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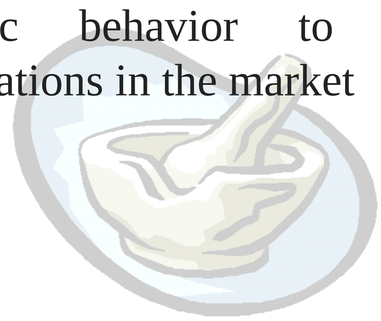
IBUPROFEN GUMMIES AS A NEW PEDIATRIC DOSAGE FORM

M.Eugenia VILLALBA[1], Adela S. ÁVILA[2], Aránzazu ZARZUELO[1]*
[1]Area of Pharmacy and Pharmaceutical Technology. Pharmacy Faculty. University of Salamanca.
[2]Farmacia Ávila Bardají. Salamanca
*drury@usal.es

Some of the daily problems that pediatricians find are the need to adapt the dose to the needs of the patient, to have pharmaceutical forms that allow a more accurate dosage and to solve frequent problems in the child population such as intolerance. The formulation of individualized medicines supposes a first level health care that provides an exceptional tool to the prescriber in order to adapt the treatment to the patient.

OBJECTIVE

The objective has been the **design**, the **production** and the **control** of *medicinal gummies of ibuprofen* (100 mg) as an alternative to the therapeutic arsenal that exists in the market, with the purpose of giving a solution to a need that paediatricians demand, that meet two premises, good organoleptic characteristics and similar pharmacokinetic behavior to the existing formulations in the market

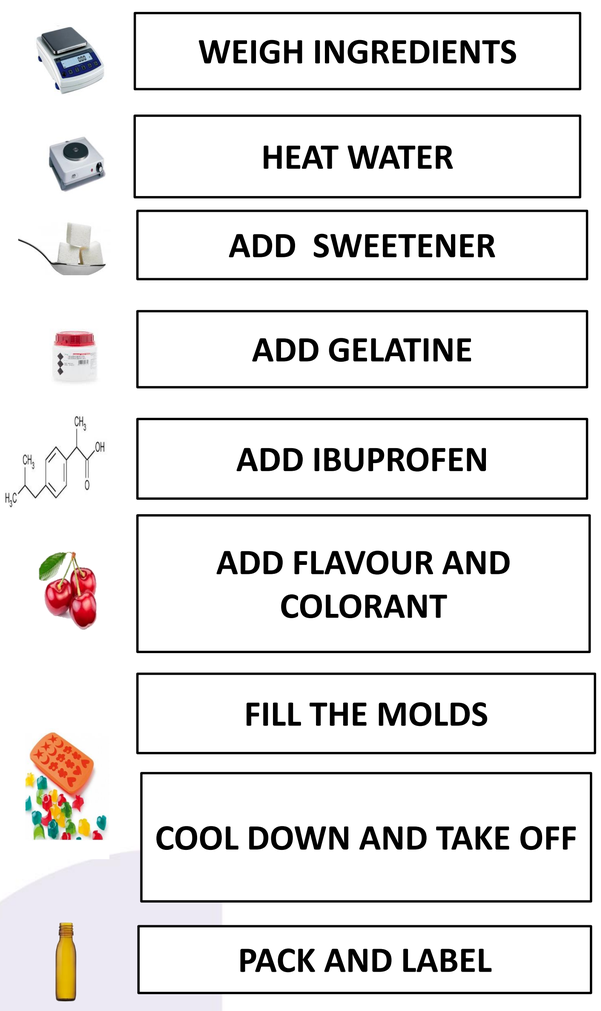


METHODOLOGY

The methodology has been the **design** and **elaboration** of the formulations (batch with different percentage of gelatin), **evaluating the assay**, **uniformity of dosage units**, **dissolution profile** and **acceptance** of the formulation.

Ingredients	Gummies 20	Gummies 17.5	Gummies 15
	Quantity (grammes)		
Gelatine	20.0	17.5	15.0
Saccharose	125	125	125
Water	100	100	100
Ibuprofen	5.4	5.3	5.3
Artificial flavor	csp	csp	csp
Colorant	csp	csp	csp
Total gummies	54	53	53

Table 1: Composition of the three final batches



RESULTS

The process of elaboration of proposed Ibuprofen gummies allows obtaining **homogeneous dosage units (AV<15)**, with an **assay of 99.79-101.12%**, a **dissolution profile** of gummies 17.5 **similar to that of solid and liquid formulations** existing in the market (figure 1), obtaining a **% dissolved at 15 minutes>85%** and with a **good organoleptic acceptance.**

Assay

	mg Ibuprofen/gummie		
	Gummies 15	Gummies 17.5	Gummies 20
Media	99.79	101.12	100.55
SD	0.55	0.66	1.87
CV	0.55	0.65	1.86

Table 2: Ibuprofen assay in the proposed formulations

Content Uniformity

	Gummies 15		Gummies 17.5		Gummies 20	
	Weigh (g)	Assay (%)	Weigh (g)	Assay (%)	Weigh (g)	Assay (%)
MEDIA	4.16	99.91	4.17	101.2	4.04	97.13
SD	0.06	1.49	0.1	2.38	0.05	1.35
AV		3.6		5.7		3.5

Table 3: Results of content uniformity test

Percentage dissolved

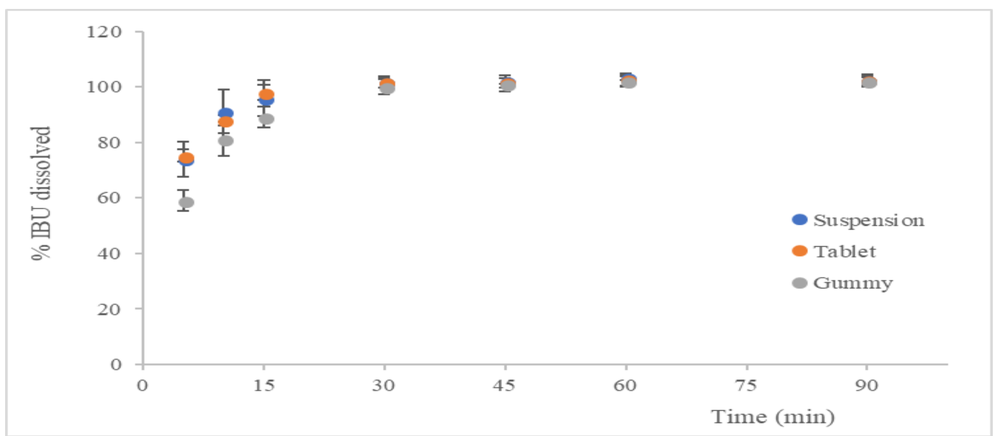


Figure 1: Dissolution profile for gummies 17.5 and commercial presentations (tablets and suspension)

	Gummies 15	Gummies 17.5	Gummies 20
	% DISSOLVED		
Time (min)	**Media**	**Media**	**Media**
5	65.20	59.50	41.80
10	82.73	80.37	72.71
15	92.16	89.02	82.45
30	98.57	100.61	95.15
45	100.96	101.40	99.21
60	101.04	101.41	100.05
90	101.32	101.69	100.75

Table 4: % Ibuprofen dissolved for proposed formulations

The interest of the formulation developed, applied to this and other active ingredients, is motivated by reasons such as filling therapeutic gaps, adapting the dose and associating different APIs with the objective of optimizing treatments with an attractive pharmaceutical form for pediatric patients that will help them to adhere to treatment in order to adapt the medication to the patient and not the patient to the medication.

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