

# Product quality review for assay and dissolution of Nimesulide tablets 100 mg

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## Introduction

Product Quality Review (PQR) is prepared according to cGMP requirements. It is an annual evaluation carried out to: verify the constancy of current process, check the correctness of current specifications, highlight any trend and minimize the risks involved in any pharmaceutical production (Manjunath et al., 2020).

Nimesulide is BCS class II drug, with low solubility and high permeability. Reducing the particle size of the drug to nanoparticles (Abd-AllRazaq et al., 2018) and microparticles (Tubić et al., 2016) and preparation of nanocrystal formulation (Gülsün et al., 2012) increase the dissolution and bioavailability of the drug as critical quality attributes. The aim of the study was to perform an annual quality review of Nimesulide tablets 100 mg.

## Materials and methods

**Materials:** Active pharmaceutical ingredient (API): nimesulide micronized (Aarti Drugs Ltd., India). Excipients: povidone (BASF, Germany), sodium dioctyl sulfosuccinate (Solvay, Belgium), hydrogenated castor oil (BASF, Germany), lactose monohydrate (Meggler, Germany), cellulose microcrystalline (JRS Pharma, Germany), sodium starch glycolate (JRS Pharma, Germany), low-substituted hydroxypropylcellulose (Shin-Etsu, Japan), magnesium stearate (Mosselman, Belgium).

**Methods:** Nimesulide tablets 100 mg were produced by high-shear wet granulation with: high-shear mixer-granulator (VG 200 from Glatt, Germany), fluid bed dryer (Aria 300 from IMA, Italy), mixer-blender (Cyclop

Miditumbler from Vima, Italy) and tablet presses (Unipress Diamond 20 from Manesty, England; E 150 Plus and S 250 from IMA-Killian, Germany). The dissolution study (900 ml phosphate buffer pH 7.4, 100 rpm, 30 minutes) was done using Apparatus 2, (G2 Classic 6 from Hanson Research Corp., USA) and spectrophotometers (UV-2600 from Shimadzu, Japan; Specord 50 plus from Analytik Jena, Germany) at 396 nm. Assay was tested with same spectrophotometers.

## Results and discussion

The annual review (assay and dissolution) for 25 batches of Nimesulide tablets 100 mg, manufactured for one byer during 2022 was done. The requirements for the tested parameters are shown on Table 1.

Table 1. Requirements for Assay and Dissolution

Parameter	Requirements
Assay	90 mg - 100 mg nimesulide/ tablet or 90 -110% of the declared content
Dissolution	min. 80% (Q) dissolved nimesulide/ tablet expressed in percentage of the declared content within 30 minutes

The average results for the assay and the dissolution were 98.72±1.68% and 94.89±1.76%, respectively.

The annual reviews of the assay (Fig. 1) and dissolution (Fig. 2) of nimesulide show that all results comply with the requirements and are within the prescribed limits.

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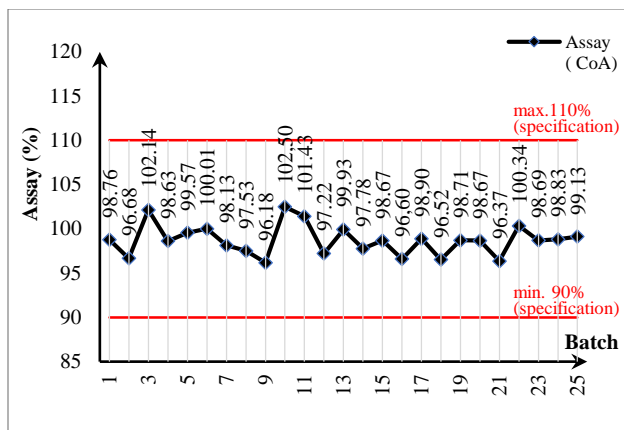


Fig. 1. Assay annual review for batches No. 1 – 25

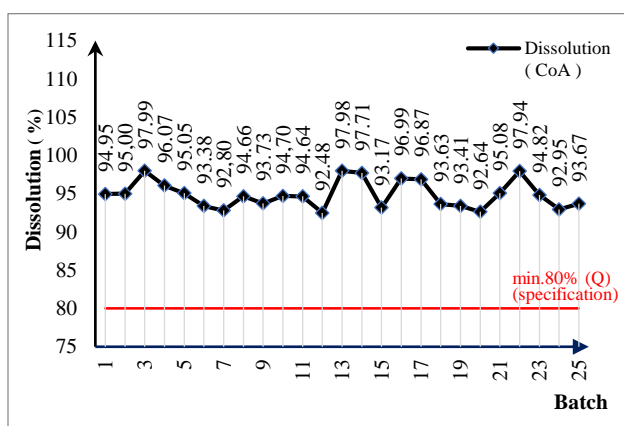


Fig. 2. Dissolution annual review for batches No. 1 - 25

All results for assay (Fig. 3) and dissolution (Fig. 4) are between the lower control limit (LCL) and upper control limit (UCL), within the 2 standard deviations from the current trend.

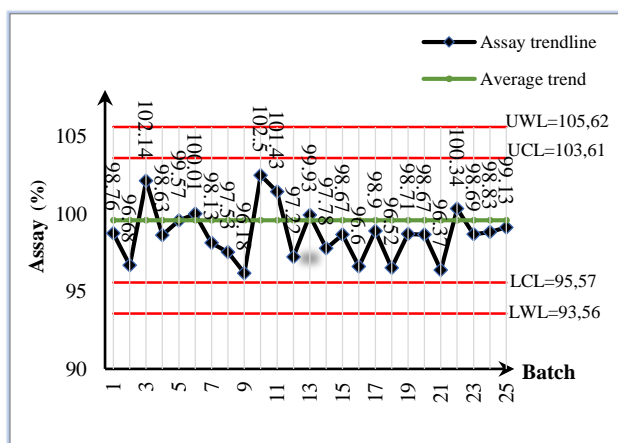


Fig. 3. Assay trend line for batches No. 1 – 25

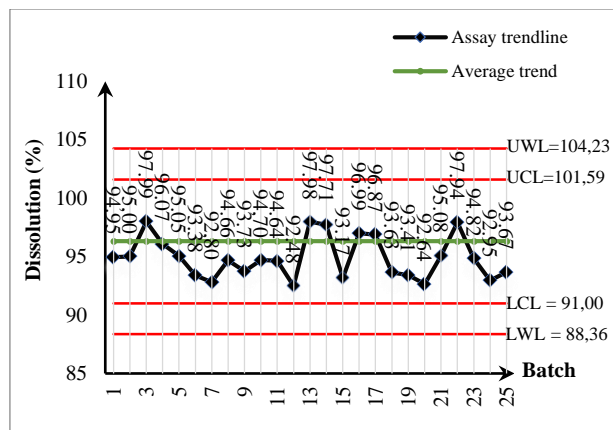


Fig. 4. Dissolution trend line for batches No. 1 - 25

The evaluated trend parameters show that the highest security level of the results is satisfied and the results are the closest to the expected trend. The  $C_{pk}=1,70$  (assay) and  $C_{pk}=0,91$  (dissolution) confirm that the process is capable to produce output within specified limits, since the values of process capability index ( $C_{pk}$ ) are between 1 and 3.

## Conclusion

Based on the results gained all manufactured batches of Nimesulide tablets 100 mg fulfill the requirements for quality, safety and efficiency.

## References

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