms. Drugs that are unstable in aqueous suspensions or solutions may be prepared in the form of granules or powders. These are intended to be constituted by the pharmacist by the addition of a specified quantity of water just prior to dispensing. Because these constituted products have limited stability, they are required to have a specified expiration date after constitution and may require storage in a refrigerator (3). Oral powders may be dispensed in doses premeasured by the pharmacist, i.e., divided powders, or in bulk.

- **Disadvantages of Powders as Dosage Forms**
- 1.Timeconsuming
  2-Inaccuracy in dose
- 3-Unsuitable for many unpleasant tasting, volatile, oxidizing, hygroscopic and deliquescent drugs.
- **Classification**:-
- **Based on Usage:-**
  -powders for external use.
  -powders for internal use.
- **Based on quantity:-**

-bulk powders

-divided powders

Pharmacodynamic Properties

- Diclofenac is a benzeneacetic acid derivative NSAID, and is available as a buffered soluble powder(8).No specific pharmacodynamic studies of diclofenac potassium powder in migraine are available. However, in its various formulations, diclofenac is a well-established drug and has been comprehensively reviewed elsewhere; this. Diclofenac has been shown to have analgesic, antiinflammatory and anti-pyretic effects; its efficacy in migraine is believed to be a result of its analgesic properties, possibly enhanced by its anti-inflammatory properties.

AIM OF THIS STUDY:-

- Formulation and evaluation of diclofenac potassium powder for oral administration free from dusting effect.

PHSICO CHEMICAL PROPERTIES:-

- Crystals. Mp 156- to 158 , . logP:4.2 and pKa 4.2.(5)
- Solubility: sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96 per cent), slightly soluble in acetone. with ultraviolet spectrum in aqueous acid—273 nm and in aqueous alkali— 275 nm.

HPMC

- Hypromellose is widely used in oral, ophthalmic and topical pharmaceutical formulations. In oral products, hypromellose is primarily used as a tablet binder, in film-coating, and as a matrix for use in extended-release tablet formulations. Concentrations
- between 2% and 5% w/w may be used as a binder in either wet- or dry-granulation processes. High-viscosity grades may be used to retard the release of drugs from a matrix at levels of 10–80% w/w in tablets and capsules

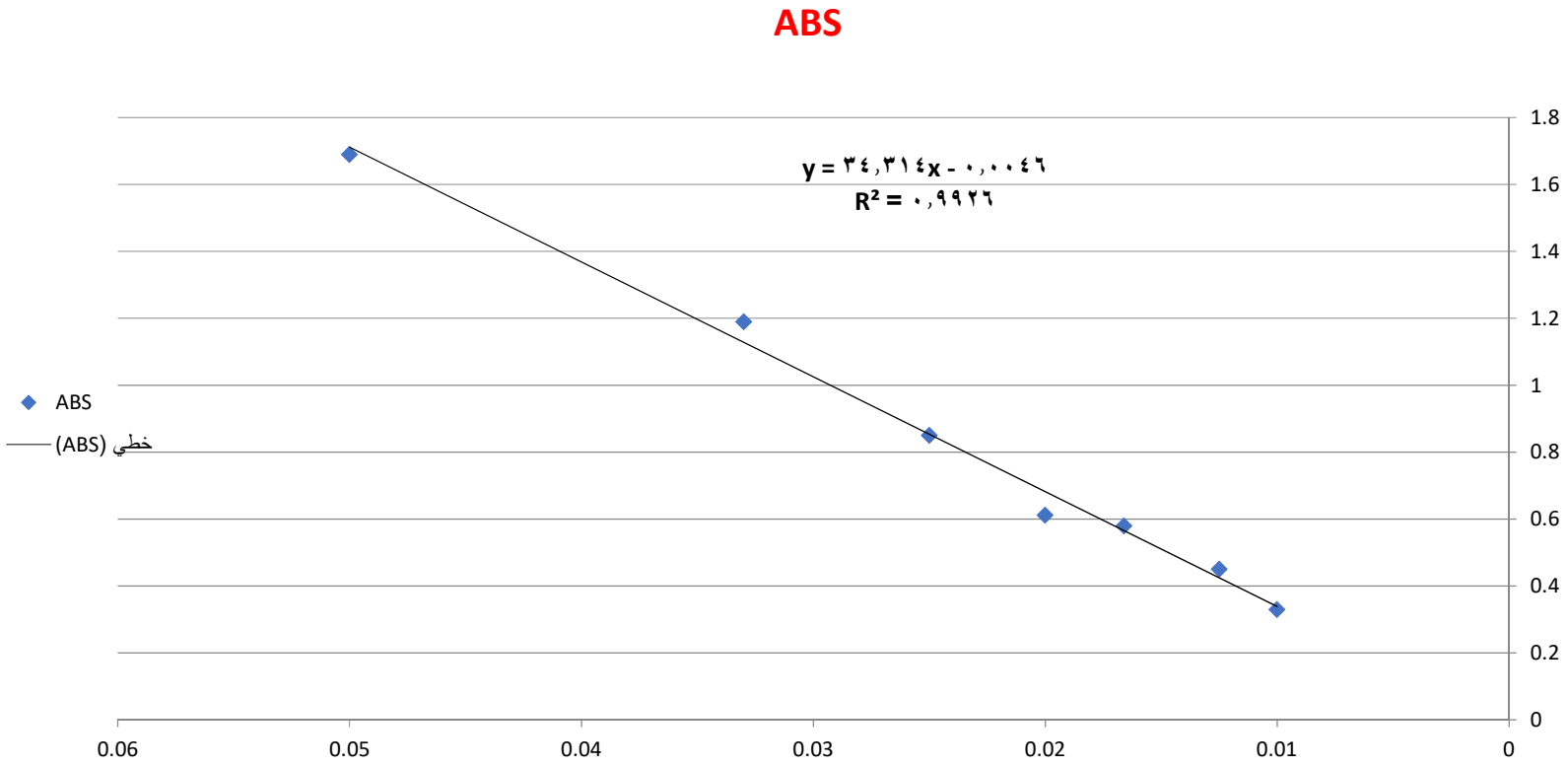
Materials and Methods

- **Materials**
- HPMC grades of LV5 and LV15 diclofenac potassium powder were purchased from Alalmia suppliers

Methods

- The calibration curve was constructed by preparing stock solution of diclofenac potassium of 50mg /100ml water and take various volume and dilute them to make series of solutions with different concentrations and measuring the absorbance of each at maximum wave length 275 nm and when we get abs under 1.5 we then prepare a stock solutions ,,finally we make calibration curve of our solutions.

Calibration curve



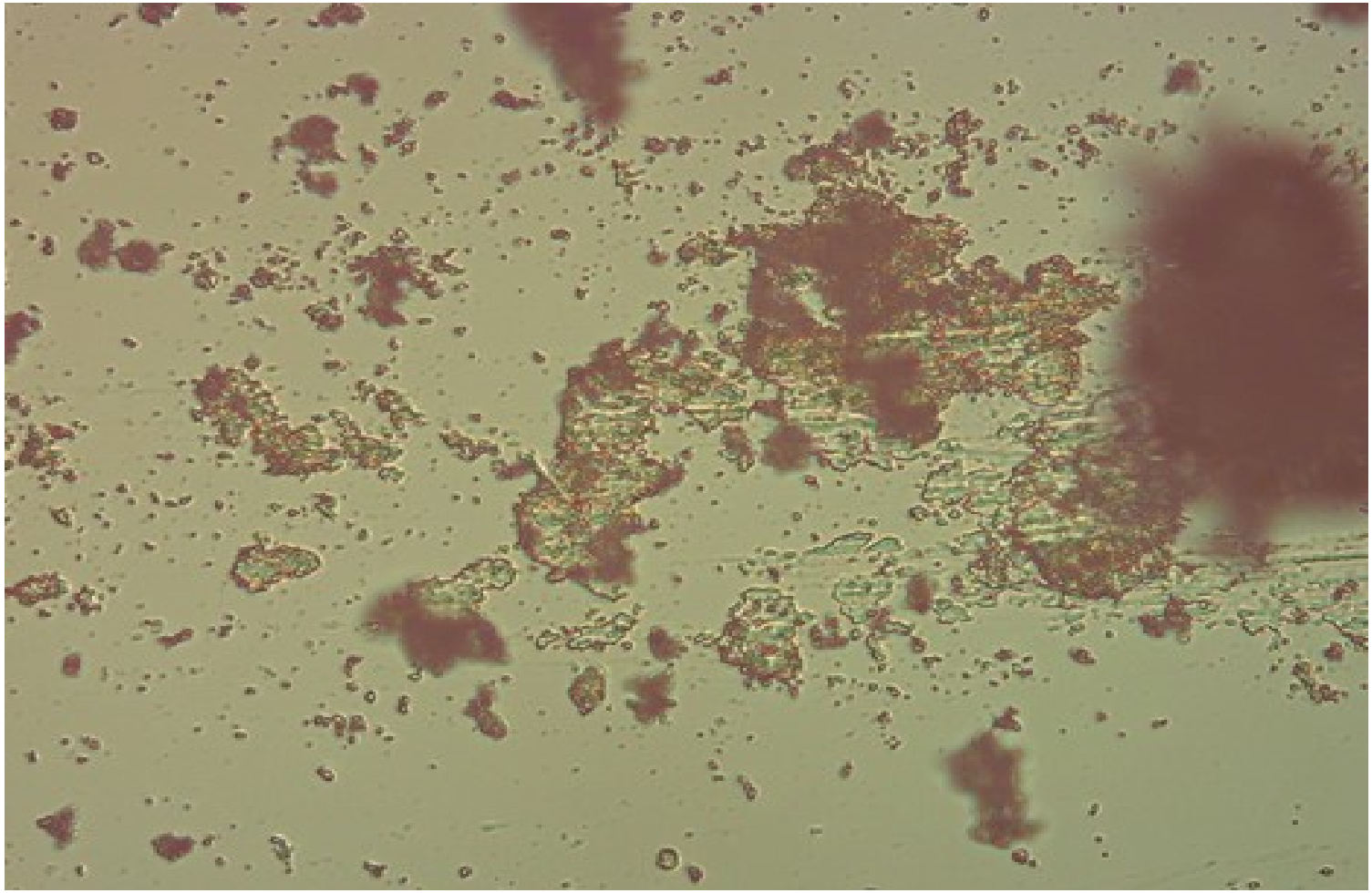
HPMC 15 spray method	HPMC 5 spray method	HPMC 15 dry powder method
F1:2spray+100mg	F4:2spray+100mg	F7: 6mg +100mg
F2:4spray+100mg	F5:4spray+100mg	F8:12mg +100mg
F3:6spray+100mg	F6:6spray+100mg	F9:18mg +100mg

RESULTS:-

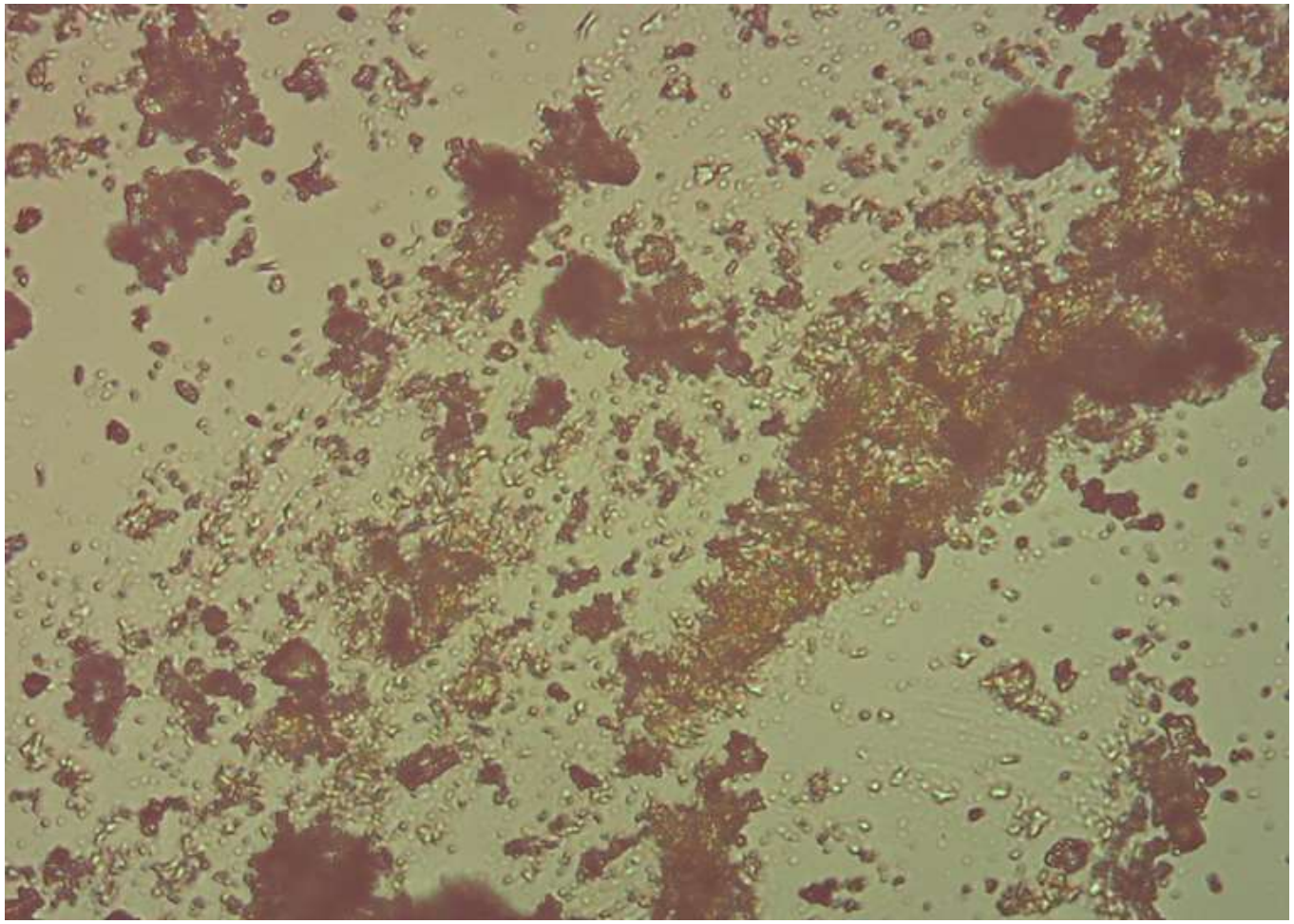
- Dissolution test:- we took 20mg of diclofenac powder and dissolve it in 50ml of water and measure the absorbance after 15 sec and 40 sec to when the complete dissolution occurs after that we took 25 mg of each nine formulas and measure absorbance after 15 sec and 40 sec to determine the effect of polymer on dissolution time of drug.

	After 15 sec	After 40 sec
F1	1.109	1.348
F2	1.08	1.339
F3	1.099	1.39
F4	1.2	1.36
F5	1.089	1.35
F6	1.144	1.39
F7	1.21	1.367
F8	1.099	1.37
F9	1.12	1.38
DRUG	1.4	1.4

F 1



F 2



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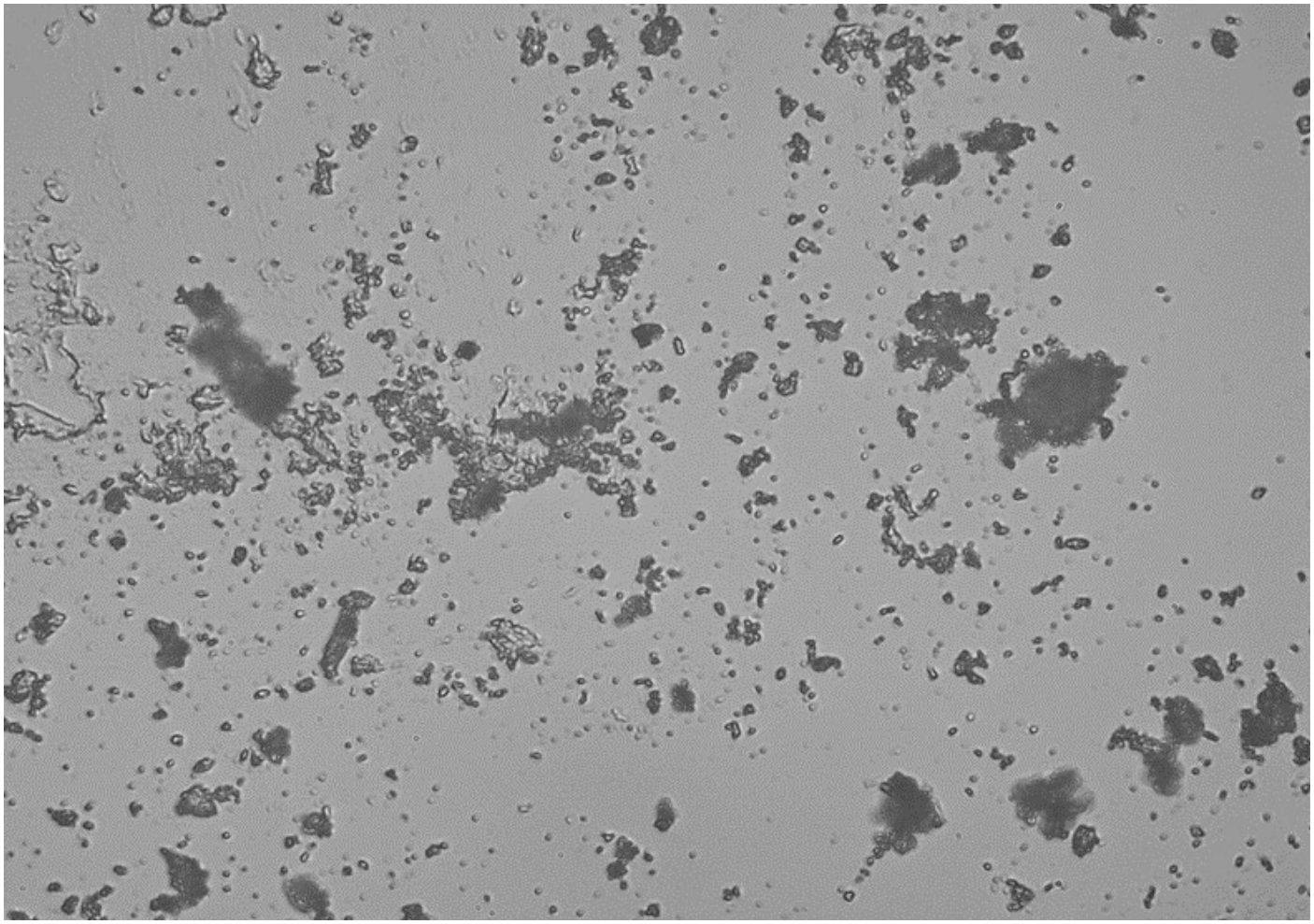

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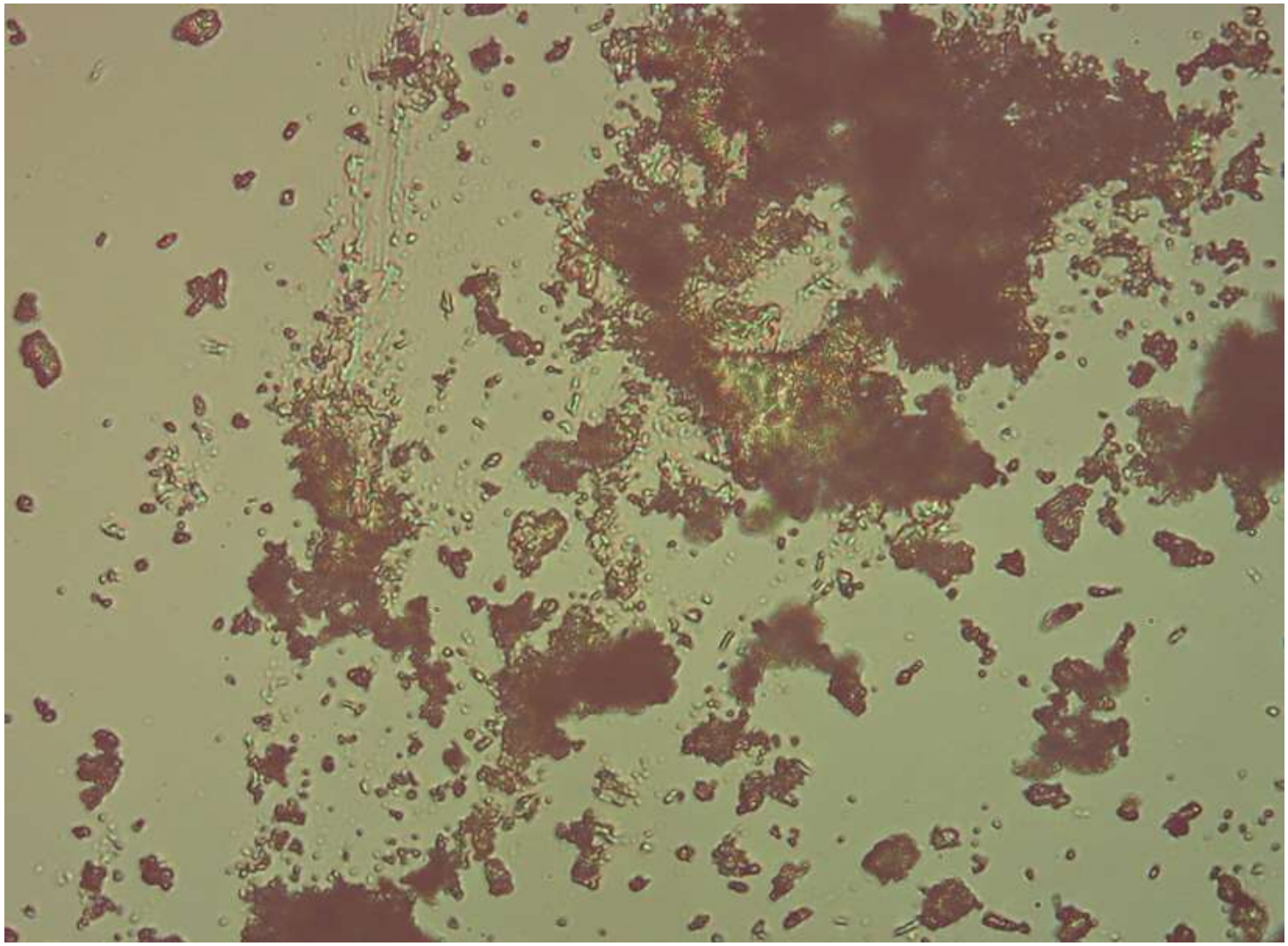
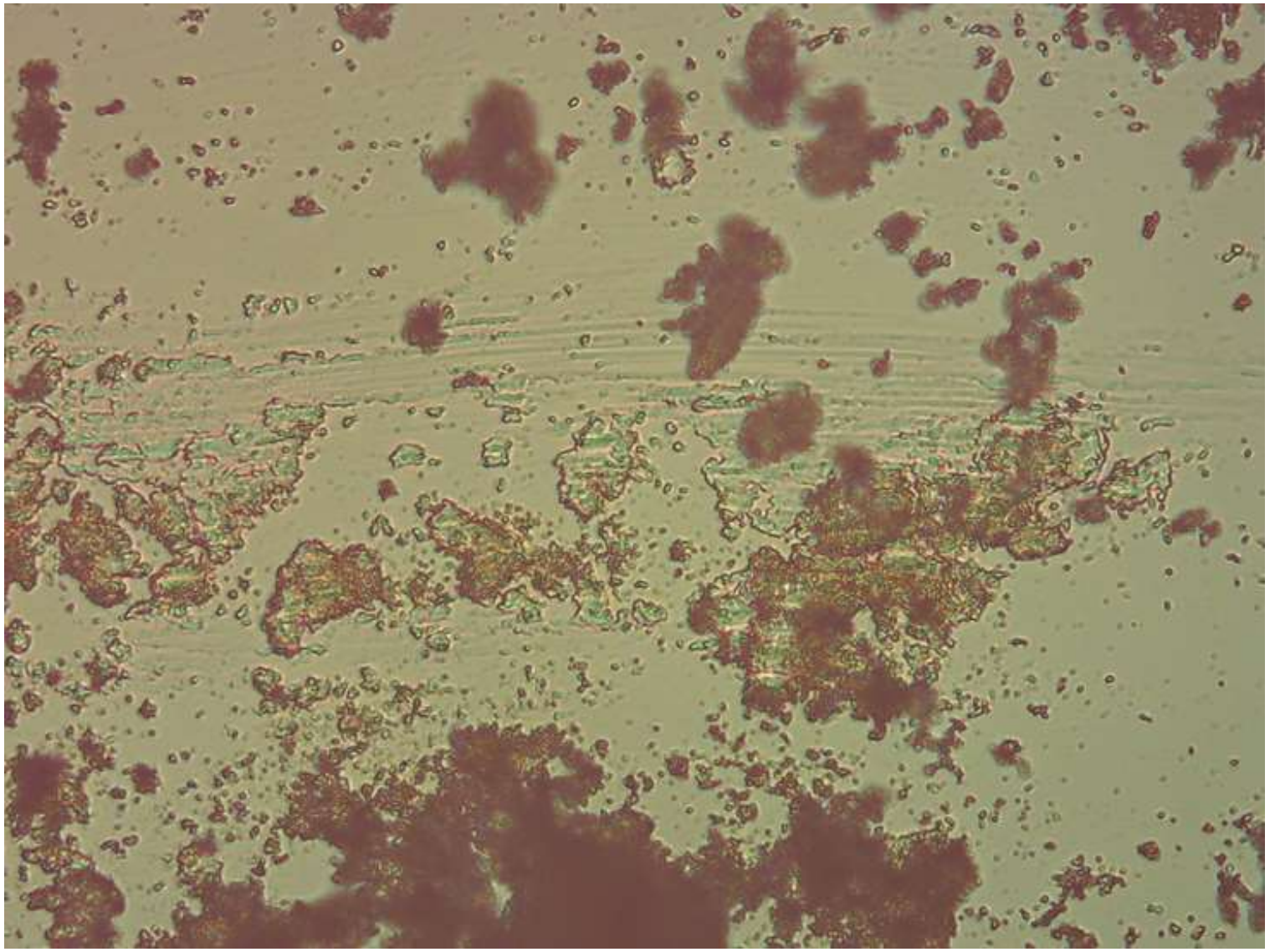


F 5



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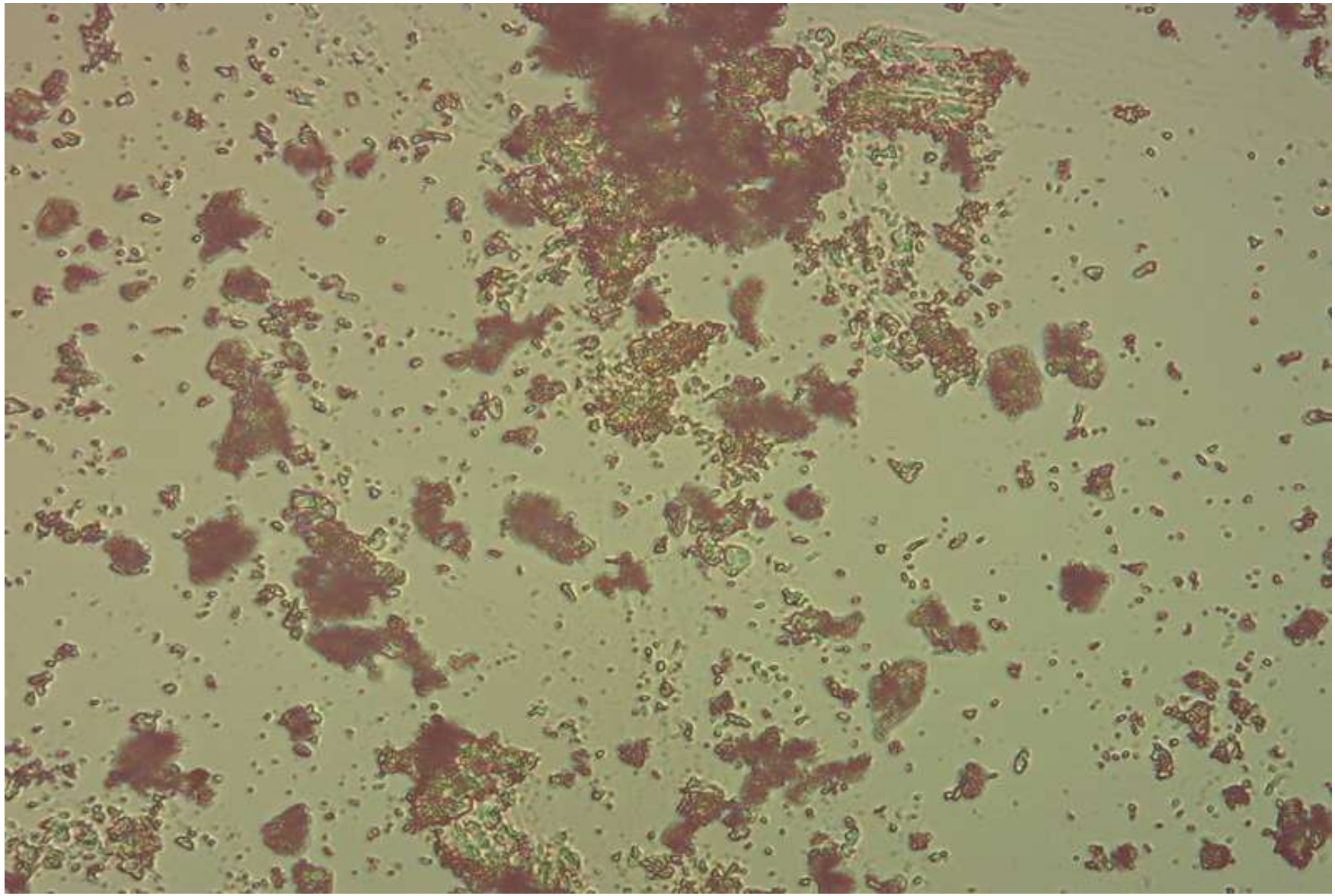

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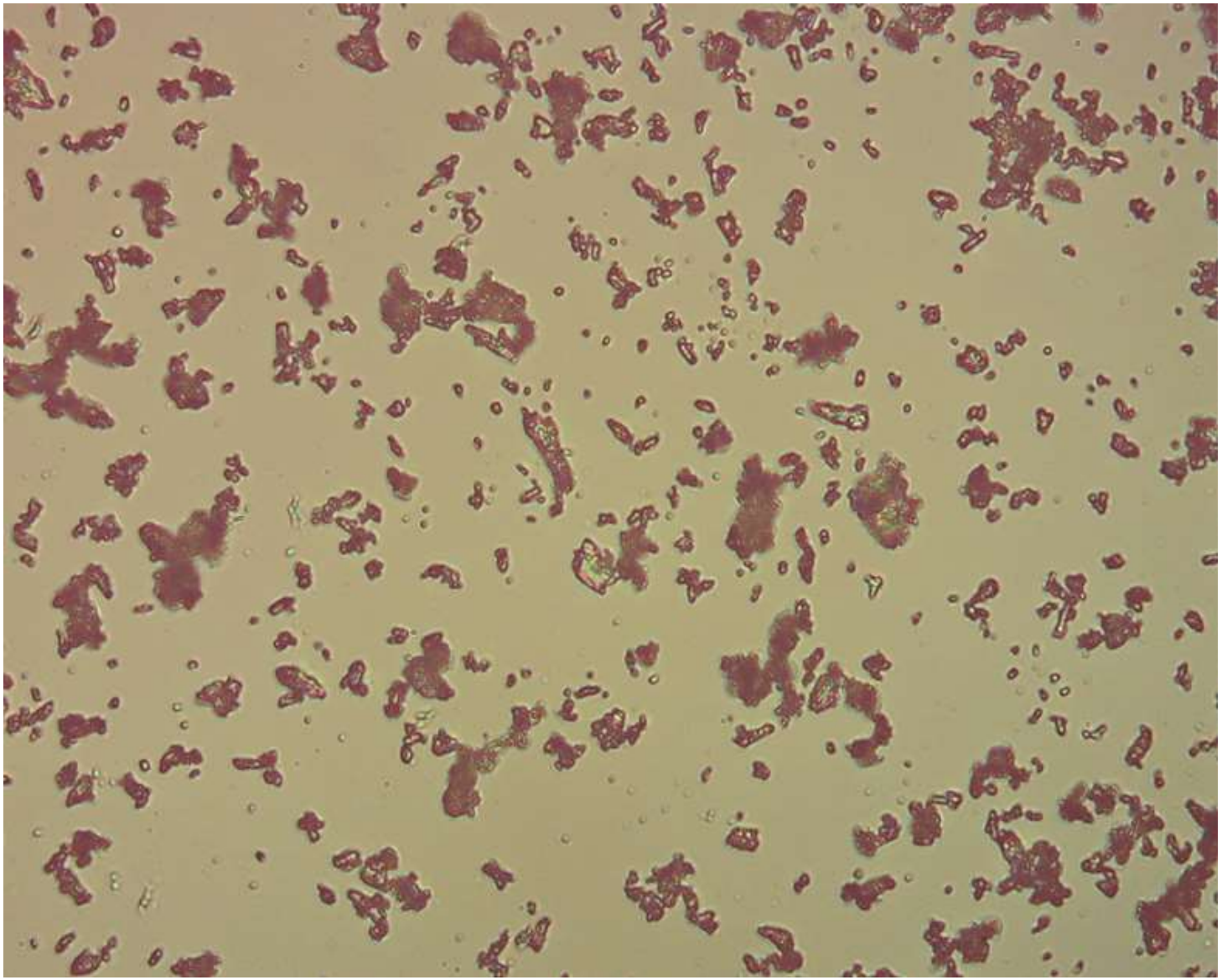
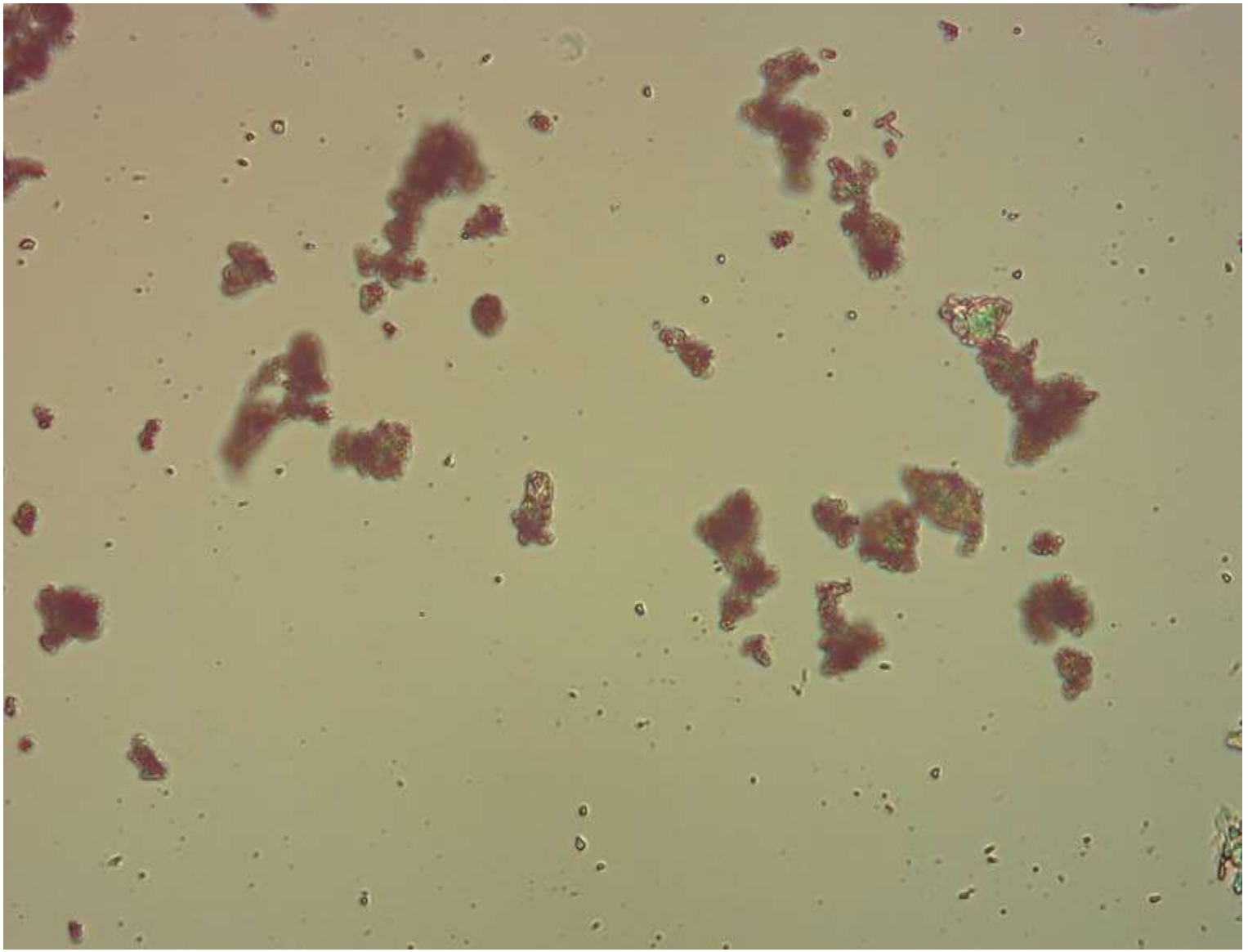
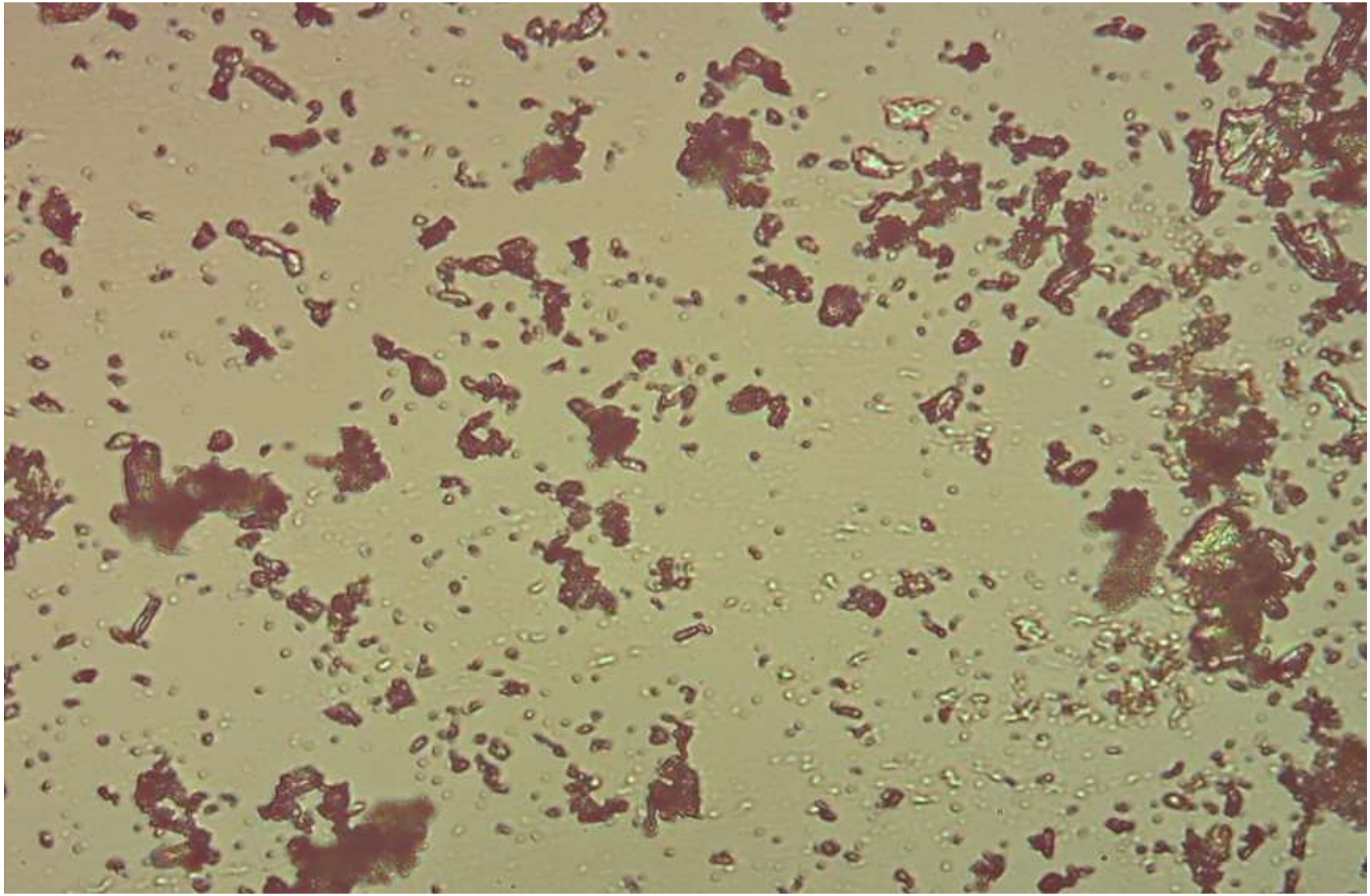


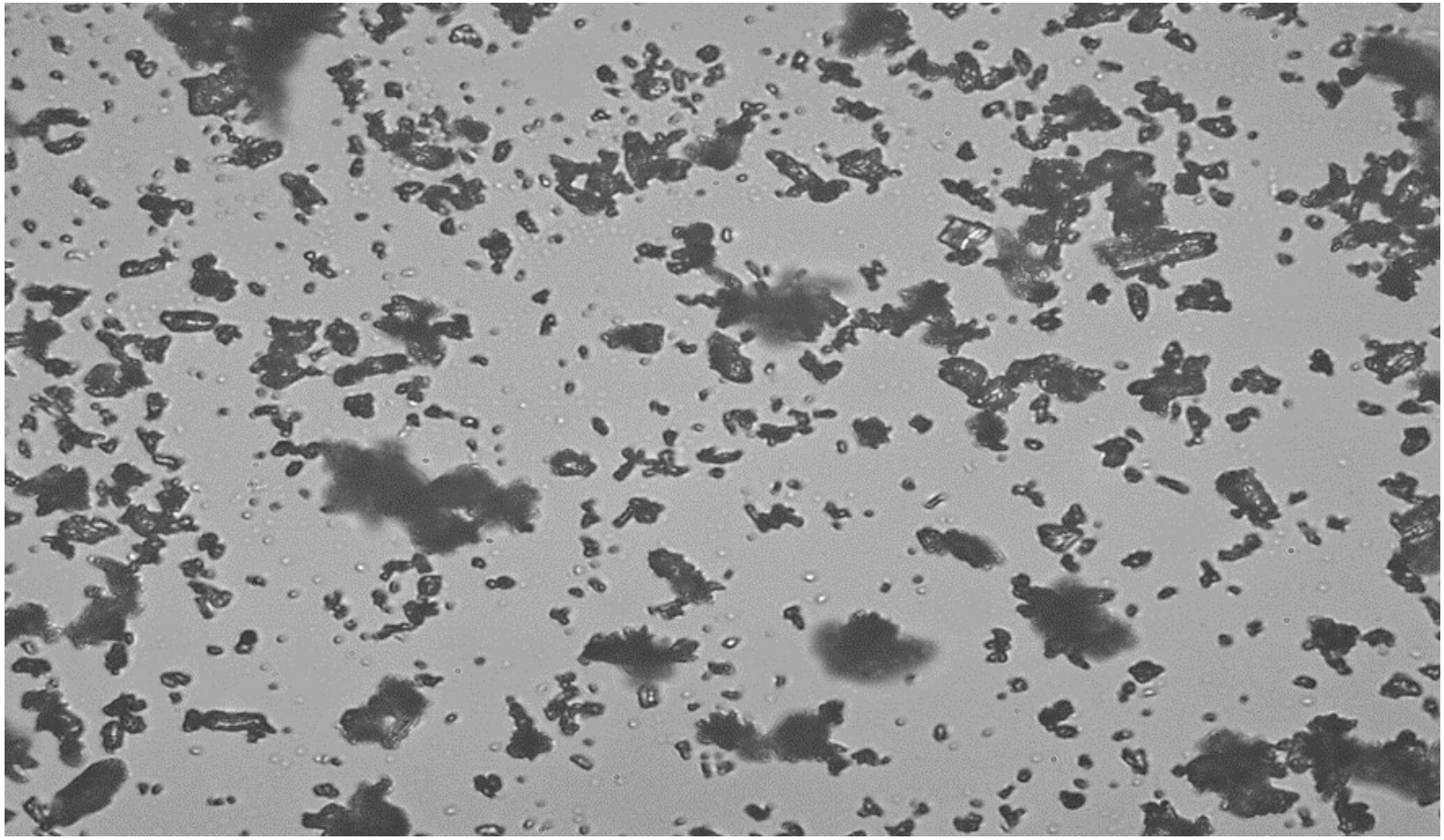
F 8



F 9



Polymer



Conclusion:

- The oral powder-for-solution formulation of diclofenac potassium is a useful option in the acute treatment of migraine with or without aura. Diclofenac potassium powder demonstrated clinical efficacy and was generally well tolerated in placebo-controlled trials in patients with this indication; it was more effective than diclofenac potassium tablets Powders are intimate mixtures of dry, finely divided drugs and/or chemicals that may be intended for internal (Oral Powders) or external (Topical Powders) use. Children and those adults who experience difficulty in swallowing tablets or capsules may find powders more acceptable. Drugs that are too bulky to be formed into tablets or capsules of convenient size may be administered as powders.
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- The effect of adding of polymer on the diclofenac powder will decrease the dusting problem with little or no effect on solubility of drug this can be deduced from the measurement of solubility of drug with time.

THANK YOU FOR LISTENING