

STUDY OF NIMESULIDE MICROSCOPY AND TECHNOLOGICAL PROPERTIES

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Introduction. Nowadays drugs with a substance Nimesulide (nonsteroidal anti-inflammatory drug that belongs to sulfonanilides) are very popular. Nimesulide has anti-inflammatory, analgesic and antipyretic effect. Furthermore anti-inflammatory, antipyretic and analgesic effects, it also reduces the adhesion of platelets to each other, thereby diluting and lowering the blood clot. Analgesic effect is achieved in 15-20 minutes after taking the drug, which is particularly important in acute pain syndrome. Appointed by the drug most often to relieve symptoms in rheumatic diseases, degenerative lesions of the joints, inflammation of the muscle tissue. Also it is used in fevers of various origins, toothache, headache, menstrual and other types of pain.

Ukrainian doctors advise to use it at a high temperature, when other drugs do not work. However, one of the advantages of Nimesulide is well tolerated and relatively low incidence of complications from the gastrointestinal tract. Nimesulide is often compared to meloxicam (a drug that is mainly recommended for the treatment of pain in rheumatic diseases and other pathologies of the musculoskeletal system). It comes in the form of suppositories, it has more duration of analgesic effect than Nimesulide, but Nimesulide acts faster.

This substance is available as a tablet, gel, suspension and granules for suspension. But there are no drugs with Nimesulide in suppository. To develop a composition and technology of suppositories with Nimesulide it is necessary to study its technological properties.

Aim. The aim is to study of nimesulide microscopy and it technological properties to justify composition and technology of suppositories with Nimesulide.

Materials and methods. It was conducted a study of technological parameters of nimesulide: moisture content, flowability, particle size distribution and study of shape, size and surface properties of a powder.

Determination of moisture content. Moisture content of raw material is the loss in weight of hygroscopic moisture and volatile substances, which determine in the raw material by drying it to constant weight. Determination of the moisture content of the powder was carried out by auto express moisture analyzer Sartorius MA-150.

Determination of flowability. Into a dry funnel, the bottom opening of which has been blocked by suitable means, introduce without compacting 20.0 g of Nimesulide weight with 0.5% accuracy. Unblock the bottom opening of the funnel and

measure the time needed for the entire sample to flow out of the funnel. The flowability is expressed in grams of powder related to 1 second. We used the apparatus VP-12A.

Determination of particle size distribution. Weigh 20.0 g of a Nimesulide, screen through a set of standard sieves (No. 355; 250; 180; 90). An assay is placed on the top sieve (No. 355) and the whole set is shaken up manually within 5 min. Then dismount a set and weigh the separated fractions of the powder on each sieve. The content of fractions are expressed in percentage of the initial weight.

Study of shape, size and surface properties of a powder. Shape, size and surface characteristics of powder particles are determined by means of microscope supplied with a digital camera DCM 300. Onto a surface of a microscope slide place the sample of powder, then eliminate the excess powder by slightly shaking glass. Examine crystals and measure their maximal and minimum length and width by using a computer program ScopePhoto.

Results and discussion. Moisture content of Nimesulide was 0.40%. So this substance is not a hygroscopic and does not need to be dried before using in technological process.

Nimesulide does not have a flowability. It means that when the bottom of the funnel is opened sample do not flow out of the funnel. It is a critical parameter in tablets technology. But in suppositories technology we can use substances without flowability. It requires only a certain raw material loading techniques in equipment.

The particle size distribution of Nimesulide was: >0.355 mm – 73.4%; 0.25-0.355 mm – 12.3%; 0.18-0.25 mm – 6.1%; 0.09-0.18 mm – 5.1%; <0.09 mm – 0.07%. So the main fraction size was >0.355 mm – 73.4%.

The powder of Nimesulide was examined in dry form by using transmitted light. The maximal and minimum length and width was measured. The surface properties of a powder was examined in dry form by using reflected light. The next step of investigation was to study microscopy of Nimesulide powder suspended in silicone oil. In dry form particle agglomerates more then 300 micron were observed. In the dry form in reflected light crystals were looked transparent and its surface was rough. The particles in silicone oil suspension were separated individually. The average particles size were about 35 microns, the smallest particles size were 17 microns, while the biggest particles size were 96 microns.

Conclusions. Thus Nimesulide does not need to be dried before using in technological process, but it requires a certain raw material loading techniques in equipment due to poor flowavailability. The particle size distribution of Nimesulide showed that the main fraction size was >0.355 mm – 73.4%, but in suspension the partial size were from 17 to 96 microns, average size were about 35 microns. This occurs because the dry powder particles tend to form agglomerates.